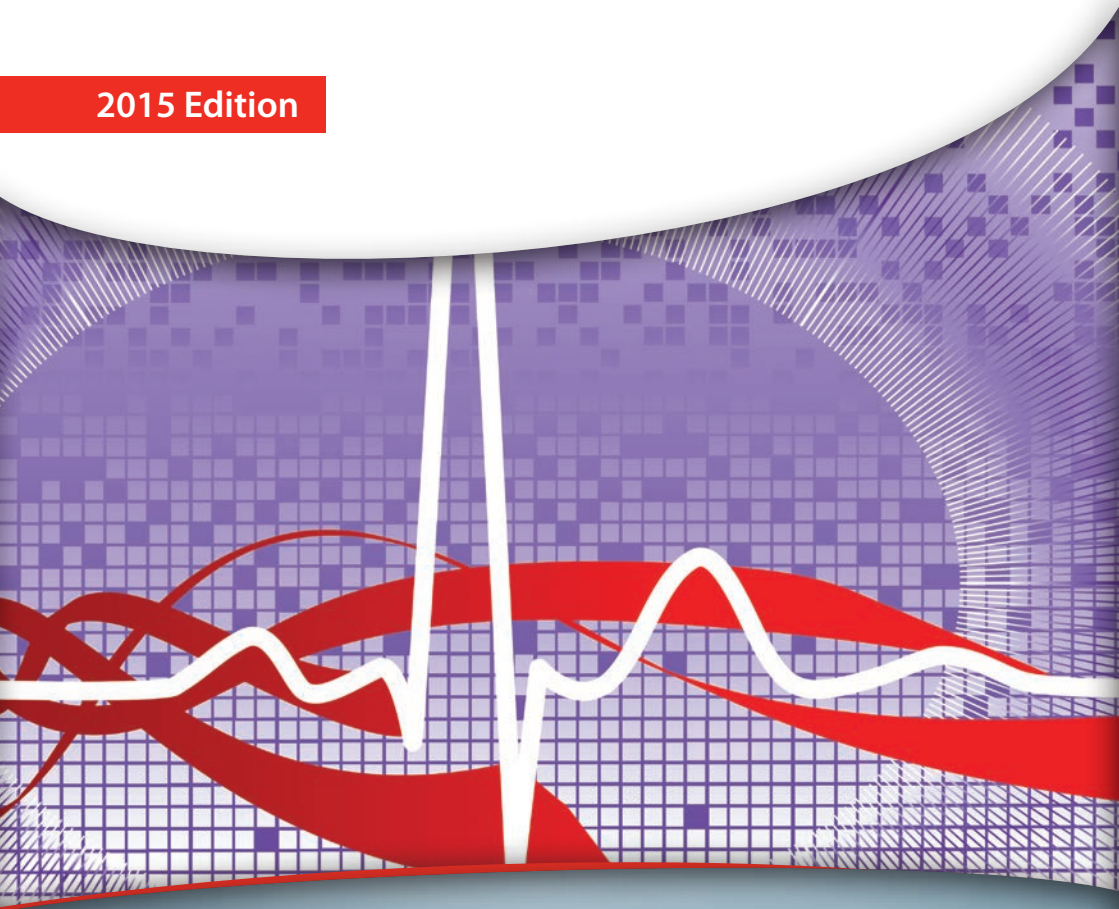
U.S. COMMERCIAL SERVICE
United States of America
Department of Commerce

Healthcare Technologies Resource Guide

A Reference for U.S. Exporters

2015 Edition



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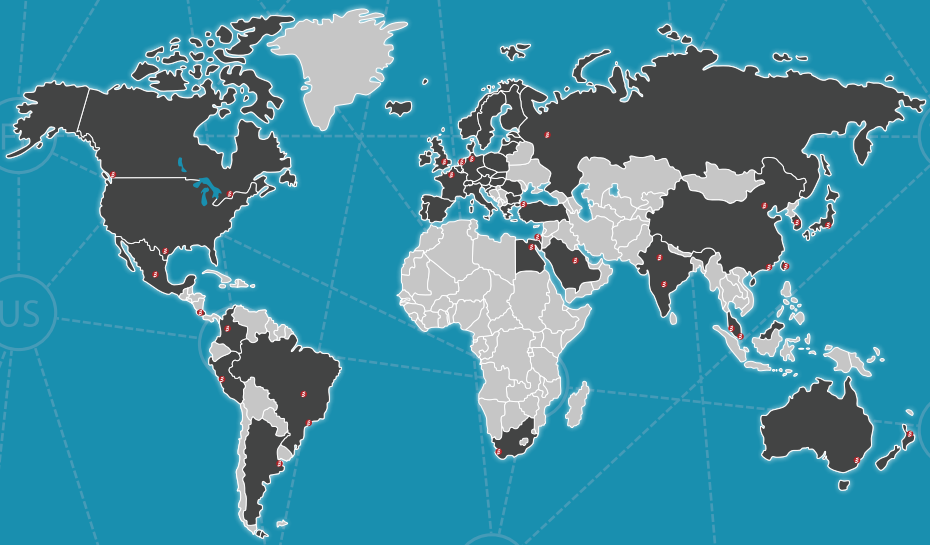

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Healthcare Technologies Resource Guide

A Reference for U.S. Exporters

2015 Edition

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Introduction

What Can the U.S. Commercial Service Do for You?

The U.S. Commercial Service (CS) is the export promotion arm of the U.S. Department of Commerce's International Trade Administration. Our global network of more than 1400 trade professionals is located throughout the United States and in U.S. Embassies and Consulates in more than 70 countries. Whether you are looking to make your first international sale or expand to additional markets, we offer the expertise you need to connect with lucrative opportunities to increase your bottom line.

Our Services

The CS Healthcare Technologies Team works to address issues and trade opportunities specific to the strong and growing healthcare sector, and to ensure you have the information you need to grow your business. This resource guide is just one of the ways we can provide the information you need to set priorities and plan for business growth. To learn more about how we can help you, visit ***export.gov/industry/health***.

For more information on how CS can help your business increase its international sales, please contact your local CS office. A list of offices appears at the back of this guide and at ***export.gov/usoffices***.

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Market Intelligence

- Analyze market potential and foreign competitors
- Obtain useful information on best prospects, financing, laws, and cultural issues
- Conduct background checks on potential buyers and distributors

Business Matchmaking

- Connect with pre-screened potential partners
- Promote your product or service to prospective buyers at trade events worldwide
- Meet with international industry and government decision makers in your target market(s)

Trade Counseling

- Develop effective market entry and sales strategies
- Understand export documentation requirements and import regulations of foreign markets
- Navigate U.S. government export controls, compliance, and trade financing options

Commercial Diplomacy

- Overcome trade obstacles to successfully enter international markets
- Benefit from coordinated U.S. government engagement with foreign governments to protect U.S. business interests
- Access U.S. government trade advocacy for your foreign government procurement bids

Albania

Summary

Albanians spend approximately 6 percent of GDP (around USD 800 million) on healthcare spending, split almost evenly between public and private expenditures. The ongoing modernization of both the private and public healthcare sector provides good opportunities for U.S. exporters. The private healthcare sector is growing rapidly with many new hospitals and clinics opening in recent years. As the sector modernizes, Albanians increasingly are demanding modern, western medical devices and treatments. Wealthy Albanians that previously traveled overseas for medical treatment are opting to stay in Albania and seeking services at private hospitals and clinics. Medical tourism also is a small but growing sector in Albania.

Albania imports almost 100 percent of its healthcare products and equipment. The number of local companies that sell medical equipment is limited due to the size of the market and there are no significant barriers to entry in the sector.

Market Entry

It is highly advisable that U.S. companies interested in entering the Albanian market partner with local companies. U.S. companies should carefully select their potential distributors or agents and also should consider after the sale services as a crucial component of their business plan. Public sector purchases are conducted electronically and notifications can be found at ***app.gov.al***.

Customs tariffs depend on the HS code and vary from 0 to 2 percent for the HS codes 9018-1919-1920-1921-1922, with majority having 0 percent custom tariffs. Medical equipment currently incurs a 20 percent value added tax (VAT).

Albanian government approved a new law on medical devices, which takes into consideration the EU Directive 93/42/EEC, dated June 14, 1993, "On Medical Devices."

Statistics

Capital:	Tirana
Population:	2.85 million
GDP (USD):	13.6 billion (2013)
Currency:	Lek (ALL)
Language:	Albanian

Contact

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According to the new law, medical device manufacturers, being domestic or foreign, who have registered their business in Albania, as well as all wholesalers and retailers that operate in the market should apply with the Ministry of Health to receive authorizations to operate in the market. In addition, the new law foresees that two years following the entry into force of the law, all medical equipment should be registered with the National Register of Medical Equipment that will be maintained by the National Agency of Drug Control and Medical Equipment.

Current Market Trends

According to Albanian customs data, during 2013, imports under the HS code 9018-1919-1920-1921-1922 totaled close to USD 24 million. In 2013, medical equipment coming from the United States accounted for 25 percent of the total imports. However, the presence of U.S. brands in the medical equipment sector likely is much higher than customs data reflect, as the importing country listed in the custom reports does not reflect the brand.

Main Competitors

All the major international healthcare equipment providers are present in the local market. Many international companies are present in the Albanian market.

Medical Imaging, Ultrasound, Monitors, and Anesthesia

GE Healthcare, Siemens, Toshiba, Hitachi, Philips, Shimadzu, Hologic, Konica Minolta, Mindray, Esaote, Carestream, Fujifilm, Canon, Agfa, Samsung Medison, EcoRay, GMM, GMI, MESA-MEDICAL, Agilent, Fukuda Denshi, Samsung Medison, Alpinion, Drager, Eppendorf, Penlon.

Dental

Kavo, Siemens, Sirona, Anthos, Ritter, Degudent, Vitali SRL, Faro, Dentaurum, MyRay, Villa Sistemi Medicali, YOSHIDA DENTAL, Heraeus-Kulzer, Carestream Dental, Planmeca, Castellini, Gnatus, UFSK, Ivoclar Vivadent AG, MIDMARK, ULTRADENT Dental-Medizinische.

Diagnostic and Surgical Microscopes

Haag-Streit, Ellex, Zeiss, Leica, Shinippon, Takagi, Nikon, Nidek, Tomey, Topcon, Huvitz, Reinchert, Motic, Atmos, Alcon, Wallach, Alltion, Karl Kaps, Oculus, Optopol technology, Breukhoven, CSO Costruzione Strumenti Oftalmici, Optopol Technology, Quantel Medical, Lightmed.

Endoscopes

Fujifilm, Olympus, Otopront, Huger, Pentax, Strorz, Applied, Vision.

Blood Diagnostic

Abbott, Roche, Becton Dickinson, Siemens, Thermo Scientific, ELITech Group, Beckman Coulter International S.A, Dirui, etc.

The major competitors of U.S. manufactured medical equipment are European companies. U.S. brand sells very well in Albania, but after-sales service remains a challenge. As such, it is highly advisable that U.S. companies aiming to enter the market consider a local partner able to provide this service.

Current Demand

The demand for medical equipment likely will continue to grow in Albania. The Albanian government has pledged to modernize and increase spending in the health sector which will lead to new investments in public hospitals. The private sector also is investing and diversifying the range of services it offers which, will increase demand for further capital investments.

Market demand for medical equipment including but not limited to computer tomography imaging systems, magnetic resonance imaging, sophisticated digitalized x-ray equipment, invasive and non-invasive surgery equipment, cardiology equipment, EKG and ultrasound, defibrillators, vascular stents, pacemakers, oncology equipment, urology, dentistry and laboratory and testing equipment will continue to grow as Albania modernizes its healthcare system.

Trade Events

No specialized medical and healthcare trade shows scheduled in Albania for 2014.

Resources

- Ministry of Health, ***shendetesia.gov.al***
- National Center of Drug Control, ***qkkb.gov.al***
- Public Procurement Agency, ***app.gov.al***

Argentina

Summary

Healthcare expenditures in Argentina have traditionally accounted for approximately 7 percent of GDP, among the highest in the region. Imports in the overall healthcare sector have been estimated to account for around 70–75 percent of the total market. The United States continues to lead the Argentine import market of medical products and equipment, and currently holds over 25 percent market share, particularly in higher-end technology products.

Argentina remains a key market for U.S. exports to Latin America. However, market challenges arising from slowing economic activity, inflationary pressures, and a host of import and foreign exchange restrictions imposed by the Argentine government in late 2011 and early 2012 are expected to continue adversely affecting imports and reducing GDP growth estimates in 2014/2015. Growth slowed markedly in 2012 to 1.9 percent (from 8.9 percent in 2011) and continued at 3.0 percent in 2013, according to official GDP statistics

Market Entry

Imports of medical products must be performed by an importer registered with ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica), the Argentine equivalent to the U.S. Food and Drug Administration (FDA), as a frequent importer of medical equipment. Imported products in general, appear under the name of the local registered importer who will fulfill the registration process as a representative of the U.S. company.

The Mercosur common external tariff (CET) applies to imports from countries outside the MERCOSUR area (Argentina, Brazil, Uruguay and Paraguay). The CET currently averages 14 percent for medical products plus 0.5 percent in a statistics fee.

Statistics

Capital:	Buenos Aires
Population:	42 million
GDP (USD):	488 billion (est. 2013)
Currency:	Peso (ARS)
Language:	Spanish

Contact

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Current Market Trends

The Argentine medical equipment and device market continues to be dominated by imports. While imports decreased in general in 2013, imports from the U.S. grew slightly. Total medical equipment imports amounted to approximately USD 405 million in 2013, with imports from the U.S., amounting to over USD 102 million. The United States continues to be the leading supplier of imported medical products and currently holds 25.2 percent market share, particularly in high-technology products. Import figures may remain sluggish during 2014.

(For statistics, imports were based on the following Mercosur HS Codes: 84.13.19.00.1; 8413.91.90.2; 84.73.3099.910x; 85.40.71.00.100B; 90.11.10; 90.11.90.90.100; 90.12.10.10.000; 90.12.90; 90.18.10; 90.18.20; 90.18.30; 90.18.40; 90.18.50; 90.18.90; 90.19.20; 90.22.10; 90.22.20; 9022.30; 90.22.90; 90.27.90.99.200)

Main Competitors

More than 2,000 companies sell medical products and equipment in Argentina, of which 25 percent are manufacturers and 75 percent are importers. Brazil poses strong competition since imports enjoy a zero percent tariff under Mercosur. U.S., Japanese and European-made equipment is known for its high technology and precision, whereas Argentine equipment, although durable, is generally low-tech.

Domestic production has been growing, although in general it is limited mainly to lower-middle range equipment and supplies, such as x-ray devices, peripheral equipment, illumination systems, furniture, operating tables, echographs and ECGs, monitors, oximeters, cobalt pumps, incubators, anesthesia equipment, sterilization equipment, basic lab equipment, instruments for arthroscopy, fixation instruments, instruments for video endoscopy surgery, wheelchairs, and scales, etc.

Current Demand

Niche opportunities for U.S. exports may include middle and higher-end equipment such as imaging diagnostics equipment, medical ultrasound equipment, and electrocardiograph equipment. While this report concentrates mainly on medical equipment and devices, there may be opportunities in other areas such as specialized disposables and implants, cardiovascular products, clinical laboratory equipment, molecular biology products, and diagnostic reagents.

Simpler technology is more easily financed and thus considered mass-market. In this competitive market the demand for these products is for the most part met. In any case, product potential should be determined on a case-by-case basis.

Registration Process

ANMAT, the local equivalent to the U.S. FDA, is the Argentine agency responsible for regulating registration of medical products, biological products, dental hygiene products, healthcare

sanitation and disinfectants, personal hygiene, cosmetics and perfumes, foods and dietary supplements, and medicines.

Imported medical products need to be registered with ANMAT through an authorized medical importer. The product registration process may take from six to 24 months.

Product classification includes Class I, II, III, and IV. Documentation required may vary according to product, and can also depend on what the ANMAT evaluator requires on each case. In general, the following documents are required:

- FDA Certificate (Certificate to Foreign Government) apostilled
- Letter or Certificate of Representation/ Distribution in Spanish with an apostille
- Users or Technical manual (in Spanish)
- ER Matrix (Essential Requirements)
- Brochures and labels

Additional documents that could be required are: electrical safety certification, manufacturing flowchart process and description; sterilization methods and parameters; scientific or clinical evidence report. Further description of ANMAT regulations on medical products can be found at ***www.anmat.gov.ar/principal_en.asp***.

Barriers

Although Argentina remains a key market for U.S. exports to Latin America, recent controls have made exporting goods from any country to Argentina more difficult due to additional processes that Argentine importers must complete in order to import goods. It is important for would-be exporters to Argentina to confirm that their Argentine customer has all the necessary permits, such as permission to import and permission to purchase foreign exchange to pay for the import prior to shipping goods to Argentina. For additional information on these measures, please visit ***bit.ly/1AHTjoE***.

Trade Events

Expomedical 2015

Centro Costa Salguero, Buenos Aires • ***expomedical.com.ar***

Available Market Research

- Medical Equipment, Instruments, and Supplies (2012)
- Dental Products Overview (2012)

Australia

Summary

The Australian medical equipment industry sector has consistently provided good prospects for U.S. exporters. Australia is the eighth largest market for U.S. exporters of medical products. Approximately 80 percent of medical devices and diagnostics used in the market are imports. The three major suppliers are the United States, the European Union, and Japan. U.S. medical equipment is traditionally well received due to its perceived high quality. The market is sophisticated, mature, and quick to adopt new healthcare technologies. Importers seek to obtain cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs.

Market Entry

Successful market entry strategies for Australia have three common elements: understanding the market, selecting the optimal partner, and providing ongoing support to that partner. It is important to gain an understanding of the Australian context for a product or service, its competitors, standards, regulations, sales channels, and applications. Success in the market will require appointing an Australian distributor or establishing a local subsidiary, and setting up a local sales presence. Typically, distributors for medical products will cover the entire country and some may also have a subsidiary office in New Zealand. Given the size of the Australian continent—the same size as continental U.S.—and the distance from other countries, local support and service is important. Most of the criteria U.S. firms use to select distributors are applicable to Australia, with expectations adjusted to the scale of the market given the population of 23 million. Performing due diligence on potential local partners is just as important as in the United States.

Statistics

Capital:	Canberra
Population:	23 million
GDP (USD):	1.521 trillion
Currency:	Australian Dollar (AUD)
Language:	English

Contact

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Current Market Trends

Australia has a high per capita income and there is demand for a full range of medical equipment. The USD 5 billion market is price sensitive and competitive. Australia spends approximately 9.5 percent of its GDP on healthcare, which is similar to the United Kingdom but less than the United States. Australia's ageing population will significantly influence the demand for products and products that serve the ageing population are likely to experience growth.

The growth of chronic disease in Australia is similar to that in other developed nations. Australians increasingly suffer from asthma; cancer; diabetes; obesity; heart, stroke, and vascular disease; osteoarthritis, rheumatoid arthritis; and osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

Main Competitors

Imports supply approximately 80 percent of Australia's demand for medical equipment. Key suppliers include the United States, the European Union, Switzerland, and Japan. Many suppliers in the Australian industry are subsidiaries of overseas corporations. The major U.S. medical companies represented in Australia (either through local representatives or subsidiary offices) include: 3M, Bard, Baxter Healthcare, BD, Boston Scientific, Cook Medical, Johnson & Johnson Medical, Medtronic, St. Jude Medical, Stryker, and Zimmer. U.S. companies may experience strong competition from U.S. firms or multinationals already in the market.

Current Demand

Australia's high standard of medical practice and aging population underpin a continued demand for a range of sophisticated, high quality, and innovative medical equipment. Importers seek to source cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs. Opportunities exist for products that provide a significant improvement in clinical outcomes, and product with clearly differentiated capabilities. There is also a growing demand for products that lead to faster patient recovery, reduce hospital and rehabilitation costs, and alleviate or manage disability and chronic pain.

Government healthcare policies and public health influence the volume and pricing of healthcare products and services. Both the public and private sectors provide healthcare in Australia. Federal and State government spending accounts for 70 percent of total healthcare expenditure. The non-governmental sector (individuals and private health insurance) funds the remaining 30 percent. Approximately 45 percent of Australians have private health insurance.

Registration Process

The Therapeutic Goods Administration (TGA) regulates the medical equipment industry. Australia's regulatory framework is based on Global Harmonization Task Force (GHTF) and European Community guidelines. U.S. exporters must appoint an Australian representative/sponsor to obtain regulatory approval from the TGA. U.S.-manufactured medical devices require an EC Certificate from a European Union Notified Body. Alternatively, U.S. manufacturers can apply to the TGA for a Conformity Assessment Certificate.

Further information is available at ***tga.gov.au***.

Trade Events

AusBiotech 2015

October 20–23, 2015 • Melbourne, Victoria • ***ausbiotechnc.org***

Austria

Summary

Austria is a dynamic EU member country with an affluent population of 8.4 million German speakers. Austria's manageable size and stable business environment make it an attractive market for U.S. exporters, as well as an attractive test market for U.S. firms with an eye toward expanding into neighboring Germany. Austria's historical and economic ties to the strong growth markets of Eastern and Southeastern Europe also make it a logical base for serving those markets. Currently 330 U.S. firms have subsidiaries, affiliates, franchisees, and licensees in Austria, of which about 150 have regional responsibilities for Central European, Eastern European, or Balkan countries. U.S. products and services maintain a good reputation in Austria.

In 2013, Austrian imports of medical equipment were approx. USD 1.9 billion. For 2014 we expect these imports to show an increase to almost USD 2 billion. Total demand for medical devices in Austria added up to USD 1.4 billion, while exports of this equipment amounted to USD 1.5 billion. Austria is a transit-trade country with strong trade relationships with Central, Eastern and Southeastern Europe, as well as the Near and Middle East. Re-exporting products is quite common here; hence the volume of imports exceeds the total market. Taking into consideration these re-exports, imports are expected to increase at an average annual real growth rate of 3 percent. The size of the market in Austria for medical equipment should also increase by about 3 percent annually over the next three years.

Austria provides its citizens with universal or nearly universal medical service. Participation in public health insurance programs is essentially mandatory. Some 6.7 million Austrians contribute to the public health insurance companies (Krankenkassen), providing health care coverage for these workers and their families, or about eight million persons. Insurance costs are shared between employers and employees. Insurance for hospital treatment, however, falls short of the actual costs, and the difference has to be met from public funds.

Statistics

Capital:	Vienna
Population:	8.4 million
GDP (USD):	416.4 billion (2013)
Currency:	Euro (EUR/€)
Language:	German

Contact

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Market Entry

U.S. firms should plan their market entry very carefully. Given its location in the center of Europe and the size of its market, small enough to allow a quick overview, Austria stands out as a desirable, affluent pilot market for advanced U.S. products. The best strategy is to screen potential distributors and select a qualified local distributor. Austrian distributors are usually knowledgeable and experienced. They regularly call on hospitals, clinics, laboratories, and medical doctors with practices. The majority of distributors are fluent in English. They are also knowledgeable about EU approval procedures and will obtain approval for U.S. suppliers if needed.

To be successful, a U.S. supplier should discuss and agree on a marketing strategy with a prospective distributor. Once the agent or distributor is selected, it is preferable to maintain this relationship for a number of years. Abrupt changes in distribution patterns distract users from trusted suppliers and have been detrimental to U.S. suppliers who have taken such action in the past. It may take up to two years to introduce a new product due to the conservative and complex nature of the Austrian market.

Current Market Trends

U.S.-made products that are on the cutting-edge will have great potential, as Austrians expect hospitals to have the latest technology. The trend, however, is to reduce the number of hospital beds and to close down some hospitals altogether. Therefore, U.S. companies that are interested in hospital construction or in the sale of "routine" hospital equipment and supplies may find their prospects reduced over the next few years.

Projected growth rates for different imaging products vary considerably. The Austrian market for medical equipment is constantly evolving and utilizing increasingly sophisticated products.

Scanning units have benefited from technological improvements since their introduction about 30 years ago. Most suppliers now offer user-friendly features like image networking, which enable the user to digitally store and project high-quality images. These products should have very good prospects in the future.

Austria is an evolving market for echographic units. This ultrasound technique continues to gain popularity as the industry discovers new applications for it. Recent technological advances have enabled manufacturers to implement Doppler technology and sophisticated probes within their designs. There is also an increasing demand for all kinds of in-vitro products in Austria.

Main Competitors

The great majority of medical equipment used in Austria is imported. U.S. manufacturers have seized a substantial share of the market and are now the second-largest supplier group, following German companies. German competition enjoys the advantages of geographic

proximity, a common language, products with the same standards, no exchange rate problems, and duty-free access through Austria's membership in the EU.

Germany supplied 34.5 percent of Austria's imports of medical equipment in 2012. The United States ranked second with 16.7 percent among foreign supplier countries, followed by Switzerland with 6.4 percent, China with 3.3 percent and Japan with 2.9 percent. Multiple countries supply the balance.

Total Austrian imports of medical devices from the United States amounted to USD 310 million in 2013 and should reach USD 326 million in 2014. Sales of U.S.-engineered healthcare equipment are actually much higher than are reflected in official import statistics, because many products imported into Austria from Western Europe and from the Far East were made or assembled by subsidiaries of U.S. firms.

The Austrian market for medical equipment is sophisticated and well-served. Industry giants such as Siemens, Philips, Hitachi, and Toshiba are well entrenched. General Electric GmbH, Agilent Technologies Oesterreich GmbH, Nova Biomedical GesmbH, and Tyco Healthcare Austria GmbH are only a few of the Austrian subsidiaries of U.S. medical device suppliers. Against the heavy German competition in this market, U.S. products can usually compete well on the basis of price and innovation.

Current Demand

Several high-quality products and devices are currently in demand in Austria:

- Nuclear medical instruments (nuclear magnetic resonance scanners)
- Diagnostic apparatus including cardiology instruments, echocardiography systems, advanced electrocardiograph equipment, monitoring systems, ultrasound equipment, gynecology and urology diagnostic systems and endoscopes
- Scanners, computer tomography imaging systems, magnetic resonance imaging
- Dialysis equipment
- Pacemakers
- Sophisticated digitalized x-ray equipment
- Clinical laboratory equipment including blood cell counters, and blood gas analyzers
- In-vitro diagnostic products

The current trend is miniaturization of electro-medical devices and nanotechnology products.

Registration Process

All U.S. medical devices have to be marked with the mandatory CE (Conformité Européenne) conformity mark. With the CE marking on a product, the manufacturer ensures that the

product conforms with the essential requirements of the applicable EC directives. Deviating from sector directives regulating other industrial goods, medical devices have to comply with "essential requirements" as described in Annex I of Directive 93/42/EEC. According to this, medical devices must not only be safe but must also function in a medical-technical way as described in the manufacturer's "intended purpose."

Barriers

Austria is a highly developed open market with relatively liberal policies and sharp competition. There are no significant trade barriers or limitations on U.S. medical devices.

Trade Events

Austria has no general medical fair. Some smaller specialized medical exhibitions are organized in connection with medical conventions. The great majority of Austrian medical importers/distributors regularly attend the most important European medical fair:

MEDICA

November 12–15, 2014; 16–18, 2015 • Duesseldorf, Germany • ***medica-tradefair.com***
Considered the world's most important and largest international fair for medical equipment. 132,000 trade visitors from 85 countries; over 4,600 distributors from 66 foreign countries.

Available Market Research

- Dental Industry (2014)

Bahrain

Summary

The government of Bahrain's expenditures for healthcare products, medicines, and medical machines peaked to USD 172.3 million in 2013, an increase of 6.7 percent compared to 2012, the highest level in several years.

In October 2013, the Ministry of Health announced that USD 716.2 million would be allocated from the GCC Marshall Plan to the Ministry of Health in the next 10 years. The funding will be used for eight major projects, including construction of new hospitals in Central governorates, clinics, upgrading medical appliances, and other services.

There is a growing market for medical equipment, which presents increased business opportunities for U.S. exporters in the future.

Market Entry

Bahrain offers one hundred percent foreign ownership. It is advisable for U.S. companies to designate a local agent/representative to conduct business in Bahrain, though it is not always necessary. It is also advisable that companies work with local legal counsel when drawing up a contractual agreement and establish a presence in the country when bidding on government tenders.

Due to the Free Trade Agreement (FTA), there is no customs duty on any U.S. imported equipment.

The public sector dominates the supply of health care services in Bahrain and accounts for the majority of health care expenditures. Public health sector spending represents 7.8 percent of total government spending. All Bahrainis receive free state-funded healthcare while most companies offer their expatriate workers healthcare coverage, either through insurance companies or through

Statistics

Capital:	Manama
Population:	1.2 million
GDP (USD):	26.04 billion (2012)
Currency:	Bahrain Dinar (BHD)
Language:	Arabic

Contact

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arrangements with one or more local private hospitals. There is an USD 8 fee for expatriates attending an emergency clinic in a government hospital.

There are talks of implementing a compulsory health insurance system for all expatriates, which would increase the private sector's contribution to the Bahraini healthcare system.

The Pharmacy and Drug Control Directorate within the Ministry of Health monitors and controls the import and distribution of medical devices and pharmaceuticals. The Bahraini pharmaceutical market is highly dependent on imported drugs. Before the approval of any medicine, two other GCC countries—one of which should be the Kingdom of Saudi Arabia—should approve it.

Morbidity and mortality statistics indicate that major diseases in Bahrain include: diabetes, respiratory infections, genetic diseases (sickle cell and thalassamia), and cardiovascular disease. Recent trends also reflect an increasing rate of oncology patients, particularly those with breast cancer.

- Over 60 percent of the population is classified as overweight.
- Almost 20 percent of the population is diabetic.
- More than 20 percent of the population smokes regularly.

Main Competitors

The Bahraini market is completely dependent on imports for medical devices and pharmaceuticals. U.S. companies are present, but European and Asian suppliers are aggressively gaining a hold on market share with their close proximity to the market and competitive prices.

Current Demand

Best Prospects include:

- Pharmaceutical industry and drug packaging and distribution
- Health complementary services
- Health support services and resorts
- Health education and training
- Medical research centers
- Information technology (E-health program)
- Biotechnology

Barriers

Despite the entry into force of the FTA, difficulties remain for duty-free access of select goods. Customs authorities occasionally attempt to collect custom duties on some items, and there have been reports that goods which are not individually labeled "Made in the USA" do not receive the preferential treatment they are accorded under the FTA.

Trade Events

No medical or healthcare events are scheduled for 2013–14. Most Bahraini companies attend Arab Health (held in Dubai, UAE) and other shows held in Germany and the United States.

Available Market Research

- Country Commercial Guide (2014)

Belgium

Summary

Belgium produces less than 10 percent of its overall needs for medical equipment. This leaves the market open for heavy competition among suppliers from the U.S., Germany, France and Great Britain.

The United States currently has a 20 percent share of total medical equipment imports into Belgium.

The Belgian market for medical equipment is estimated at USD 2.2 billion and employs 18,000 people. Over the past five years, this sector has seen an annual growth of approximately 3–4 percent. The Belgian Social Security System, which includes the Health Care System, is considered among the most extensive and efficient in Europe. It covers nearly 100 percent of the population of 11 million inhabitants. In 2013 total healthcare expenditure was estimated at USD 36 billion.

Market Entry

Belgium is an effective starting point for marketing medical equipment to the rest of Europe due to its geographical location, its effective healthcare system, and its relatively open attitude regarding procurement. Belgium is a distribution center for many multinationals: products are imported into Belgium and exported to other European countries.

In order to enter the medical equipment market in Belgium, U.S. suppliers should be familiar with the EU directives concerning the registration, marketing, and health/safety standards required throughout Europe as well as regulations specific to Belgium. It is therefore advisable to work with a local partner/distributor.

Since July 1, 2013, the European Directive 2004/18/EC on public procurement applies to all hospitals for the purchase of medicines and medical devices. The directive requires that for purchases over the threshold of €200,000 a European

Statistics

Capital:	Brussels
Population:	11 million
GDP (USD):	421.7 billion (2013)
Currency:	Euro (EUR/€)
Language:	Dutch, French, German

Contact

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tender should be released and published in the supplement of the Official Journal of the European Union. Procurement with a threshold between €85,000 and €200,000 requires a tender in Belgium and publication in the Official Journal

Current Market Trends

Belgium's healthcare system is currently facing several challenges. Belgium's growing aging population and the higher health expectations will have an important impact on healthcare expenditures in the coming years. The GOB is therefore looking at various cost-saving measures. Thus, innovative technologies and equipment offering cost savings will have a strong market potential. Orthopedic products, homecare products, obesity and diabetes products are as a consequence in high demand. Furthermore, there is a trend towards miniaturization of medical devices allowing more minimally-invasive and non-invasive procedures. Medical software, telemedicine and e-health are also sectors with a strong market potential.

Main Competitors

Belgium has approximately 800 companies manufacturing or distributing medical products. The majority of these firms are small or medium-sized, employing an average of 20 to 50 people. Belgian suppliers do well in niche markets, including anaesthesia equipment, diagnostic imaging, cancer diagnosis, and teleradiology.

Belgium is home to many subsidiaries of U.S. companies such as GE Medical Systems, 3M, Abbott Vascular, Baxter, Johnson & Johnson Medical, Medtronic, Becton Dickinson, Boston Scientific, Cyberonics, and St. Jude Medical. Siemens and Philips also have a strong presence in Belgium.

Current Demand

Best prospects include:

- Innovative technologies
- Minimally-invasive and non-invasive equipment
- User-friendly home care products
- E-Health
- Orthopedic and implantable products
- Diabetes products.

Additionally, there is a trend towards treating chronic diseases with new technologies, allowing patients to stay home and minimizing the impact on their quality of life.

Registration Process

The distribution of medical devices is regulated by Belgian law. Distributors of Medical devices including active implantable devices should notify the Federal Agency for Medicines and Health Products. For more information, please visit ***bit.ly/190svUY***.

Effective 2014, some implantable medical devices have to be registered, from bringing the product on the Belgian market to implanting the medical device. A databank will collect information regarding all implantable medical devices that are available on the Belgian market, allowing patients to check if an implant is registered or not.

Medical devices must bear the CE marking for conformity when marketed. Custom made implantable and non-implantable devices and devices for clinical investigation do not require CE marking. If a notified body has been involved in verifying the procedure of conformity, the CE marking must be accompanied by a four-figure number indicating the notified body. (***export.gov/cemark***)

Barriers

There are no significant trade barriers on U.S. medical devices.

Trade Events

Healthcare

October 1–3, 2014 • Brussels, Belgium • ***health-care.be***
Trade show for home healthcare products.

Available Market Research

- In-Vitro Diagnostics (2011)

Bolivia

Summary

There is significant interest in importing medical equipment and products to Bolivia. Multiple hospitals have approached the Embassy to express interest in buying U.S. equipment. So far the Embassy has not specifically facilitated any deals, but would like to work to promote U.S. medical equipment more actively in the future.

Market Entry

Bolivia allows the importation of medical devices and pharmaceutical products. All importers of such products must comply with the regular importation duties and taxes, as well as the proper registration process. To learn more about the importation process, please review the Bolivian customs medical imports guide (in Spanish), available at ***bit.ly/1oh7tTH***.

Current Market Trends

The Bolivian government prioritizes that all citizens have access to proper health services and medicines. Paragraphs I and II of Article 41 of the Bolivian Constitution stipulate that the state guarantee public access to medicines and prioritize generic drugs by promoting domestic production.

Since the Bolivian production of medicines does not satisfy the Bolivian demand for pharmaceuticals, and there is virtually no local production of medical devices, the import of those products is still required. Multiple companies exist whose sole function is to import medical equipment to Bolivia.

Main Competitors

U.S. and European Union (EU) companies traditionally dominated the import of medical devices. However, in the last decade there has been an increase of

Statistics

Capital:	La Paz
Population:	10,059,856
GDP (USD):	27.232 million (2012)
Currency:	Boliviano (BOB)
Language:	Spanish

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Chinese medical device imports due to their cheaper prices and aggressive marketing. After an initial boom in Chinese equipment purchases, government institutions realized that the equipment did not last very long and did not have reasonable service or spare parts. As a result of negative experiences with Chinese vendors, several local governments decided to include a quality specification in addition to price in their purchases of medical devices.

Chile and Argentina continue to be the main manufacturers of medicines available to the Bolivian market, although the United States and EU also play a role. Bolivia is not known to produce counterfeit medicines; however imports of counterfeit medicines from Peru and Colombia have been detected in recent years. No reliable figures exist to estimate the size of the counterfeit market.

Current Demand

2014 is an election year, so the Bolivian government is investing millions of dollars in new hospitals and equipment. The national government purchased its medical devices from several sources including China. After complaints on the quality of this equipment, the national government is rethinking its purchasing processes.

Regional and municipal governments are also purchasing medical devices. The Department of Santa Cruz spent USD 33.38 million in 2013 on new medical equipment and hospital supplies. The investments include a higher budget for blood bank infrastructure, cancer treatment equipment including a new linear accelerator, a new state-of-the-art hospital wing with more than 100 beds, and digital x-ray equipment.

Registration Process

All pharmaceutical products, including generic, brand name, and over-the-counter, must have sanitary registrations, as established by the Pharmaceutical Law (Law 1737) and related regulations. Products must be registered with the Ministry of Health and Sports and approved by the ministry's National Pharmacology Directorate (Unidad de Medicamentos y Acreditación de Laboratorios, or UNIMED). The latter grants sale permit certificates to products approved by the U.S Food and Drug Administration.

UNIMED requires a detailed description (monographed copy) of each new product, with the exception of essential pharmaceutical products. The monograph must include the quantitative formula (specifying active ingredients), the pharmaceutical formula, the recommended dosage, expected product benefits, and possible side effects. Three samples of the product must also be provided to the National Laboratory (Instituto Nacional de Laboratoris de Salud, INLASA) so that specialists can verify content. UNIMED requires that products comply with World Health Organization and Pan-American Health Organization guidelines.

UNIMED takes an average of six to 12 months to review new products and one month to review essential products. For more information, please visit ***www.sns.gob.bo***.

If pharmaceutical products contain drugs covered by the Vienna Convention, importers must obtain special import permits from the Ministry of Health and Sports.

To import, manufacture, or distribute pharmaceuticals, companies must register with the Ministry of Health and Sports, a process that requires from 10 to 30 days. Imported products may be sold through established agents or distributors or through subsidiaries, although given their direct access to UNIMED, it may be easier to market products through agents or representatives. If the latter register pharmaceutical imports, they must have exclusive rights to import and be qualified to act as legal representatives.

Pharmaceutical brand names must also be registered with the National Intellectual Property Service (SENAPI, ***www.senapi.gob.bo***).

U.S. firms should note that Bolivia does not have a law prohibiting copycat registration of pharmaceutical products. Firms may experience difficulties protecting their intellectual property rights and cannot expect chemical information to remain confidential.

Obtaining medical device registration in Bolivia also requires approval from the Bolivian Ministry of Health's Unit of Drugs and Health Technology (UNIMED). The health ministry's medical device manual, the "Manual Dispositivos Médicos," as well as the Manual of Sanitary Registration provide specific guidance on how to comply with Bolivian regulatory requirements and commercialize medical devices.

There are companies and law firms in the country that can assist interested companies in evaluating the Bolivian medical device regulatory framework as it applies to the device(s) to be imported.

It is recommended that medical devices and pharmaceutical products' importers review the Bolivian medicines law (Law No. 1737), its implementing regulation (Supreme decree No. 25235), and the Bolivian Health Registration Manual, and then take into account:

- UNIMED regulatory information and background
- Product assessment
- Device classification according to UNIMED criteria
- Bolivian authorized representation requirements
- Medical device registration requirements
- Medical device labeling requirements
- Costs and timelines

Barriers

There are not specific barriers for U.S. products. Importers need only to comply with the proper registration processes. Bolivian bureaucracy takes its time, so importers should take this into consideration.

Trade Events

Fexpo Salud ut on by Fundacion para la feria internacional de Cochabamba, Bolivia (FEICOBOL)

September 2015 • ***bit.ly/1ut5Nhg***
Latin America's largest medical event.

The largest trade event in the country is the multi-sector fair in the city of Santa Cruz, which takes place annually around September: ***www.fexpocruz.com.bo***.

Available Market Research

- Import of Medicines (2013)
- Import of Medical Devices (2013)

Brazil

Summary

Brazil is the largest medical equipment market in South America and should continue to expand through the next years. Brazilian medical equipment revenues in 2013 reached an estimated USD 6.8 billion, which represents an increase of 9.4 percent from the previous year. Brazil is both a major medical equipment producer and importer.

The United States accounts for approximately 30 percent of the import market, mainly by using through local agents, distributors and importers who sell to hospitals and clinics. The market for electro medicine equipment is around USD 200 million, which represents approximately 50 percent of total sales in Latin America. In 2013, imports for In Vitro Diagnostics reagents and devices increased approximately 10 percent, reaching sales of USD 230 million.

Market Entry

For medical products, it is necessary to have a local agent or distributor to import products from manufacturers. Because of regional economic disparities, varying states of infrastructure, and a host of other issues, it is often difficult to find one distributor that has complete national coverage. Main cities are São Paulo, Rio de Janeiro, Belo Horizonte, Brasília, Porto Alegre, Salvador, Recife and Curitiba.

Either setting up a company in Brazil or acquiring an existing entity is an investment option for Brazil. Setting up new companies is relatively complex, although the Ministry of Development has signaled a desire to simplify the process.

Companies are also joint venturing with Brazilian industries for final assembling and packaging of products. This process reduces import duties and documentations that are required for finished goods. In addition to that, Brazilian

Statistics

Capital:	Brasília
Population:	192 million
GDP (USD):	3.033 trillion
Currency:	Real (BRL)
Language:	Portuguese (Brazil)

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government is offering margins of preference in the public purchase of medical products for local made products.

Current Market Trends

Brazil's recently strengthened currency has meant that private and public hospitals have greater purchasing power, and with continued expansion of Brazil's private health care sector, the market should grow. New opportunities for U.S. exporters abound, particularly for:

- Clinical Chemistry, Biomedical and advanced medical devices—high demand for new technologies;
- Laboratory equipment—investments in Research and development, including some duties and registration exemptions;
- Disposables and surgical—high consume from private and public hospitals;
- Diagnostic devices and monitoring equipment—high demand for innovative products to replace bigger and more expensive equipment;
- Orthopedics and Implants—high demand of imported products, despite higher sanitary requirements;
- Health IT—demand in hospitals, including education and second opinion programs;
- Dental—Brazil has one of the highest number of dentists in the world;
- Drugs, Pharmaceuticals and Nutrition Supplements—high dependency on imported products. New rules to facilitate imports of supplements. High demand for modern life products.

Main Competitors

There are few high-quality Brazilian manufacturers of advanced medical products so Brazil's reliance on imports should continue for some time. Local buyers view U.S. and other foreign products (mainly Canadian and European) as having comparable quality and reliability. Thus, financing terms often become the differentiating criteria in making a sale.

Current Demand

An interesting trend in Brazil is the growing market for home health care products, which has increased dramatically in recent years. Brazil has approximately 150 home health care companies compared to approximately 1,440 in the U.S. In Brazil, these companies are increasingly viewed as good ways to cut hospitalization costs while offering better services for patients. Brazilian health insurance companies are responsible for paying 99 percent of the costs related to home care treatment, and as such, the U.S. Commercial Service sees the market for home health care products growing dramatically during the coming years. Brazil's Regional Nursing Council is currently developing procedures on how to regulate this market, including standards for health professionals.

In addition to the attractive size of the Brazilian medical market, U.S. exporters should consider the opportunities offered by Mercosur, and use Brazil as a "spring board" for export into Argentina, Uruguay and Paraguay. Since compulsory product registration before sale is required for all of Mercosur countries, U.S. exporters should consult a local lawyer/consultant before signing a contract with any agent/distributor.

Barriers

Medical products in Brazil are highly regulated by Anvisa, the Brazilian counterpart of FDA. All products must be registered or be notified in order to be commercialized. For products with higher grade risk, it may be necessary to have additional local certifications, international market data and even inspections in manufacturing plants.

The import system is very complex and can add up to 100 percent fees over products. For more information, please refer to ***bit.ly/1nbOTMC***.

Trade Events

Hospitalar

May 19–22, 2015 • São Paulo, Brazil • ***hospitalar.com***
Latin America's largest medical event.

MD&M

Summer 2015 • São Paulo, Brazil • ***mdmbrazil.com***
Latin America's largest medical technology show.

Reabilitacao

Summer 2015 • São Paulo, Brazil • ***reabilitacao.com***
Orthopedic and rehabilitation products.

Bulgaria

Summary

Following a five-year trend since 2009, Bulgaria's healthcare budget for 2014 remained at 4 percent of GDP amounting to 1,317 million EUR. In 2009 and 2010 it amounted to 1.573 billion EUR and 1.329 billion EUR respectively. The healthcare budget for 2011 amounted to 1.659 billion EUR (4.2 percent of GDP). It increased to 1.875 billion EUR in 2012, in 2013 it reached 1.607 billion (4.1 percent of the GDP) and in 2014 it is estimated at 1,317 million.

Individual segments of the healthcare market indicate a slight increase. This refers mainly to the pharmaceuticals market with a trend of 3–5 percent increase per IMS Health prognosis.

According to Eurostat data, Bulgaria's public spending in the health sector as a percentage of GDP is lower than that in other EU countries, but its rate of increase for the 2007–2011period is the highest in comparison to the rest of the European Union.

With the implementation of the EU directive on cross-border healthcare, the way healthcare in Europe is planned and the range of providers to which patients have access could look very different in the years to come.

The directive outlines the right of patients to receive healthcare in other EU member states. Legislation that will extend patient choice beyond national borders, with significant implications for both National Health Service commissioners and providers, came into force in October 2013.

Healthcare coverage for Bulgarian population is universal. Practically everyone has access to healthcare services. Healthcare contributions are 8 percent of the incomes and are split among employees (called deductions—3.2 percent) and employers (called contributions—4.8 percent).

Statistics

Capital:	Sofia
Population:	7,245,677
GDP (USD):	53,872,414
Currency:	Bulgarian Lev (BGN)
Language:	Bulgarian

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The short and long term development of the healthcare sector in Bulgaria is strongly determined by the ongoing healthcare reform, a fundamental reform aiming at an efficient allocation and expenditure of healthcare assigned funds, improvement of primary and ambulatory care, improvement of emergency healthcare services, reform of the existing hospital system, introduction of eHealth and mHealth tools, improvement of the National Health Insurance Fund's operational efficiency, and strengthening the institutional capacity of all healthcare related institutions.

The ongoing health sector reform has several components, the first one being reform and sustainability of the primary and ambulatory care sector. The second component targets reform of the hospital system. The third component aims at assisting the National Health Insurance Fund (NHIF) to establish the technological infrastructure including the hardware, software systems and respective training and technical assistance required.

The fourth component aims at strengthening the management and institutional capacity of the Health Ministry, the NHIF, and the health system in general.

Market Entry

There are no specific challenges to the business environment which could be considered a serious threat. The institutions responsible for regulatory monitoring of market entry rules and laws are the Ministry of Healthcare (***www.mh.government.bg***), National Health Insurance Fund (***www.nhif.bg***), National Veterinary Institute (***www.vetinst.bg***), and Bulgarian Food Safety Agency (***babh.government.bg/en***).

Current Market Trends

The official government agency Invest Bulgaria (www.investbg.government.bg) has identified few priority sectors with growth potential. Healthcare and healthcare tourism are among them. Among the short to medium term priorities in the healthcare sector are improvement of prevention, prophylaxis, emergency services, early diagnosis of breast and prostate cancer; introduction of non-invasive surgeries; introduction of hight-tech biotechnology and innovative products. Bulgarian Healthcare Ministry and Food Safety Agency target sanitation, prevention and eradication of pandemic diseases.

Businesses, government institutions and NGO-s realize that introduction of eHealth/ telemedicine and Health2.0 will provide better access of patients to quality services and good value-for-money spending ratio. This process started in 2012 with segmented development of electronic birth registers, registers for patients with mental disorders, invasive cardiology procedures, IVD procedures, and other procedures.

Dentistry

Ninety percent of dental practices are privately-owned.

Members of the Association of Dental Dealers in Bulgaria (***addb.bg***) import, distribute, and provide service of dental equipment and instruments, and. They are

About 7,000 Bulgarian dentists have modern dental practices in Bulgaria (***stomatolozi.bg***).

Bulgariq's dentist-per-person ratio is almost twice the EU average. In Bulgaria, one dentist treats about 1,000 people, and in the EU the number is one dentist per 1,800 patients.

Some of the dental services are reimbursable, with the exception of the purely aesthetic dental procedures.

Medical Tourism

Popular services include:

- Balneology
- Dentistry
- Plastic surgery
- Orthopedic services
- Auditory system care
- Noninvasive Procedures
- Weight loss therapy
- Spine surgery
- Physiotherapy and rehabilitation
- Assisted reproduction

Registration Process

Mandatory required certifications are the CE mark, as well as some ISO standards (such as ISO 9001, ISO 13485, and ISO 13795).

Few of the medical device directives are aligned to those of the EU:

- Directive 90/385/EEC for implantable medical devices
- Directive 93/42/EEC for medical devices in general and
- Directive 98/79/EEC for in vitro medical devices

Barriers

There are no significant barriers to trade on healthcare related products in Bulgaria. Some tariff and non-tariff barriers are reported in the pharmaceutical market sub-sector by the LAWG and might be viewed in the National Trade Estimate Report when existing.

Trade Events

Bulmedica/Buldental

May 2015 • ***bulgarreklama.com***

Medicus

June 2015 • ***fair.bg/en***

Canada

Summary

Canada's health care industry depends heavily on the demand created by the country's publicly funded and insured health care system. The medical device industry consists of firms that produce a wide range of products used for diagnosis and treatment of ailments, which include the following: medical, surgical and dental equipment (including electro-medical equipment and related software), furniture, supplies and consumables, orthopedic appliances, prosthetics and diagnostic kits, reagent and equipment.

The Canadian healthcare system falls under the jurisdiction of each province and territory. While funding is subsidized through federal transfer payments, the delivery and management of healthcare services are controlled by the provincial governments. Healthcare systems in Canada use various competitive tendering processes for the procurement of medical devices and diagnostics technologies. These change depending on the province, but are generally conducted by each hospital and depend on the need and resources available to the hospital.

The Canadian medical device market was valued at approximately USD 6.4 billion in 2012. Canada's medical device imports totaled approximately USD 5.5 billion in 2012. The United States is the biggest exporter of medical devices to Canada, accounting for 52 percent of imports.

Currently, eighty percent of the Canadian medical device market is comprised of imported goods. There is particular demand for diagnostic equipment, as well as consumables, patient aids, orthopaedic and prosthetic equipment, and dental equipment. The orthopaedic and prosthetic equipment subsector is experiencing the strongest growth.

Medical device manufacturers should develop partnerships with Canadian distributors to sell their products. To do this, they must obtain an establishment license and, if necessary, a device license. Imported medical devices are subject to

Statistics

Capital:	Ottawa
Population:	35.34 million (est. 2014)
GDP (USD):	1.785 trillion (est. 2014)
Currency:	Canadian Dollar (CAD)
Language:	English, French

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Canadian safety and effectiveness regulations and packaging requirements. Few other barriers exist for U.S. businesses looking to sell in Canada.

Market Entry

Health Canada, under the authority of the Food and Drugs Act, regulates the sale of medical devices in Canada. Health Canada is an equivalent regulatory agency to the U.S. Food and Drug Administration (FDA). Medical equipment imports must comply with marking, labeling, and packaging requirements as described in the Food and Drug Act. In particular, instructions (operator's manual) accompanying the equipment must be in both of Canada's official languages (English and French).

Current Market Trends

Hospitals and other public health institutions are the principal purchasers of medical equipment and supplies, accounting for about 70 percent of total market demand in Canada. These organizations buy directly from manufacturers for capital equipment and use group procurement and distribution for regular medical equipment including devices, instruments, and supplies.

The primary growth in sales of medical equipment is tied to demand for diagnostic equipment, which accounted for 25.8 percent of the market's value in 2012. The primary demand for diagnostic equipment will be for technologies such as nuclear medicine cameras, MRI (magnetic resonance imaging), and CT (computed tomography). Other medical electro-diagnostic and patient monitoring equipment, including ultraviolet or infrared rays and ultrasonic scanners, will also see an increased demand. Other top contributors to the medical device market in 2012 were consumables (15.3 percent), patient aids (12.3 percent), orthopaedic and prosthetic equipment (11.9 percent) and dental products (6.9 percent).

Main Competitors

The United States is by far the biggest exporter of medical devices to Canada, accounting for approximately 52 percent of the country's medical device imports. Other key import sources include China (7 percent), Germany (6.3 percent) and Mexico (4.7 percent).

Current Demand

The Canadian medical device market depends upon imports for around 80 percent of its consumption. It expects to see a compound annual growth rate (CAGR) of 4.4 percent from 2011 to 2016, better than the expected global growth rate of 4.0 percent. Orthopaedic and prosthetic equipment expects particularly strong growth at 8.3 percent, while markets for all medical device categories are expected to grow by at least 3 percent per year.

Canada's elderly population continues to grow. 16.8 percent of the population is aged 65 and over, and this is expected to increase to 18.2 percent by 2016. This rapid aging of the population presents a key market opportunity for businesses in the medical device industry.

Registration Process

Canadian authorities have worked at harmonizing regulations with those of the United States and Europe. In keeping with international trends, medical devices are regulated under the Food and Drugs Act as Class I (low risk), II, III or IV (high risk) devices, subject to Health Canada approval. All medical devices require an establishment license, and Class II, III and IV devices require a device license. All products are subject to safety and effectiveness requirements, including Class I devices, and these requirements must be satisfied with objective, documented evidence.

Barriers

Trade in the medical device market presents a number of advantages to U.S. firms. U.S. firms benefit from similarities between U.S. and Canadian regulations concerning the safety and quality of medical devices. Other advantages include: the similarity between general business practices, the established reputation of U.S. firms in Canada, and the close geographic proximity to Canada. Partnerships with the provincial and territorial health authorities responsible for the delivery of health care services are essential for the importing success of medical devices.

Trade Events

HealthAchieve

November 3–5, 2014 • Toronto, Canada • ***healthachieve.com***

The largest health care gathering in Canada. Conference program with educational sessions; exhibition floor hosting 350 exhibitors showcasing health care products, services, and technologies. Approximately 9,000 delegates annually.

Available Market Research

- Available at ***statcan.gc.ca***

Chile

Summary

The current administration (2014–18) recently announced a USD 2.2 billion healthcare investment plan for the construction of six new hospitals and the expansion, repair, and modernization of 56 older public hospitals. It also informed that the following issues are a priority: information technology and communications strategies for shared digital medical records in the public system, an increase in the number of healthcare professionals, and an enhancement of the use of telemedicine and teleradiology, in particular for isolated locations of the country. Additionally they strive to strengthen attention and results at the primary healthcare level due to increase in the number of patients with chronic diseases such as diabetes, high blood pressure, high cholesterol, obesity, and asthma. Treating these patients at outpatient centers will avoid frequent hospital readmissions and will provide patients with better quality care at lower cost for the public healthcare system.

The public healthcare system is comprised of 183 hospitals: 59 high-complexity, 24 medium-complexity and 100 low-complexity hospitals. In all, the public sector has approximately 26,300 beds. In the private sector, there are 109 hospitals, with approximately 11,000 beds. The uncertainties in the impact of fiscal reforms of the current administration are expected to slow down healthcare expansion projects in the private the sector.

FONASA, the government-run healthcare insurance system, covers 75 percent of the population; of the remaining 25 percent, approximately 5 percent lacks any type of insurance, and 20 percent (bordering on 2.6 million people) pay into the private sector insurance system provided by entities called ISAPRES. There are seven Isapres currently operating in the Chilean market.

Chile's Universal Access to Healthcare government program, ex "Plan AUGE," currently known as "GES" (Garantias Explicitas en Salud) started in 2005 and consists of government-funded subsidized healthcare coverage for—

Statistics

Capital:	Santiago
Population:	16.5 million
GDP (USD):	281 billion
Currency:	Peso (CLP)
Language:	Spanish

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currently—80 diseases considered to be high-incidence. A recent report by the Ministry of Health indicated that 10 years ago, the number of patients with cataracts that were operated reached 7,000. In 2013, the number of cataracts patients operated was 46,000.

Market Entry

U.S. medical equipment and devices are well regarded in Chile. A strategy that has proved successful is to appoint a qualified agent or distributor. Chilean distributors in the medical sector are usually knowledgeable, experienced, and with a good network of sales people throughout the country. Reliable after sales support is a priority in this market. Local distributors/representatives should be experienced in selling to the public sector through Chile's government portal, ***www.mercadopublico.cl***.

The metric system of weights and measures is standard in Chile. The electric power supply is 220V/50Hz. Since the implementation of the U.S.-Chile Free Trade Agreement, in 2004, medical equipment, medical devices, and pharmaceuticals enter Chile duty-free, provided a U.S. certificate of origin is presented to Chilean Customs. Imports to Chile, alike all foreign and domestic products are subject to Chile's 19 percent VAT (Value Added Tax).

Mandatory registration at the Institute of Public Health is required for all pharmaceuticals. Medical devices such as contraceptives, gloves, needles, and syringes have to be quality tested.

Current Market Trends

U.S. state-of-the-art medical technology has good market potential in Chile, especially in the private sector with regular expansion projects. The Chilean private healthcare system is well regarded in the region. Private hospitals receive foreign patients for treatment on a regular basis. Some of these private hospitals have Joint Commission accreditation; therefore maintaining high standards is a permanent goal. Many Chilean physicians have U.S. post-graduate degrees and maintain regular contact with important U.S. healthcare institutions.

Main Competitors

The majority of the medical equipment present in the Chilean market is imported. Local statistical data shows that the United States has approximately 33 percent of Chile's market share, followed by Germany with some 21 percent, and China with approximately seven percent market share. Price is an extremely important factor, especially in the public sector where limited funds cover a large segment of the population. The private sector is also price-sensitive, but is far more likely to consider recognized brands that have good quality and after-sales reputation.

Current Demand

Best prospects include autoclaves, surgical tables, nondisposable and disposable surgical instruments, cardiology equipment including pacemakers, monitors (low and medium complexity), central monitors, ventilators, aspiration pumps, imaging equipment, trauma equipment, anesthesia instruments and appliances, and hospital furniture.

Registration Process

In general, there is no health-required registration imposed on medical devices except for contraceptives, gloves, needles, and syringes that do need authorization/quality control assessment to certify its safety.

X-Ray equipment or nuclear medicine equipment does need special authorization from other government agencies: i.e. Chilean Nuclear Energy Commission and the Electricity Superintendency. Pharmaceuticals have mandatory registration at the Institute of Public Health (ISP, ***www.ispch.cl***). ISP is the authority for pharmaceuticals, homeopathic, natural preparations with therapeutic properties, cosmetics, and pesticides for home and sanitary use. The registration has to be carried out by companies—local or foreign—legally established in Chile. Applications for registration are submitted in official ISP forms that may be downloaded from the Institute's website, in Spanish, with samples and background documents that include: application form, legal background, qualitative and quantitative formula, clinical monograph, packing or label project, draft of medical brochure, draft of information leaflet to the patient, scientific information if applicable, copy of Free Sale Certificate or Manufacturing Agreement, analytical methodology, stability study proving the efficacy period proposed in the form, quality and purity specifications for raw materials used, sterility, microbiological and toxicity reports, if applicable. Foreign documents must be duly notarized and stamped by the Chilean Consulate at the country of origin.

Barriers

Chile has a favorable import climate. There are no known barriers to U.S. medical equipment, devices, pharmaceuticals, laboratory equipment, or diagnostic test.

Trade Events

None planned in 2015.

Available Market Research

- Medical Equipment Industry Overview (2011)
- Nutritional Supplements Industry Market Insight (2010)
- Cosmetics Industry Overview (2010)
- Pharmaceutical Industry Overview (2009)

China

Summary

China has been one of the fastest growing economies in the world with a GDP of 7.7 percent in 2013. China's medical device market is ranked second largest in the world. Driven by both an increase in discretionary income and a population that is aging faster than any other nation's population, the market has been growing at about 20 percent since 2009. It is expected to maintain this pace over the next three to five years, far exceeding the predicted growth rate of the global market. By 2020, China will have 400 million people who are 60 years-old or older, and 100 million older than 80. By 2050, a third of the 1.4 billion Chinese will be at least 60.

China offers significant potential for U.S. companies interested in entering and expanding into the Chinese medical device market. In 2013, the medical equipment market reached a size of RMB215 (USD 34.68) billion for the first time in history, representing a growth of 22 percent since the close of 2012. The market size is expected to exceed RMB300 (USD 48.39) billion by 2015. With a rising Chinese middle class and improved health insurance to cover all nationals, the demand for quality equipment and supplies is growing at an unprecedented pace.

Statistics

Capital:	Beijing
Population:	1.37 billion (est. 2013)
GDP (USD):	9.3 trillion (2013)
Currency:	Renminbi (RMB)
Language:	Mandarin Chinese

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86-24-2322-1198 x8143

China's medical device market is dominated by domestic suppliers, the majority of which generally lack the expertise and experience deemed appropriate by Western standards. While only a few Chinese medical device companies are upgrading to provide some mid- to high-range technology and products, the high-tech large medical equipment is dominated by foreign suppliers. Compared with domestic products, imported products are better accepted by the Chinese hospitals and the Chinese view foreign medical device companies as more credible than their Chinese counterparts. Therefore, the Chinese healthcare market is poised to be explored by those foreign enterprises that have interest.

The new regulation (Order 650) was implemented on June 1, 2014. There are some modifications in the new regulation, all imported medical devices and products must be registered with the China Food and Drug Administration (CFDA). Barriers still exist for U.S. companies looking to do business in China, thus the medical device market should be approached systematically. The strategy should be part of a company's long-term goals, and possibly initiated by way of strategic alliance.

Market Entry

China's rapidly changing regulatory environment will likely have a short-term negative impact on the overall market. China Food and Drug Administration (CFDA) is the government body responsible for regulating medical devices by testing, evaluating, and giving administrative approval for medical devices to be sold in the Chinese market.

Regulations and Standards

Recently, China's State Council promulgated the Regulation for Supervision and Administration of Medical Devices (Order 650) which went into implementation on June 1, 2014. It is the revision of the old regulation Order 276 which was implemented in 2000 by the former CFDA, (SFDA). Based on this new regulation, all import medical products must be registered or notified with the CFDA through the foreign manufacturer's authorized distributor, or through its representative office or subsidiary in China. Modifications concerning product registration, including extending existing registration certificates from four years to five and Class I products require notification with CFDA. Class II and III products are required to be registered with CFDA. Additionally, all medical devices must have product description and labeling in Chinese to meet the regulation and related compulsory standards. The product manual must also state the country of origin and the detailed contact information of the distributor.

Set up representative office

A great number of foreign companies have selected to set up a representative office to manage product registration, promotion, marketing, training and support while appointing regional or local distributors for sales, actual operation, logistics and receivables with hospitals.

Set up your own trading company

Models for establishing your own trading company do exist. For example, if you establish a FICE (short for a foreign invested commercial enterprise), it is not necessary to use a local partner. A FICE has the right to distribute in China as well as to export to foreign markets.

Designate distributors

China is a big market, varying greatly from one region to another. China is normally divided into three major regions: north China, south China, and east China. However, it can be further divided into northeast China and mid-west China. Depending on the type of products, U.S. companies can enter the Chinese market through regional distributors that can broadly cover secondary markets but usually rely on local Tier II or Tier III distributors for sales in each locality. Direct contact with the right local distributors may give foreign companies greater control and better representation. These local distributors are also highly product or department-oriented. Selecting the "right" distributor can be an important key success factor.

Participate in technical seminars or exhibit in industrial trade shows

Participating in shows/events, ideally with an agent or distributor, offers new-to-market companies greater exposure. This provides networking opportunities with key contacts in their specialized field and provides direction for future market expansion.

Current Market Trends

China is the most promising medical device market in the world. The average annual growth rate has been over 20 percent since 2009 and is expected to maintain that growth rate during the next three to five years. Based on a recent report by Medical Device Branch, China Pharmaceutical Materials Association, the medical equipment market reached a total size of RMB215 (USD 34.68) billion in 2013 for the first time in history, a yearly growth rate of 22 percent. The market size is expected to exceed RMB300 (USD 48.39) billion by 2015. Driving factors include world's largest population and aging population, the government's increased investment in establishing and improving the healthcare infrastructure, and improvement of basic health insurance for all the population. This has created huge demand for better healthcare services and thus needing for medical devices and products in China.

Currently, China's medical device market has two distinct categories: 1) domestic manufacturers who supply low to mid-range products; 2) foreign-sourced, high-end products supplied by large companies like GE, Philips, Siemens, etc.

According to statistics from the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), China's total import and export value of medical equipment reached 34.31 billion U.S. dollars in 2013, an increase of 14.13 percent over 2012. The top three medical device exporters to China by country are the United States, Germany, and Japan.

2012–13 Chinese Medical Device Imports and Exports				
(USD Billions)	2012	% growth	2013	% growth
Total Trade Value	30.06	13.03	34.31	14.13
Import	12.47	14.56	14.97	20.07
Export	17.59	11.96	19.34	9.92

Source: China Association for Medical Device Industry (CAMDI) and China Chamber of Commerce for Health and Medicine Products

2012–13 Chinese Imports of Medical Devices by Top Three Countries					
(USD Billions)	2012	% share	2013	% share	% growth
World	15.331	100	17.137	100	11.77
United States	5.219	34.04	5.918	34.54	13.39
Germany	2.713	17.7	3.132	18.28	15.44
Japan	2.347	15.32	2.201	12.84	-6.24

Source: Analysis of representative HS codes from World Trade Atlas data (HS Code: 9018, 9019, 9020, 9021, 9022,382200, 902720, 902730,902750, and 902780)

Main Competitors

Depending on specific product type, the main competitors include EU countries (specifically Germany) and Japan. Current government policy supports and encourages medical device innovation inside China. Some domestic manufacturers such as Shenzhen Mindray and Shandong Shinva etc. now create high-quality products and are beginning to compete against foreign suppliers in medium- to high-level technology niches.

Current Demand

Due to the growing demand for access to better health services and with the government's support and investment in the establishment of a healthcare infrastructure meant to benefit every Chinese citizen.

China has over 16,000 hospitals, 85 percent of which are publicly-owned. Chinese hospitals consider U.S. products to be of superior quality and the most technologically advanced. However, domestic medical device companies are consolidating, upgrading quality, and beginning to compete in medium-level technology niches. Given the status of the Chinese medical device market, significant potential exists for U.S. companies interested in entry or expanding into the Chinese market. Additionally, the healthcare reform which started in 2009, is advancing reform on public hospitals. The government has invested RMB 2,243 billion during the last four years for establishing and improving healthcare infrastructure.

Best prospects include:

- In vitro diagnostic equipment and reagents—clinical and diagnostic analysis equipment, diagnostic reagents, medical test and basic equipment instruments, and point of care testing equipment.
- Implantable and intervention materials and artificial organs—interventional materials, implantable artificial organs, contact artificial organs, stent, implantable materials, and artificial organ assisting equipment.
- Therapeutic products—tri-dimensional ultrasonic focused therapeutic system, body rotary gamma knife, simulator, linear accelerator, laser diagnostic and surgery equipment, nuclide treatment equipment, physical and rehabilitation equipment.
- Medical diagnostic and imaging equipment—black and white or color supersonic diagnostic unit, sleeping monitor, digital x-ray system, MRI, CT, DR, and ultrasound equipment.
- Surgery and emergency appliances—anesthesia ventilation systems and components, high frequency surgery equipment, and high frequency and voltage generators.
- Healthcare Information Technology related equipment and products: Medical software, computer-aided diagnostic equipment, and hospital information systems (HIS, CIS, and HLT).
- Medical equipment parts and accessories.

Registration Process

All imported medical devices require registration or notify with the CFDA before being sold or distributed in the Chinese market. In China, medical devices are divided into three classes depending on levels of risks similar to but different and stricter than that of USFDA. According to Order 650, all Class II and III are required to be registered with CFDA while Class I products are required to be notified with CFDA. Clinical trials are required for Class III and some Class II medical devices unless they are on the CFDA's exemption directory for clinical trials.

Generally speaking, the process is complex and time consuming. Depending on the product class, it can take one to three years after submission of all necessary documents and respective samples for testing. U.S. companies are encouraged to register their products through their authorized distributors if they do not have a representative office or subsidiary in China. The CFDA has a comprehensive system for medical device registration and inspection, including product testing and factory audits. A company is required to provide a testing report for the product conducted by a Chinese lab. The company is also required to submit a product standard according to China's "Product Regulation Standard," for CFDA's record. In addition to the service fee charged by a local company for translation and product standard compiling, the cost varies for registering a product with CFDA, which includes product testing in an

authorized Chinese lab, the technical evaluation at the CFDA's Medical Evaluation Center, and final administrative approval by the CFDA.

Barriers

Barriers exist with an uncertain regulatory environment and extensive delays in registration and re-registration of products. Additionally, pricing control, tender, and bar code systems also play a role of delaying a company's entry into the Chinese medical device market.

While reform of the healthcare sector is creating new opportunities, it has not completely opened the market to foreign companies. Despite the enormity of the market, U.S. companies face significant challenges when entering the Chinese healthcare market. Barriers include onerous pricing and reimbursement policies on pharmaceuticals and medical devices, inadequate intellectual property protection, and bureaucratic delays in registering products for sale. Numerous restrictions and an ever-changing regulatory environment add to the challenges faced by U.S. companies trying to enter the healthcare market in China.

The Chinese government has issued new policy giving more support to domestic suppliers by encouraging innovative new products inside China. Domestic manufacturers whose products are defined, by CFDA, as innovative are expected to get an expedited approval in product registration, allowing them more lead time to enter the market and to complete against foreign suppliers in China.

Trade Events

China Med 2015

March 21–23, 2015 • Beijing, China • ***www.chinamed.net.cn/en***

China International Medical Equipment Fair (CMEF)

April 2015 • Shenzhen, China • ***en.cmef.com.cn***

SINO-Dental 2015

June 9–12, 2015 • Beijing, China • ***sinodent.com.cn/en***

Colombia

Summary

Due to the 1993 health care reform, also known as Law 100, Colombia benefits from one of the most extensive insurance systems and medical financial protection in Latin America, second only to Chile. This reform created the social security system and covers standards governing the general system of pensions, workplace injury insurance and complementary social services. Currently approximately 80 percent of the Colombian population is covered by health insurance, and the government of Colombia sees universal health insurance coverage as a goal.

The country's healthcare infrastructure is adequate in the larger urban areas, but is in need of modernization. The healthcare system is complex, and coverage is not yet universal. Currently the Colombian Congress is working to develop an updated health care reform law, which they expect would modernize the system.

According to Espicom (a business monitor international company for medical devices and pharmaceuticals), "the Colombian medical device market has benefitted from the country's increasing political stability and GDP growth above the Latin American average in recent years. It now ranks fourth in Latin America and is projected to register one of the world's top 10 fastest 2013–18 medical device Compound Annual Growth Rate (CAGR). Per capita medical device expenditure is low but healthcare and regulatory developments implemented over the last three years will provide new growth opportunities for medical device companies in the long-term. Multinationals that already have a presence in the Latin American market will have a distinct advantage over new entrants."

According to a study by America Economia Intelligence, seven of the twenty best hospitals and clinics in Latin America in 2013 were located in Colombia. In fourth place is the Fundacion Valle del Lili in Cali, in sixth is Fundacion Cardioinfantil in Bogota, in eighth Fundacion Cardiovascular de Colombia in Bucaramanga, in tenth

Statistics

Capital:	Bogotá
Population:	47,689,570
GDP (USD):	378.1 billion
Currency:	Colombian Peso (COP)
Language:	Spanish

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Hospital Pablo Tobon in Medellin, in fourteenth Centro Medico Imbanaco in Cali, in nineteenth Clinica las Americas in Medellin, and in twentieth Hospital San Ignacio de Bogota.

Market Entry

To successfully penetrate the Colombian market, U.S. firms should offer competitive pricing and financing. Additionally, modern technology coupled with efficient post-sales service and parts support is a winning combination.

New-to-market exporters should develop product or service information in Spanish and check to see whether their competitors already have a presence in the market. U.S. equipment suppliers are generally encouraged to find a local representative/distributor, although this is not a legal requirement for doing business in Colombia. Local companies may operate as a manufacturer's representative (sales agent), importer/distributor, or dealer, separately or all at the same time. U.S. Companies may find the use of a local sales representative useful given their knowledge of the local market, and their understanding of local regulations and import procedures.

Finally, U.S. companies are advised to be on the lookout for relevant trade events to promote their products or in order to test the market. Trade missions to Colombia have also proven to be an effective means for promoting new U.S. products.

Current Market Trends

U.S. imports enjoy the largest share of the Colombian market, accounting for around a third of all medical equipment imports. With the May 2012 implementation of the FTA, tariffs on 96 percent of U.S. medical equipment exports to Colombia went from an average of 7.6 percent (ranging from zero up to 15 percent) to zero. Colombia also has FTAs with leading medical device producers such as the European Union and Canada.

Main Competitors

Colombia is a price-sensitive market; prices are a major selling factor for most. Currently the strongest competitors are China, Germany and Japan. China is quickly increasing market share.

Current Demand

Best prospects for U.S. medical equipment manufacturers include:

- Medical, surgical, dental and veterinary instruments
- Electro-diagnostic apparatus
- Orthopedic devices
- Prosthetic devices
- Diagnostic imaging equipment
- Laboratory equipment and consumables
- Ultrasound, mammography, and cardiovascular equipment.
- Dermatological and laser treatment apparatus and apparel (boosted by medical tourism and expanding plastic surgery demand)
- Intensive care, cardiology, neurology, and oncology related equipment

It is expected that a number of Colombia's clinical laboratories will be upgraded in the near future, which will provide an opportunity for exporters of clinical laboratory equipment. Opportunities also remain in medical, surgical, dental and veterinary instruments and electro medical equipment.

In 2013 Colombia imported medical equipment and supplies valued at USD 1.09 billion, the highest level ever. Of this total, USD 369 million was from the United States.

The medical device industry is concentrated around the capital Bogotá. Per capita spending on medical devices is average for the region. The medical device market is heavily reliant on imports, especially in the high tech sectors. There is some domestic capacity for more basic items. A few multinationals manufacture within the country.

In addition, Colombia is seriously promoting the country as a health destination (Health/ Medical Tourism). Colombian medicine is well-known in Latin America and the rest of the world as a pioneer and leader in health services, positioning the country as one of the most attractive destinations to receive medical treatments. This becomes an important market opportunity for the U.S. because the success of this industry requires high quality standards, technology and infrastructure. This has led Colombian hospital and clinic management to upgrade existing facilities, adding/renewing medical equipment and providing English language training for their staff.

Registration Process

U.S. companies should be aware that medical devices require registration at the "Instituto Nacional de Vigilancia de Medicamentos y Alimentos" (INVIMA), the country's medical device regulator. It is strongly recommended that U.S. companies process the registration under their name and not under the local distributor name, as if it is listed under the local distributor name, the U.S. company will not be able to change or add distributors, during the lifetime of the registration, which is 10 years. Classification of devices in Colombia follows a four-tiered risk model (Class I, Class IIa, Class IIb and Class III). Colombia's device classification scheme

is similar to those of the European Union and other Global Harmonization Task Force (GHTF) systems. If the device falls into a lower-risk category in Colombia (Class I or IIa), the company may qualify for an expedited review process and achieve market entry in a shorter time.

Access to this market is not easy for newcomers. The market is mature and competitive, with many foreign firms selling medical equipment and medical products. It should be noted that registration procedures can often be challenging and may pose a barrier to entry into this market.

Barriers

Although distribution and sales of imported medical equipment in Colombia is handled principally through importers, distributors, representatives, and agents, a large percentage of materials, supplies, and equipment, are imported directly by end-user firms and/or associations. U.S. manufacturers should maintain close contact with end-users and familiarize themselves with the equipment through training and demonstrations. This strategy is being used effectively in Colombia by European and Japanese manufacturers.

Access to this market is not easy for newcomers. The market is very competitive and there are already many firms (local and foreign) selling medical equipment and medical products.

It should be noted that registration procedures can often be challenging to U.S. companies and may pose a barrier to entry into this market.

Trade Events

Meditech Colombia

August 12–15, 2014 • ***feriameditech.com/?stridioma=en***

Supplies, services, and technological advances to foster development of the medical industry in the Andean region, Central America ,and the Caribbean. Typical attendees include hospital and clinic managers, Directors General, financial and administrative managers, and purchasing managers; health sector officials; and health sector service providers. Typical exhibitors include manufacturers and distributors of medical, surgical, dental, and clinical laboratory equipment; hospital staffing firms; distributors and marketers of direct inputs related to the health sector; entities administering benefit plans; and prepaid medical institutions.

Belleza y Salud (Beauty and Health Fair)

August 12–15, 2014 • ***feriabellezaysalud.com/?stridioma=en***

A leading health and beauty event. The latest trends, product developments, equipment, and services for the men's and women's beauty industry.

Costa Rica

Summary

Costa Rican Medical Equipment Market, 2011–14				
(USD Millions)	2011	2012	2013	2014 (est.)
Total Market Size	96	101	118	109
Total Local Production	8	10	11	11
Total Exports	7	7	12	12
Total Imports	95	98	119	124
Imports from the U.S.	43	47	53	61

Source: Estimates based on information from importers/distributors along with data on previous economic growth.

Costa Rica has a socialized healthcare system identified as the Costa Rican Social Security System (Costarricense de Seguro Social: CCSS, or "Caja," as it is popularly known). This system includes 30 hospitals: 10 general hospitals, seven regional hospitals (one in each geographic region/province), and 13 peripheral hospitals, which vary in size. 16 of the hospitals are located in the Central Valley region of the country, where about one-half of the population lives. Additionally, the CCSS is responsible for approximately 500 clinics, and approximately 1,000 small attention units with only basic equipment, known as "Equipos Basicos de Atencion Integral" (EBAIS), which provide basic medical assistance to patients in remote areas of the country.

The CCSS hospitals have approximately 6,000 beds, while there are approximately 223 beds in three private clinics/hospitals. The "Caja" buys approximately 90 percent of the medical equipment in Costa Rica. The public is very sensitive to the government's programs in public health and encourages, almost demands, replacement of obsolete medical equipment in the principal hospitals and clinics.

Statistics

Capital: San José
Population: 4.5 million
GDP (USD): 49.62 billion (2013)
Currency: Costa Rican colón (CRC)
Language: Spanish

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There are several private hospitals and clinics in the country, mainly in the Central Valley. Hospital Clínica Bíblica (HCB) is the largest followed by CIMA Hospital, owned by the International Hospital Corporation (headquartered in Dallas, Texas), and Hospital Hotel La Católica (HCC). These three private hospitals are accredited by the Joint Commission International (JCMI). The HCB is also accredited by the Medical Tourism Associations. Both CIMA Hospital and Hospital Clínica Bíblica are building new facilities in the Guanacaste Province. Hospital Metropolitano, in San José downtown, accredited by the Association for Ambulatory Healthcare (AAAHC), is the newest hospital and among their services they offer assistance to U.S. veterans, they accept medical insurance under the Foreign Medical Program (FMP) and Tricare.

The number of small, private clinics is growing constantly, as the population is demanding quicker and better health services. The largest private clinics in Costa Rica are Clinica Santa Catalina, Clínica Santa Rita, Clínica Santa Fe, and Hospital Clínica Jerusalem. The influx of foreigners, mainly from North America (U.S. and Canada), is also contributing to this private growth, in what is often known as "medical tourism."

Current Market Trends

There are several projects for the construction of new hospitals and the expansion of existing hospitals. The CCSS will start the construction of the new tower of the Calderon Guardia Hospital (Torre Este del Hospital Calderon Guardia) in 2013; the project is already assigned to a local construction company. Total cost of the project is approximately USD 120 million. It is expected to be completed in 2016. The CCSS is also designing two new hospitals to be built, one in Cartago Province, no further information has been provided on this project and the other one in Puntarenas Province. This hospital will have an estimated cost of USD 130 million and the tender is expected to be ready before the end of 2014.

Main Competitors

Costa Rica is competing with other countries such as Brazil, Mexico, India and Malaysia in the medical tourism arena. Costa Rica appears to have an advantage because it is closer to United States and Canada, the principal sources of medical tourists, and many professionals here have had training in the U.S. Several North American insurance firms are looking at the prospects for insuring medical tourists in Costa Rica.

Current Demand

The market size for medical equipment and supplies has remained relatively stable during 2011 and 2012. In 2011, the market size amounted to USD 96 million. In 2012 it amounted to USD 101 million, an increase of approximately 6 percent from 2011. In 2013, the imports increased to USD 118 million, a 14 percent increase from 2012.

The United States is the largest exporter of medical equipment to Costa Rica, with USD 43 million in 201, USD 47 million in 2012 and USD 53 million in 2013. This volume represents a market share of approximately 48 percent each year of total Costa Rican imports. Major competitors to the U.S. in medical equipment, are China, Germany and Switzerland.

The level of demand for medical equipment in Costa Rica is expected to rise, as most hospitals need to continue replacing obsolete equipment, in virtually all categories of products in the sector. Imported medical equipment and supplies are exempt from custom duties.

The Costa Rican government authorities and the Central American Bank for Economic Integration (BCIE) signed a loan in the amount of USD 270 million for construction and renovation of various infrastructure projects across the country to be executed in the next year. This investment includes medical equipment of medium and high complexity, such as X-ray equipment, surgical tables, gamma cameras, pulmonary ventilators, anesthesia machines, and sterilizing equipment, among others. Resources included for industrial units including: industrial washing machines, boilers, among others.

The Costa Rican Institute of Social Security (Caja Costarricense de Seguro Social-CCSS) is the second largest government entity that requires products and services for their operations (drugs, pharmaceuticals, medical equipment, supplies, etc.) The CCSS also has its own website (available at ***bit.ly/1qQgOtA***) where they publish their requirements for all the public hospitals (10), clinics (500) and "EBAIS" (Small medical units with basic equipment-1000).

Registration Process

In July 2011, the Costa Rican Ministry of Health accepted a petition submitted by U.S. Embassy San Jose to recognize U.S. Food and Drug Administration (FDA) authorizations of medical devices to be sold in the U.S. market as permissible for sale in Costa Rica without additional evaluation on the part of the government. This decision—the result of three years of work—will benefit U.S. exporters of medical devices. Since all medical devices shipped from the U.S., will no longer be required to undergo additional clinical trials or obtain additional documentation (with the exception of a Certificate to Foreign Government, issued by FDA stating that the product is sold freely in the U.S. market and the plant follows good manufacturing practices), U.S. exporters will enjoy lower cost-to-market and significantly faster time-to-market. Costa Rican patients will also be able to benefit from state-of-the-art medical devices and the improved medical care that will result from their use. The market in Costa Rica for medical devices is growing and the United States is the largest exporter of this type of equipment to Costa Rica.

The Costa Rican Ministry of Health implemented since October a digital platform to submit medical device registrations. Medical device manufacturers seeking market authorization in Costa Rica will be able to submit registration applications online once they have chosen a Costa Rican distributor. Currently the timeframe to register new product is around six months once all the documentation is submitted to the Ministry of health.

Croatia

Summary

In July 2013, Croatia became the 28th member of the EU. On the accession date, a new medical device legislation was introduced, replacing the previous Medical Devices Act of 2008.

According to the data provided by the World Health Organization (WHO), Espicom estimates that Croatia spent an estimated 8.3 percent of GDP on healthcare in 2013, equal to USD 4.7 billion, or USD 1,087 per capita. Around 5 percent of this was spent on medical equipment. Most of the medical equipment in Croatia is imported from EU countries and the United States.

Orthopedics and prosthetics, and diagnostic imaging are product areas with the best prospects. Health IT sector will also present great opportunities in the upcoming years.

Market Entry

Medical equipment products exported to Croatia must include:

- CE mark
- Directions for use in the Croatian language.

The EU common Customs Tariff schedule applies to products exported from non-EU countries. All products, regardless of origin, are subject to the value-added tax (VAT). For medical products embedded in body by surgical procedure and medical products substituting physical disabilities the VAT is 5 percent, and for all other medical products 25 percent.

The institutions responsible for regulatory monitoring of market entry rules and laws are the Ministry of Health (***www.zdravlje.hr/en***), the Agency for Medicinal Products and Medical Devices (***almp.hr/?ln=en***), the Agency for Quality and

Statistics

Capital:	Zagreb
Population:	4.475 million
GDP (USD):	79.14 billion
Currency:	Kuna (HRK)
Language:	Croatian

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Accreditation in Health Care and Social Welfare (***aaz.hr***), and the Croatian Institute for Health Insurance (***www.hzzo-net.hr/en***).

Small purchases of medical equipment and supplies are usually made directly by hospitals and local health authorities, while for larger items, a tender is issued by the Institute for Health Insurance. The appointment of a local distributor will therefore be essential, to navigate the tendering process and reach end-users throughout the country. Some of the leading local distributors are Medika (***medika.hr/en***), Medical Intertrade (***www.inel-mt.hr***), and Phoenix Farmacija (***www.phoenix-farmacija.hr/en***).

Current Market Trends

In 2013, the Croatian market for medical equipment and supplies was estimated at USD 232.1 million, or USD 53 per capita. It is expected that the market will expand at a rate of 5.0 percent per year, reaching USD 295.6 million, or USD 68 per capita by 2018.

The government aimed to bring the performance of the healthcare system into line with that of other EU member states through the National Health Strategy 2006–11 and National Healthcare Development Strategy 2012–20. Health IT is an important part of the strategy, and some of the goals have already been achieved—the implementation of a prescription system, followed by an e-waiting list, and a centralized information system. Even though informatization of healthcare has been in place for 10 years, it is expected that it will be fastened with use of EU structural funds now available to Croatia. The strategy also anticipates the reorganization of health institutions, integrating local clinics, family practitioners, hospitals and specialized hospital services. One of the projects is construction of new facilities at the Clinical Hospital Centre Rijeka through private-public partnership that will be worth USD 500 million. The new hospital will contain 1,000 beds, as well as polyclinic, diagnostic and therapeutic facilities.

Main Competitors

Croatia has a small domestic production sector and there is very little multinational manufacturing activity. Around 93 percent of the medical device market is supplied by imports. Market leaders are European and U.S. manufacturers, namely General Electric, Johnson & Johnson, 3M, Bauerfeind, Astra, Drager, etc. Some of these companies have established their own local subsidiaries, while most companies will use third party distributors to supply the market.

Current Demand

Croatia imported medical equipment and supplies valued at USD 198 million in 2013. This represented a decrease of 3.6 percent compared with 2012. Medical device imports decreased by 1.9 percent in the three months to January 2014, to USD 52.2 million. Imports fell in all

products areas except for consumables and dental products. Even though imports have fluctuated in recent years, the general trend has been upward, from USD 109.2 million in 2002.

Funding for healthcare in Croatia is principally through the compulsory health insurance system. It was introduced in 1993 and is operated by the Croatian Institute for Health Insurance (HZZO). The HZZO collects contributions from the working population and the government makes payments on behalf of those exempt, such as the elderly, the unemployed and dependents. The USD 4.46 billion budget of the HZZO provides treatment for approximately 4.36 million insured persons annually in 49 public health centers, 22 general hospitals, 12 clinics, 40 special hospitals and 363 polyclinics.

Total spending on medical equipment, surgical instruments, accessories, laboratory equipment and various supplies in Croatian hospitals amounts to USD 208 million, of which approximately USD 45 million is spent on medical equipment. Clinical centres in Zagreb and Rijeka are the most active buyers. The most prospective product areas of the medical device market are orthopaedics and prosthetics, diagnostic imaging, and consumables.

Registration Process

The Agency for Medicinal Products and Medical Devices (HALMED) is responsible for placing medical equipment on the Medical Devices and Homeopathic Products Register. All applications submitted to HALMED are preceded in accordance with EU legislative. In order to register a medical device, manufacturers should submit a written application to HALMED, accompanied by the extensive documentation.

More information on registration process is available at www.almp.hr.

Barriers

Companies exporting medical equipment to Croatia will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers could include the complex system of approving for government subvention list or inefficiency of the health-care system causing long delays in payments to the suppliers

Trade Events

International Medicine and Technology Fair

May 2015 • Zagreb, Croatia
Medicine, pharmacology, analytics, and rehabilitation.

Cyprus

Summary

The Republic of Cyprus is moving forward with plans to reform its health care system, including bringing its public and private health care under the umbrella of a new National Health Insurance Scheme. Cyprus is the only EU member state without universal health coverage and as part of its Memorandum of Understanding with the Troika (IMF, European Commission, and European Central Bank) is required to implement national coverage. Full implementation of the new system is required by mid-2016. The changes may open new commercial opportunities for U.S. health-related products and services.

The Ministry of Health (MOH) is responsible for the overall management and oversight of Cyprus' public health care sector, which is centralized and funded through the central state budget. The approved health care budget for 2014 is €530.5 million, a decrease of 12.8 percent million EUR compared to 2013.

Cyprus does not have a domestic medical device manufacturing industry; therefore, all medical devices are imported. According to the latest report on Cyprus by Emergo Group (a leading consultancy firm in medical devices), about 90 percent of medical devices are imported from EU countries including (non EU manufactured) medical devices that are re-exported from EU countries to Cyprus. The market size of medical disposables in public and private sectors amounts to €40 million whereas the market size of medical devices in public and private sectors amounts to €12 million. As a result of the economic downturn that began in 2012, a drop of 20 percent and 50 percent hit both markets and limited investment respectively; however, the sectors are expected to pick up as a result of the current restructuring efforts.

Market Entry

As a member of the EU, Cyprus' local legislation concerning medical devices complies with relevant EU directives: active implantable medical devices

Statistics

Capital:	Nicosia
Population:	1.17 million
GDP (USD):	21.78 billion (2013)
Currency:	Euro (EUR/€)
Language:	Greek, Turkish, English

Contact

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90/385/EEC, medical device 93/42/EEC and in-vitro medical devices 98/79/EC as well as all the supplemental EU directives over the years. Medical trade is duty-free within the EU, as are most of the products coming from non-EU countries. Manufacturers from non-EU countries have to identify an EU-based authorized representative unless the manufacturer has a registered business in the EU. The representative serves as the point of contact for the appropriate authorities in Cyprus and can serve purely as an administrative agent or as an importer/distributor. A product for final sale or use in Cyprus should be marked with the CE identification. To affix the CE mark, the device has to be in conformity with the general requirements contained in the first annex of the three directives on medical devices. If a medical device is correctly CE marked, it does not need any additional approval or certification to be marketed in the entire EU. Furthermore, depending on the medical product, some requirements might be in place in relation to the language of the device information.

Current Market Trends

The Department of Electronic Communications (DEC) of the Ministry of Communications and Works, with the guidance of the Advisory Committee for Information Society, has developed a comprehensive "Digital Strategy (DG) for Cyprus" for the period 2012–20. The strategy promotes the use of Information and Communication Technologies (ICT) in all sectors of the economy and society including health. The overall vision of the DG for Cyprus on health includes but is not limited to:

- Install and operate in all public hospitals the Integrated Health Care Information System that covers the key elements of the hospital procedures in order to control both quality of service to patients and hospital cost
- Install and operate the drug management system in all hospitals
- Create regional health networks to exchange information between all health care providers
- Create an Internet portal to provide private physicians access to patients' electronic health records
- Design and implement an Ambient Assisted Living (AAL) program
- Use Telemedicine

Main Competitors

U.S. exporters' main competitors include companies from Germany, France, Japan, and China. Other competitors include United Kingdom, Italy, Sweden, Switzerland, Netherlands, and Poland.

Current Demand

Cyprus' restructuring program under its 2013 Memorandum of Understanding with the Troika, calls for far-reaching reforms within the country's health care sector, including the

process of switching to a National Health Insurance Scheme (NHIS) that will cover all citizens through both the public and private sector, make public hospitals autonomous, and introduce information technology systems in all public hospitals and health centers. Tenders for the implementation of the NHIS are expected within the next two years. The tenders will call for applications for electronic medical record systems, health care information systems, business intelligence for health, electronic content management, and decision support and knowledge management. Tools will include software and hardware devices as well as equipment.

Registration Process

Cyprus joined the EU in 2004 and has since adapted its national legislation with the instructions to abide by the EU. In accordance with the relevant legislation, the authority for the implementation of regulations related to the medical equipment is the Medical Devices Competent Authority of Medical and Public Health Services. The duty of the Competent Authority is the development and operation of all necessary mechanisms so that medical devices are correctly registered and safely placed in the Cyprus market. The medical devices sector includes a wide variety of products ranging from bandages and syringes to more sophisticated products which incorporate advanced technologies such as nanotechnology and tissue engineering. Please refer to the "Market Entry" above for a full explanation of the registration process.

Barriers

There are no restrictions on imports in Cyprus, as long as they comply with EU regulations. Import climate is open to equipment that is innovative and of good quality.

Trade Associations

- European Union Medical Devices Directives, ***bit.ly/1cCGz67***
- Cyprus Medical Devices Competent Authority, ***cymda.eu***
- World Health Organization, ***bit.ly/1sd2wS1***
- Department of Electronic Communications, ***bit.ly/1rXbnIS***
- Ministry of Health's Medical and Public Health Services, ***bit.ly/1zEs9h5***
- European Union Certifying (Notified) Bodies (NANDO), ***bit.ly/1AIpMez***

Czech Republic

Summary

The health care sector is very active and prominent in the Czech Republic. Czech healthcare system reform has been one of the most important political topics and several changes in the system were prepared in past years including changes in fees, above-standard services and a switch of insurance companies. The system is predominantly financed by the public sector through mandatory insurance. Approximately 76.6 percent of total health expenditures are covered by compulsory health insurance; the state and territorial budgets covered 7.2 percent and private voluntary expenditures covered 16.2 percent. The share of private expenditure in the total expenditure on health rose particularly after year 2008 due to new regulation fees in health services. Total expenditure on health amounts to nearly USD 15,2 billion (USD 1.330 per capita), which represents about 7.7 percent of the country's GDP. The market has proved generally resilient to the economic downturn. Although the government is examining ways to reduce healthcare expenses, including limiting purchases of expensive equipment and pharmaceuticals or adopting e-tenders, which would procure equipment via tenders based solely on the cost of the equipment, the Czech Republic offers strong opportunities for medical device companies. About 7 percent growth is expected in the sector over the next two years.

Market Entry

A recommended strategy for a U.S. company interested in penetrating the Czech market would be to find a local partner/representative or open an office in the country. Without a local representative who can support everyday contact with customers and government representatives, it is very difficult to succeed in the market. Although products may be manufactured in accordance with international standards, it may still be necessary to localize them for use in the Czech Republic.

Statistics

Capital:	Prague
Population:	10.52 million
GDP (USD):	198.4 billion
Currency:	Czech Crown (CZK)
Language:	Czech

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Current Market Trends

One of the most basic issues facing healthcare in Czech Republic is the spiraling cost of healthcare. Current market trends reflect increasing life expectancy and unhealthy lifestyles (obesity and heart disease are on the rise). Devices used to monitor symptoms and manage disease are in increasing demand. The most common cause of death is circulatory system problems (heart disease, stroke etc.). Czechs continue to be heavy smokers, and the air in many industrial cities is somewhat polluted. Growing interest in joint Czech-U.S. projects in the health care field could generate new opportunities for U.S. medical equipment providers. The most significant projects include the International Clinical Research Center (ICRC) at St. Anne's Hospital in Brno; center of scientific excellence in Brno (CEITEC); biotechnology center in Vestec u Prahy (BIOCEV), and the biomedical center called 4MEDia in Ostrava. All of these projects are receiving funding from European Union funds. In late 2014 American MSD—a global leader in healthcare known as Merck & Co. in the U.S. and Canada—will open a new global IT innovation center in Prague. It will be analyzing patient data for the best and most efficient treatment. Prague has been selected from a number of highly-regarded European locations mainly due to the quality of local IT specialists and the Czech Republic's excellent education system.

Main Competitors

The Czech Republic has a small but skilled medical device manufacturing sector. Local producers focus on exports, an estimated three-fourths of production is exported. Although domestic manufacturers are increasingly competitive, the majority of medical devices used in the Czech Republic are imported. Around 80 percent of the medical device market is supplied by imports mainly from the U.S. and European Union countries. Germany and U.S. were the leading suppliers, accounting for almost 50 percent of all imports.

Current Demand

In the Czech Republic the best market opportunities exist for cutting-edge, high-quality sophisticated medical equipment, especially equipment that increases efficiency and reduces occupancy rates in hospitals. Products, such as the following, have the best sales potential in the Czech market: mini invasive surgery systems (MIS), patient monitoring systems, video endoscopes, digital image processing, high-end ultrasounds, home-care equipment, etc.

Registration Process

To sell medical devices in the Czech market, typical requirements include:

- Assessment of conformity of the device with technical requirements set out by Act No. 22/1997 Coll.
- The CE mark affixed to the device (except for custom made devices and devices intended for clinical trials).
- Written declaration of conformity of the device.
- Clinical assessment of its suitability to provide health care.
- Notification of the Ministry of Health.
- Additionally, instructions for use of the device and declaration of conformity with guidelines in Czech must be enclosed.

There are several possible procedures for registering medicinal products:

- Mutual recognition procedure registration is based on the fact that the medicine is already registered in one of the EU Member States via national registration. The reference member state where the product is already registered shall draw up an assessment report. Consequently, it is decided whether the national registration will be recognized in the concerned member states or not.
- Decentralized registration used if the medicine has not been authorized in any of the EU Member States yet. All States chosen by applicant will assess the application request in the national registration proceedings and decide whether the application will be approved or not.
- Centralized registration is done centrally by the European Medicines Agency (EMA). Such registration is valid throughout the EU.
- National registration is done by the Czech State Institute for Drug Control. An applicant for a new marketing registration must have a registered office of the company within the EU/EEA.

Barriers

The Czech Republic is a highly developed, open market with liberal policies and intense competition. One of the challenges manufacturers and importers of medical devices and pharmaceuticals will face is getting the product on the reimbursement scheme that is covered by the insurance companies. This can, in some cases, be a time consuming process. Also, products from non-EU countries are subject to import duties. Customs duty rates are updated annually and are harmonized within EU countries. The import duty for medical device depends on the specific product and matching HS code. In general, duties range on average from 0–5 percent. Medical devices and pharmaceuticals are also subject to a value added tax (VAT). Electrical installations in the Czech Republic operate on 50 hertz cycles; power is supplied at

the rate of 220V (single phase), and 220V and 380V (triple phase). More than half of Czech company representatives are able to communicate in English or in German.

Trade Events

Pragomedica + Nonhandicap

October 22–24, 2014 • Prague, Czech Republic • ***incheba.cz/veletrh/pragomedica.html***
One of the two largest medical fairs in the country. Organized together with a specialized fair for the handicapped.

Pragodent

October 2014 • Prague, Czech Republic • ***pragodent.eu/en.html***
Focused on dental care, services, and hygiene.

Opta

March 20–22, 2015 • Brno, Czech Republic • ***bvv.cz/en/opta***
One of the most important fairs for eye optics and ophthalmology in the Central and Eastern European region.

Medical Fair + Rehaprotex

May 12–15, 2015 • Brno, Czech Republic • ***bvv.cz/en/medical-fair-brno***
Rehaprotex, focused on prosthetics and orthopedics, Pro Senior, Health/Wellness, and E-Health segments. Part of Messe Düsseldorf group (organizer of Medica).

Available Market Research

- Healthcare IT (2010)
- Eye Care Market (2009)
- Dental Market (2009)
- Medical Device Market (2008)

Denmark

Summary

Healthcare is an important part of the Danish welfare system: all citizens have the right to good health and healthcare on equal terms, regardless of income. The a healthcare system experiences very little inequality and is heavily financed by public funds (85 percent).

The healthcare sector has three political and administrative levels: the government, the regions, and the municipalities (national, regional, and local). Denmark is divided into five regions and 98 municipalities that cover at least 20,000 inhabitants each. Regions are responsible for providing hospital care, including owning and operating hospitals and prenatal care centers. They allocate finances for general practitioners (GPs), specialists, physical therapists, dentists, and pharmacies. Municipalities are mainly concerned with preventive care, rehabilitation, and long-term elderly care. Danes are generally satisfied with their experiences, with 89 percent of those polled stating that they are very or somewhat satisfied the when using the services, e.g., when consulting a GP.

Nearly 5.2 million Danes (almost 92 percent), contact their doctors annually. Each year, over one million are admitted to hospitals for inpatient care and over seven million outpatient procedures are conducted. Although the number of hospitals in Denmark has decreased in the past decade, the number of hospital visits has increased, bringing facilities near capacity and providing incentives for more efficient methods of treatment.

As of 2014, Denmark's health sector has 53 public hospital-premises and 23,190 physicians. Over the next decade, approximately 7.1 billion USD will be invested in 16 new (or renovated) modern hospitals, eight of which will be super hospitals. As of 2014, all hospitals had received final approval.

Statistics

Capital:	Copenhagen
Population:	5.6 million
GDP (USD):	330.8 billion (2013)
Currency:	Danish Krone (DKK)
Language:	Danish

Contact

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Market Entry

The World Bank ranks Denmark as the 5th easiest country to do business in in the world. According to the Economist Intelligence Unit, Denmark will be the 10th best place to do business in 2014 and the next four years. These findings are based on Denmark's pro-business policies, structural reforms to enhance labor market stability, and a fiscal policy that preserves the large amount of public services while achieving budget surpluses. Additionally, Denmark's flexible labor market and highly educated workforce are particularly attractive to businesses.

Recommended entry modes vary with the different subsectors and nature of the product. The sale of medical devices is typically accomplished with a traditional distribution model, whereas pharmaceuticals and health IT products may require a local presence or a strategic partnership with a local vendor. For the biotech sector, strategic proximity to the local pharmaceuticals sector may also be the best solution, possibly by being co-located with a university or other research institution. For further guidance, contact a local trade specialist.

Current Market Trends

In 2013, total healthcare spending was USD 36.86 billion and the estimated public health care spending was around USD 31.36 billion. More than three quarters of healthcare funding comes from the government. Total healthcare expenditure in Denmark has expanded faster than GDP over the past decade and now accounts for 11.2 percent of GDP. Approximately 17.5 percent of Denmark's population is 65 and older and nearly one-third of hospital expenditure goes to this segment. Denmark will face future challenges regarding expected increases in healthcare costs as the population continues to age.

In 2013, the Danish government announced plans to restructure the national health system. These plans involve consolidating services into larger and fewer clinics and hospitals, transforming inpatient procedures to outpatient procedures, and tackling health inequalities in an effort to reduce cost and increase efficiency. The new hospitals represent the largest capital investment ever made in Denmark—20 to 25 percent of which will be spent on IT and technology. The largest project, the NUH at Aarhus, will be the size of a provincial town, expanding Aarhus University Hospital with a budget of USD 1.1 billion.

While total healthcare spending is projected to increase in the next several years, the percentage of public health expenditure is projected to decline; however, technology and innovation will be spending priorities. The government has focused on e-health and telemedicine projects in areas like pregnancy, diabetes, and inflammatory bowel disease in order to achieve cost and efficiency goals. The Danish government has also allocated USD 21.3 million over the next four years to partnerships between municipalities, civil society, and the private sector that encourage health improvement in the population. Furthermore, Denmark is entering into joint research projects with India in the field of human health science biotechnology.

Of total health expenditure, 15 percent is privately sourced. The majority of privately sourced funding is paid by patients out-of-pocket; less than 2 percent of total health expenditure comes from private health insurance. This is in part due to the reimbursement schemes the government makes available to the population. The majority prefer the referral system, which is free of charge. Only a minority uses the second option, in which the patient does not need a referral to visit specialists, but must cover extra costs incurred themselves or with additional insurance. All patients are reimbursed for pharmaceuticals, but patients must pay some user charges for healthcare such as dental care, long-term nursing, physiotherapy, and pharmaceuticals. There has been an increase in private health insurance (voluntary health insurance or VHI) for this reason. Complementary insurance is taken out by 30 percent of the population, and supplementary insurance is commonly offered by employers to their employees. Sygeforsikringen "danmark" is the single major private, non-profit, health insurance company and has approximately two million members.

Main Competitors

Denmark has many local manufacturers that possess fair shares in the global market. They specialize in the production of hearing aids, diagnostics, and orthopedic and prosthetic devices. Denmark is home to major companies in the medical device, biotech, and pharmaceutical industries, including Ambu, Bavarian Nordic, Coloplast, GN ReSound, H. Lundbeck, Novo Nordisk, Oticon, and Widex. About 90 percent of the local production is exported.

Current Demand

In 2013, the average life-expectancy in Denmark was 78.0 years for men and 81.9 years for women, which is among the lowest in Europe. The low life expectancy may be explained by the fact that Denmark's medicine expenses per capita are among the lowest in Europe. Additionally, lifestyle factors such as high consumption of tobacco and alcohol may help explain the numbers. While these factors negatively affect Denmark's life expectancy, other characteristics of the population are healthier than average. For example, Denmark's rate of obesity and diabetes are among the lowest in the OECD.

Non-communicable diseases amounted to 89 percent of the total disease burden in 2012. By a large margin, the most common causes of death in Denmark are cancer (29.7 percent) and heart disease (14.5 percent). Other common causes of death are cerebrovascular diseases (6.4 percent), bronchitis and asthma (6.6 percent), and mental disorders (5.9 percent).

It should be noted that since healthcare in Denmark is free, Danes are very reluctant to spend money on healthcare and treatment themselves, resulting in only 14.5 percent of health expenditures coming from private sources. Nevertheless, Danes are generally concerned about their health and are willing to spend money on preventive measures including healthy food, dietary supplements, and gym memberships.

Barriers

All products sold in Denmark must carry the CE mark. All medicines, herbal medicines, and strong vitamins and minerals must be authorized by either the Danish Health Medicines Authority (Sundhedsstyrelsen, SST) or the European Commission, which requires documentation of the effect, safety, and quality. The summary of product characteristics (SPC) is the basis of patient instructions leaflets and provides a framework for permitted advertising. The SPC for authorized medicines is available at ***www.produktresume.dk*** or at the website of the European Medicines Agency. Under special circumstances, the SST may withdraw authorization.

Unlike manufacturers and authorized representatives based in Denmark, manufacturers and authorized representatives based outside Denmark are not required to register with the SST. As of September 1, 2013, distributors and importers based in Denmark are required to register with the Danish Health and Medicines Authority; however, Danish manufacturers and representatives representing manufacturers outside of Europe are not required to do so. Required forms may be found on the website of the Danish Health and Medicines Authority (***sundhedsstyrelsen.dk/en***). There is a fee to register, as well as an annual fee.

The SST issues Certificates of Free Sale to Danish manufacturers with a registered place of business in Denmark, requiring that the manufacturer be responsible for the design, manufacture, packaging, and labelling of a device before it is placed on the market. A CE-marked device issued a Certificate of Free sale may be manufactured and sold in Denmark without approval from the SST.

All labeling and instruction manuals must be available in Danish (e.g., inserts). Software and service manuals, displays, buttons, and keys do not have to be translated, but the manufacturer must define information necessary for using the device safely and symbols must be explained in the instructions. The SST may grant exemptions in certain cases for a limited period of time depending on the professional and linguistic qualifications of the user, the characteristics of the device, and if alternative products are available on the market. Information on applying for exemptions may be found on the SST website, in addition to suggested translations and other resources.

Trade Events

- Anti-Aging Fair, ***antiagingfair.com***
- EDSR Annual Meeting, ***esdr2014.org***
- Lægedage, ***laegedage.dk***
- Scandefa, ***scandefa.dk/en-gb***
- Health & Rehab Scandinavia, ***health-rehab.dk/en***
- eHealth Observator, ***e-sundhedsobservatoriet.dk***

Available Market Research

- Medical Technology
- Dental Equipment
- Lab Equipment
- Biotechnology with Healthcare Application
- Pharmaceuticals
- Vitamins and Food Supplements
- Healthcare Services
- Telemedicine
- Health IT

Egypt

Summary

The healthcare sector in Egypt offers significant opportunities for U.S. exporters of medical equipment and devices, as well as for U.S. service providers in the long term, cutting across the entire spectrum of medical-related activities and requirements. In 2013, consumer healthcare expenditures grew by 12 percent to USD 24.2 billion. Sales in medical devices totaled USD 484.7 million in 2013, a five percent increase from the previous year. It is estimated that the market for medical devices, most of which will be imported, will be worth USD 970 million by 2016.

The Ministry of Health and Population (MoHP) operates 1,300 hospitals or 60 percent of hospital beds. Universities, the Army, and the private sector constitute the remaining 40 percent. Egypt's burgeoning population and subsequent strain on the healthcare industry means that much of the equipment needs frequent replacement. Government pledges to improve healthcare have recently boosted the purchase of medical devices. The proliferation of privately-owned hospitals and clinics also added to the substantial growth in the demand for high-tech medical equipment in the last 10 years.

The government's Healthcare Reform Program is generating demand for high-tech medical equipment and healthcare items. MoHP is currently undertaking an ambitious plan of building 26 new hospitals, and renovating and refurbishing existing medical facilities with up-to-date equipment, especially in the rural, underserved areas. The public sector is expected to account for the majority of expenditure growth in the next few years due to the government healthcare reform program's target of achieving universal access to healthcare. The private sector's demand for sophisticated medical equipment is also growing.

Currently there are no production facilities operated by international medical device manufacturers in Egypt. Local production is negligible with just one Egyptian company producing a limited range of ultrasound scanners. Specialized medical equipment such as radiography and ultrasound apparatus, vital statistics

Statistics

Capital:	Cairo
Population:	85 million
GDP (USD):	271 billion
Currency:	Egyptian Pound (EGP)
Language:	Arabic

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monitors, and dialysis machines are imported and distributed by a handful of companies that benefit from low import tariffs, the biggest of which, El Gomhoureya, is wholly owned by the government.

Private healthcare providers are thus limited in choice and price and often choose to personally import the equipment they need, which must be brand new and unused according to customs laws to be brought into the country. This can be a slow and complicated process, yet it is pursued anyway as it is popular amongst Egyptian physicians to travel abroad for medical seminars and conferences where they are kept abreast of the latest technologies and can acquire devices not offered by El Gomhoureya.

Market Entry

U.S. medical equipment and products are traditionally well-received in Egypt and are known for their quality and longevity. Egyptian law requires foreign companies bidding on public tenders to retain Egyptian commercial agents. U.S. companies find it beneficial to engage a local agent to handle communications, bureaucratic procedures, local business practices, and marketing. A U.S. company can appoint multiple agents in Egypt based on geographical location or product basis to further enhance its success. Agent commissions vary depending on the services provided and the value of the contract.

Supplying reliable after sales service as well as spare parts and maintenance services is key to maintaining a competitive advantage. Agents of medical equipment have found that keeping approximately 40 percent inventories of spare parts will satisfy the needs and demands of their clients. FDA approval is key to having medical products registered and approved by the MoHP in Egypt, although the MoHP may still do additional testing on any medical device. The importation of used and refurbished medical equipment and supplies into Egypt is banned without prior approval of the MoHP.

Current Market Trends

Egypt's medical device market is the second largest in the Middle East, but one can attribute that to the sheer number of people residing in Egypt. More specifically, Egyptians only receive 2.5 medical tests per year as opposed to Saudi Arabia, where they undergo six medical tests per year. Furthermore, 32 percent of the Egyptian population is under 14, indicating a strong need for investment in the healthcare industry. Recent reports have stated that the Egyptian government prefers investments in preventative medicine, a specialty that caters to medical devices. According to the World Bank, less than 5 percent of total investments are allocated toward health services. With strong demand and expected lessening of barriers to market, the medical device sector will be ripe for substantial economic growth in the mid-term.

Main Competitors

Main competitors are from Germany, China, and India.

Current Demand

Best prospects include:

- Oncology and high-tech radiological equipment
- Highly specialized disposables
- High-tech surgical and medical equipment
- Software for hospital management/ network
- ICU monitoring equipment
- Sophisticated laboratory and scientific equipment
- Mobile clinics

Registration Process

The Drug Policy and Planning Center (DPPC) of the MoHP requires the following documents in order to register and approve medical devices and equipment:

- Original Free Sale Certificate (issued by official health authorities in the country of origin, stating that the product is freely sold), certified by both the Chamber of Commerce and Egyptian Embassy/Consulate.
- Copy of Pro-forma Invoice.
- Copy of FDA approval (Certificate to Foreign Government) certified by the Egyptian Embassy/Consulate (importer may be required to show the "original" certificate for confirmation).
- Copy of the legalized Agency Agreement.
- Certificate of Origin (in case of exporting components to a factory for local manufacture/assembly).
- Declaration of Conformity (in case of class 1 non-sterile devices, non-measuring product or equipment).

Barriers

Red tape remains a challenge for businesses operating in Egypt. Working directly with the government is time-consuming and bureaucratic, and the tender announcement process is not fully transparent. Identifying a good, well-established local agent is a key to navigating the system.

Trade Events

Egymedica Expo

May 7–9, 2015 • Cairo, Egypt • ***10times.com/egymedica-expo***

Healthcare Equipment, Services, and Technologies Trade Mission to Egypt

May 16–25, 2015 • ***1.usa.gov/1ogwYtb***

European Union

Summary

As the European Union (EU) does not have a Food and Drugs Administration (FDA), the task of harmonizing requirements and regulating medical devices is handled by the European Commission in close cooperation with Member State's Health Authorities. The purpose of the EU harmonization effort is to merge the differing national requirements into one law which will be applied throughout the European Union. Legislation adopted through this process covers implantable, non-implantable and in vitro diagnostics medical devices in three separate directives that provide manufacturers the basics to certify their compliance with EU-wide safety requirements.

Adopted Legislation

The following EU directives are in force throughout the European Union consisting of 28 Member States (Austria, Belgium, Czech Republic, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Romania, Bulgaria and the United Kingdom):

- Active implantable medical devices (90/385/EEC): Active implantable medical devices (AIMD), such as heart pacemakers or defibrillators are defined as "any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure." Considering the potentially high risk factor of such devices for the patient, manufacturers cannot self-certify and have to rely on the services of an accredited test laboratory to complete the process of compliance.
- Medical devices (93/42/EEC): Medical devices are broadly defined as "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper

Statistics

Capital:	Brussels, Belgium
Population:	505.7 million
GDP (USD):	15.85 trillion
Currency:	Euro (EUR/€)
Language:	24 languages

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application intended by the manufacturer to be used for human beings" for several purposes such as diagnosis, treatment, alleviation of disease and more. As the range of this directive is broad and leaves room for interpretation, the Commission has written guidance for manufacturers. Medical devices include syringes, bandages, wheelchairs, endoscopes, prescription glasses and contact lens solution among others. As the range of devices covers minimal risk as well as higher risk devices, the classification of the product will determine whether a manufacturer can self-certify or needs to involve the services of an accredited test laboratory.

- In vitro medical devices (98/79/EC): An in vitro diagnostic device (IVD) is a "reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body solely or principally for the purpose of providing information." It covers items such as pregnancy test kits and blood analysis machines. While manufacturers of simple IVD test kits such as for diabetes can self-certify compliance with the requirements, more high risk test kits such as HIV will require the services of a notified body.

The directives have been supplemented over time by six modifying and implementing directives. The last technical revision was Directive 2007/47/EC (***bit.ly/17yl1mD***), which entered into force on March 21, 2010. The main changes introduced by this directive impact medical devices and active implantable medical devices. New elements include:

- The conformity assessment procedures and classification of devices as well as the essential requirements for active implantable medical devices (AIMDs) and medical devices (MDs) have been somewhat simplified, harmonized and enhanced.
- Software with an intended medical purpose is now a medical device in its own right.
- All certificates issued by notified bodies are limited to a maximum validity of five years.
- With the emphasis on clinical data for all devices in the new directive, the European Commission published guidance on the clinical evaluation dossier in December 2009: ***bit.ly/H1N1bZ***.
- Use of PVC softeners in certain types of devices will require labeling. Following a mandate from the European Commission for medical devices, CEN, the European standards organization, has developed a standard, EN 15986 (***bit.ly/1i2aQvr***), which includes a symbol to show the presence of phthalates in medical devices.
- Custom-made devices will be subject to a post-market review system.

Since directive 2007/47/EC is not easy to read, the changes have been merged with the original directives to create a single, readable text which is up-to-date. The consolidated versions as well as guidance can be downloaded at:

- Directive 90/385/EEC on active implantable medical devices: ***bit.ly/1bFC2yJ***
- Directive 93/42/EEC on medical devices: ***bit.ly/18t79Oi***
- Directive 98/79/EC on in vitro diagnostics: ***bit.ly/1bFChK7***
- Guidance document from the Commission on Interpreting Directive 2007/47/EC: ***bit.ly/PnzKLS***

CE Marking

Known as "new approach" directives, these directives outline a set of "essential requirements," rely on use of voluntary EU wide harmonized standards, and offer a choice of conformity assessment modules. The distinguishing feature of new approach directives is CE marking, which is a conformity mark, affixed to the product, the instructions for use and the packaging, an indication to inspection authorities that the product complies with the directives.

Exception to CE Marking

While CE marking is generally required on all medical devices, there are a few exceptions. All custom made implantable and non-implantable devices and devices for clinical investigations are subject to a different conformity assessment module which does not require CE marking at the end of the process. In vitro diagnostics for performance evaluation or research purposes only are not subject to the IVD directive although they may be subject to national requirements. In general, devices shown at trade fairs, exhibits, for demonstrations etc do not need to have CE marking. However, it is recommended to indicate clearly that non-CE marked devices are for demonstration purposes only.

Classification

Manufacturers should note that the differences in regulatory approach between the EU and the U.S. mean differences in classification and compliance verification. It would be wrong to assume that meeting the requirements for the U.S. market would satisfy the EU requirements. To illustrate this point, hospital beds including accessories, according to FDA guidance, are either Class I or II depending on the type of bed. In the EU, hospital beds and accessories are classified as Class I devices, allowing self-certification. In addition, the beds and their accessories would have to be considered separately, each as medical devices in their own right, especially when such items are sold separately.

The AIMD directive has but one class and does not allow self-certification. The medical device directive covers four classes, ranging from Class I, II a and b to Class III. Only Class I devices can be self-certified. Manufacturers have to involve the services of a notified body in all other cases, and sterile Class I devices or those with a measuring function must also use a notified

body. The IVD does not distinguish classes but rather groups: general tests, self-testing kits, and Annex II lists A and B. For simple tests, self certification is usually an option. To help with classification in case the annexes in EU directives are difficult to interpret, the Commission has published new guidance at ***bit.ly/PfkVYa***.

Borderline Products

For the majority of medical devices, the purpose is obvious: pacemakers, endoscopes, syringes and wound dressing are clearly to be used for medical purposes. Products where the intended purpose is not so clear are known as borderline products and they may be subject to several directives. For example, a scale to weigh patients in a hospital would be subject to both the non-automatic weighing scale and the medical device directives. Disinfectants for exclusive use with a medical device may be classified as an accessory to a medical device because the intended purpose is medical rather than general. The intended purpose is usually supported by appropriate statements on the company's website or in promotional literature. It is possible to get an official interpretation to clarify borderline products but manufacturers should be able to make the determination in most cases themselves by using the guidance provided by the Commission.

For more information, please review the Commission's guidance on borderline products, updated June 2013: ***bit.ly/1sda4UB***.

Compliance with "Essential Requirements"

The "essential requirements" for the protection of health, safety and environmental concerns form the core of the directives. They cover risks and hazards that may occur at the design, production and handling stages. The manufacturer has to address the essential requirements which apply to a product and identify relevant risks for the patient. Non-relevant essential requirements do not have to be considered. As an example, manufacturers of arm braces made of stretch fabric would have to consider the essential requirements related to "compatibility between the materials used and biological tissues," in other words, the fabric's potential to cause skin allergies. A non-relevant requirement for arm braces would be "protection against radiation." Choice of packaging is an essential requirement for prepackaged devices, as damage resulting from mishandling could have an adverse impact on the device making it harmful for the patient upon use. These are just examples, bearing in mind that there are many other elements to verify and that the manufacturer should carefully review the complete list of essential requirements.

Use of EU-Wide Harmonized Standards

The task of complying with essential requirements can be simplified by voluntarily using EU-wide (EN) harmonized standards. The risk assessment management standard which facilitates the initial checking of the relevant essential requirements is ISO/EN 14971. Manufacturers may also establish their own checklists for risk assessment of medical devices.

Other than the risk assessment standard mentioned above, the Commission has listed over hundred EU-wide harmonized medical device standards addressing various essential requirements. These standards have been developed and/or identified by the European standards organizations. They are often based on international standards. References to EN standards are published in the Official Journal (the EU equivalent of the U.S. Federal Register). As a result, the standards are uniquely linked to EU legislation and are known as harmonized standards. Use of EN harmonized standards gives "presumption of conformity." When a manufacturer opts not to use an EN harmonized standard or prefers to design/manufacture to other standards, then the manufacturer has to show in great detail how their medical device meets the essential requirements in EU medical device legislation. All other existing standards not published in the Official Journal are either national or industry standards.

Modules of Conformity Assessment

To facilitate acceptance of the final product as meeting EU requirements, the manufacturer will have to choose a conformity assessment module as described in the annexes of EU medical device legislation. The choice of the module is determined by the classification and the preference of the manufacturer for a given module.

The conformity assessment modules address the design and production stages. For design, the manufacturer must provide the evidence of how the device meets the essential requirements. For production, the manufacturer has to put in place and document a quality system to ensure continuity in complying with the essential requirements.

Low risk products, such as Class I medical devices or self-test kits, generally allow self-certification based on conformity assessment module A which consists of establishing a Declaration of Conformity and compiling a technical file. All modules between B and H combine design and production compliance such as type examination and verification of manufacturing to type based on technical file inspection (modules B and F) or full quality assurance (module H). As these are conformity assessment modules for higher risk products, the services of an EU notified body or U.S. based subcontractor will be required to some degree depending on the classification.

Roles of a Notified Body

All active implantable medical devices and certain types of IVDs as well as medical devices belonging to Class II a or b or higher require the involvement of a notified body, the official term for accredited test laboratory based in the EU. Only notified bodies in the European Union can make the final assessment of conformity certification in accordance with EU directive(s). A U.S. based subcontractor of an EU notified body, such as UL or Intertek Testing Services, can also handle the tests for certification, but the certificate of conformity will still have to be supplied by the EU based notified body.

Technical File

The technical file contains all relevant information to support the claims of compliance with EU requirements such as a general description of the product, documentation of the quality system, design information, list of standards used, result of design calculations/inspections, test reports, performance evaluation data, sample of label and instructions for use, and Declaration of Conformity. It is to be kept either by the manufacturer or his/her authorized representative with the understanding that it should be quickly accessible upon request from an official national inspection authority.

Declaration of Conformity

Among the final steps in the CE marking process of medical devices is the drawing up of a Declaration of Conformity which consists of name and address of the manufacturer and/or authorized representative, product name, type, model number and any relevant supplementary information, the reference numbers of standards, the date, a signature with title and a statement regarding responsibility of manufacturer or authorized representative. By applying the CE marking on the product, packaging and on the instructions for use, which can be done either by the manufacturer or his importer/distributor, the manufacturer has completed the CE marking process.

Authorized Representative

Manufacturers outside the EU have to identify an EU-based authorized representative unless they have a registered business in the European Union. The primary task of the authorized representative is to be the point of contact for the national health authorities of the Member States. The representative will have to notify the national authority in the country of residence whenever a new Class I device is brought on the EU market. Some national authorities have standardized forms on their website. In addition, the authorized representative's name must be mentioned on the Declaration of Conformity.

The arrangement between the authorized representative and the manufacturer is purely administrative and subject to a commercial contract specifying the role that can be limited (authorized representative only) or broader (importer/distributor). Details about the responsibilities of manufacturers and authorized representatives can be found in the new legislative framework which covers all CE marking legislation: ***bit.ly/1bFDtwX***.

Other than single notification, authorized representatives or manufacturers typically also register devices in individual member states. In the future, registration will become easier. With the Commission's 2010 Decision to enforce use of Eudamed (***bit.ly/19eE3l2***)—the EU-wide database for devices on the market—registration of in vitro diagnostics in each country became redundant. The system for medical devices, however, will remain unchanged for the time being. Exporters/authorized representatives will still have to register their devices nationally until and when the Commission decides to move to a centralized registration for manufacturers of devices. In the meantime, Eudamed will be of use to member states for

internal communications and for post-market surveillance purposes. To facilitate registration, the EU encourages use of the Global Medical Device Nomenclature (GMDN) based on EN/ISO standard 15225.

Post-Market Surveillance

As the EU regulator allows manufacturers to self declare conformity, with or without involvement of an accredited test laboratory, verification of compliance to ensure safety of consumers is left to the Member States after the products have been brought on the market. As Member States each have their own system, it is possible that some countries grant extensive inspection powers to their national customs service where others may focus their resources in local inspections. When caught in an infraction, the measures imposed on manufacturers may vary from a simple warning to a hefty fine or complete withdrawal from the market, depending on the type of infraction.

EU medical device legislation requires that Member States put in place safeguard procedures. In case of an incident involving injury or death, the Commission will be notified, thereby triggering an EU-wide rapid alert system. The Commission has been putting more emphasis on post-market surveillance, with a goal to strengthen the infrastructure of cooperation among national inspection authorities.

With the adoption of measures in September 2013, the Commission further tightened control by strengthening the criteria for the designation and supervision of notified bodies and addressing the tasks to be fulfilled by notified bodies when conducting audits and conformity assessment procedures. These measures have proven to be successful.

Coming Soon: New Regulatory Framework for Medical Devices

The existing medical device directives (MD and AIMD) are currently being reviewed following the 2008 public consultation. The purpose is to recast the regulatory framework. A proposal for a new framework was released in September 2012. The review focuses on extending the scope, introducing pre-scrutiny system for high risk devices, and improving the vigilance and post-market surveillance system.

In June 2010, the Commission launched a separate public consultation to review in vitro diagnostic device legislation. The review focuses on scope, classification and conformity assessment methods of IVDs, among others. The proposed legislation was released in September 2012 and is still undergoing review in tandem with the new proposed medical device legislation.

For more information about the review of existing legislation, please visit ***bit.ly/RDKx6g***.

Medical Devices and Machines

Overlap with the new machinery safety directive 2006/42/EC has been clarified for medical devices that are also machinery. Only one single conformity assessment is required under the medical device directives 93/42/EEC and 90/385/EEC. The risk assessment to be carried out is the risk/benefit analysis as set out in the essential requirements of the directives concerning medical devices. Harmonized standards for medical devices which are also machinery should cover in their scope any requirements of the machinery directive that are applicable to the devices. Such standards will be reviewed and amended or revised if needed.

Interpretation of the relation between the revised Directives 90/385/EEC and 93/42/EEC concerning (active implantable) medical devices and Directive 2006/42/EC on machinery can be found at ***bit.ly/Od4cUM***.

MRI Equipment

The revision of directive 2004/40/EC on worker exposure to electromagnetic fields was finalized in June 2013 with the adoption of Directive 2013/35/EU. The directive sets exposure limits for workers but allows a derogation for MRI. Stakeholders affected by this directive successfully lobbied the EU and Member States in order to obtain an exemption for MRI equipment. A practical guide covering procedures for hospital workers exposed to electromagnetic fields will be developed.

Packaging/Labeling

The amended EU directive on units of measurement (the so-called "metrics" directive 80/181/EC) entered into force on January 1, 2010, which means products must bear metric units of measurement. Use of supplementary units, such as U.S. customary inch-pound, are also allowed.

Specific requirements for labels are included in medical device directives. As for choice of language on labels, EU medical device legislation defers to Members States. Please read our market research on language requirements (***bit.ly/19RpuAQ***) and/or contact our CS posts in other countries for more details.

Medical Devices Using Animal By-Products

The occurrence of bovine spongiform encephalopathy (BSE) in the European Union led to stringent measures regarding traceability of tissues of animal origin for use in medical devices. Risk assessment was addressed in guidance and standardization. The Commission adopted an animal by-product regulation in 2002, repealed in 2009 by Regulation 1069/2009, which covers use of raw material of animal origin for non-food use. Medical devices are subject to specific transport and labeling requirements. The material has to be sourced from approved plants and the process has to be documented. For more information, we suggest you contact the Foreign Agricultural Service at the U.S. Mission to the European Union (***usda-eu.org***).

Environmental Requirements

Growing mountains of waste of electrical and electronic equipment have forced the EU to consider ways to reduce, recover and recycle packaging and appliances. Also, the use of hazardous substances has led to environmental damages; therefore certain substances such as lead or mercury have been banned. Those issues have been tackled by the Waste of Electrical and Electronic Equipment legislation (WEEE) and the Restriction of Hazardous Substances in Electrical and Electronic Equipment legislation (RoHS).

Medical devices will fall within the scope of the RoHS directive as of 22 July 2014; for IVD the date is 22 July 2016. Others laws such as the Waste Electrical and Electronic Equipment (WEEE) directive require OEM manufacturers to dispose of products they manufacture in an environmentally responsible way once the equipment reaches end of life. Medical devices are covered by this directive but with a specific exemption today for "implanted and infected medical devices," ***go.usa.gov/DfQP***.

Chemical Substances and Mixtures in Medical Devices

Medical devices containing or consisting of chemical substances and mixtures are subject to specific requirements under the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) Regulation and the Classification, Labeling and Packaging of substances and mixtures (CLP) Regulation (***export.gov/europeanunion/reachclp***). REACH entered into force on June 1, 2007. It changes the former legislative framework for chemicals to ensure a high level of protection of human health and the environment. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. Under REACH, the EU can also take measures to ban the use of highly dangerous substances. CLP aligns previous EU legislation on classification, labeling and packaging of chemicals to the UN GHS (Globally Harmonized System of Classification and Labeling of Chemicals).

Resources

- European Commission, ***bit.ly/1cCGz67***
- National health authorities, ***bit.ly/15OLFKE***

Finding/buying harmonized standards:

- ***bit.ly/19CMJ3l***
- ***ansi.org***
- ***cen.eu***
- ***www.cenelec.eu***

Associations:

- AdvaMed, Advanced Medical Technology Association (***advamed.org***)
- Medtech Europe (formerly Eucomed, Medical Technology, and Edma, European Diagnostics Manufacturers Association (***eucomed.org*** and ***edma-ivd.eu***)
- COCIR, European Radiological, Electromedical and Healthcare IT Industry (***cocir.org***)

Notified Bodies/Conformity Assessment Bodies:

- ***bit.ly/15WqqXw***

Consultants/Authorized Representatives

- ***go.usa.gov/DfUF***
- ***eaarmed.org***

Guidance:

- European Commission guidance on medical devices (***bit.ly/1gRDimd***)—Please note that these guidance documents only reflect the views of the European Commission. They are not legally binding like decisions of the European Court of Justice and can be challenged by Member States authorities or competitors.
- CE marking (***go.usa.gov/DfPm***)

Finland

Summary

High-quality and technically-sophisticated medical equipment has market potential in Finland. The United States has a 28 percent share of the total market and accounts for 33 percent of Finland's overall health technology exports. Finland also produces high technology medical equipment. Increasing competition in the market is expected as local production expands.

Market Entry

As a member of the EU, Finland's local legislation concerning medical devices complies with EU directives. The National Supervisory Authority for Welfare and Health, Valvira (***valvira.fi/en/licensing/medical_devices***), monitors the compliance of medical devices with legislation and regulations, monitors the marketing of medical devices and promotes their safe use. Please visit ***ec.europa.eu/enterprise/index_en.htm*** for further information from the European Commission, Enterprise and Industry, Medical Devices.

Medical trade is duty-free within the European Union. Import duties are collected from production coming from non-EU countries. The amount of duty for medical equipment exported from the United States fluctuates according to specific product, ranging from 5–12 percent.

Current Market Trends

The Finnish health technology market has experienced strong sustained trade growth in recent years with 2013 being a record setting year for both imports and exports in medical technology. 2012 saw an increase of 13.4 percent and 9.6 percent in exports and imports respectively, which were followed by only slight increases in 2013. The total amount of health technology exports received USD 2.27 billion with a one percent increase from the previous year. Imports did not see a great increase either, bringing a total of USD 1.24 billion, with only a minor

Statistics

Capital:	Helsinki
Population:	5.4 million
GDP (USD):	257 billion (2013)
Currency:	Euro (EUR/€)
Language:	Finnish, Swedish, others

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increase. The more rapid increase in exports brought a two percent growth and record high in the trade balance of the Finnish health technology industry.

The total domestic market size for medical equipment was estimated at USD 1.1 billion in 2013. Total local production was estimated at USD 2.0 billion in 2013, with fast growth from USD 1.2 billion in 2012. The operating costs of Finnish hospitals have been reduced, and major hospital procurement is mainly replacing older equipment and buying some new. However, investments in new medical equipment within the private health care sector are expected to continue. Currently, the city of Helsinki is constructing a new children's hospital to replace the old children's wing with limited space and technology. The hospital is to be finished in 2017 and will treat children with difficult illnesses from all around Finland.

Finnish hospitals are very eager to try out new technology in the implementation of most modern treatment methods. Implementation of new technologies is effective, as Finnish medical personnel are very technology literate. Local distributors provide the market with equipment packages and maintenance programs.

Main Competitors

Local production for medical equipment is well known for its quality and high technology. It is concentrated in specialized sectors, such as dental equipment and specialized x-ray and IVD equipment. About 90 percent of local production is exported because of the small domestic market size. It is important to note that internationally Finnish products have garnered attention as being particularly user friendly.

The leading destination for Finnish health technology exports in 2013 was the U.S. with an overall share of 29 percent of total exports. Europe accounted for 39 percent, the main constituents including Germany and France. Elsewhere, China constituted six percent and the Russian Federation constituted five percent of overall exports.

In 2013 seventy percent of the medical equipment imported to Finland came either from or through the European Union. Direct imports from the U.S. accounted for 12 percent. Specifically the important external supplier countries were Germany, the United Kingdom, France, Japan, and China.

Current Demand

High-quality and technically-sophisticated medical equipment has the best market potential in Finland, especially equipment that increases efficiency and reduces occupancy rates in hospitals. Products with the best sales potential in Finland include:

- Patient monitoring systems
- Minimally-invasive surgery (MIS)
- Day surgery equipment
- Magnetic resonance imaging (MRI) equipment
- Video endoscopes
- Digital image processing
- Picture archiving

The Finnish government has recognized the need for a more stable synergy regarding Health IT communications and EPR sharing between municipalities, regional districts, and private care providers. Finland has long been a Health IT forerunner with a history of user satisfaction and ease of accessibility to information. The country is continually developing and improving its nationwide electronic archive of patients' health information (KanTa), as well as health-related services such as the Electronic Prescription program. In addition, innovative and ambitious projects are in the works at the municipal, regional, and national levels, all of which are viable entry points for U.S. products and services.

In other segments, strong growth was also seen in smaller medical furniture and medical implants. Additionally, In-Vitro Diagnostics was considered a contributor to market growth.

Registration Process

Manufacturers must include contact details and information on the products they manufacture. The National Supervisory Authority of Welfare and Health maintains a registry in the case the manufacturer:

- Places medical devices on the market in its own name
- Puts together systems and procedure packs to form medical devices for the purpose of placing these on the market in its own name
- Sterilizes systems, procedure packs, or medical devices bearing a CE marking.

Representatives established in Finland must submit the same details.

Extra notification is necessary if the medical product is high-risk and includes IVDs intended for self-testing and if the device contains substance of human origin.

To submit the notification, the party must be:

- Entitled to represent the company
- Authorized manufacturer's representative
- Or responsible for placing the product on the market

Notification of the cases mentioned above must be submitted within two weeks before placement on the market. This time limit applies also to the start of importing of self-testing devices.

Barriers

There are no restrictions on imports in Finland, as long as they comply with EU qualifications. Although marketing requires thorough knowledge of end user needs, the import climate is receptive to equipment that is new and of good quality. There is keen competition in the market, however.

Trade Events

Terveysteknologia

2015 January 7–9, 2015 • ***bit.ly/1pu4Akh***

eHealth 2015

January 7–9, 2015 • ***bit.ly/1ugUaKk***

Finnish Dental Congress and Exhibition 2015

Helsinki, Finland • ***bit.ly/18607xL***

Finland's leading event for dentistry professionals.

The Finnish Medical Convention and Exhibition 2015

Helsinki, Finland • ***bit.ly/18s8zrY***

Finland's leading event offering further training for doctors and physicians. Finland's biggest medical exhibition is organized at the same time.

Available Market Research

- Health IT and Telemedicine
- Dental Industry Overview (2012)
- Medical Industry Overview (2012)
- Finland's Health Technology Trade (2012)
- ***bit.ly/190z61A***

France

Summary

(USD Billions)	2013	2014 (est.)	2015 (proj.)
Total Market Size	6.608	7.114	7.327
Total Local Production	5.730	5.901	6.078
Total Exports	2.427	2.500	2.575
Total Imports	3.605	3.713	3.824
Imports From the U.S.	1.189	1.225	1.262

Total market demand in France for medical equipment was estimated at USD 7.114 billion in 2014, with imports accounting for USD 3.713 billion. Imports from the United States were forecast at USD 1.225 billion, or 30 percent of total imports. This percentage is expected to remain approximately the same over the next three years, with overall demand growing at three percent annually.

France ranks among the top five largest medical device markets in the world. France spends three percent of total health expenditure on medical equipment and supplies and 0.3 percent of GDP, which is average for a West European country. The overall market is generally well developed, however certain sub-sectors in the more innovative forms of technology still present opportunities for entry. While the public sector is the largest purchaser of diagnostic, therapeutic and surgical equipment, the private sector is also a very dynamic player.

The continuing deficit of the national health insurance funds has prompted new measures to control spending on medical devices, similar to those already in force for pharmaceuticals.

Statistics

Capital: Paris
Population: 67 million (2012)
GDP (USD): 2.71 billion (2012)
Currency: Euro (EUR/€)
Language: French

Contact

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Market Entry

To export medical devices to France, a foreign producer should have an agent/distributor. Medical devices in the French market, whether for imported products or domestically-manufactured lines, must have obtained the CE mark and must have enclosed directions in French.

Current Market Trends

The medical market is likely to only to see moderate growth, rising from USD 7.114 billion in 2014 to USD 8.258 billion by 2019. The medical manufacturing industry has seen an entry of foreign companies; larger manufacturers are now subsidiaries of multinational groups. With flagging domestic production in several sectors the French medical device market is increasingly reliant upon imports, which now account for around 50 percent of consumption.

Main Competitors

U.S. companies can expect to face competition in this market from major global suppliers such as Siemens, Fresenius, Hitachi, Toshiba, Philips, and Smith & Nephew, as well as from French players such as Air Liquide, Asklé Santé, Coloplast, Landanger, Mediprema, Moria, Paul Hartmann, Peters Surgical, Proteor, Systam, Thuasne. France is home to many subsidiaries of U.S. companies such as Abbott Vascular, Alcon, BD, Boston Scientific, 3M Santé, Baxter, Covidien, Edwards Lifesciences, GE Medical, Johnson & Johnson Ethicon, Medtronic, Boston Scientific, St. Jude Medical, and Zimmer.

Current Demand

Diagnostic Equipment

The diagnostic subsector represents 35 percent of the total medical equipment market. State-of-the-art diagnostic medical imaging systems are in great demand. Applications for this technology already exist for pediatrics, cardio-vascular care, digestion, urology, and spinal/nerve treatment. As it is well accepted and effective, the demand for this type of technology will continue to grow. Health care professionals are very optimistic about a feature of medical imagery equipment known as "image networking." This will dramatically improve diagnostics by providing an image data bank that would enable a specialist to compare the image of a current case to hundreds of previous cases.

Rehabilitation

This subsector represents 26 percent of the total medical equipment market. It includes all types of disposable medical products. The increasing elderly population reinforces the demand for all kinds of disposable equipment and supplies such as incontinence products and care kits used by nurses and families for home-care.

Surgery
The surgery instrument and supplies subsectors represent approximately 17 percent of the total sector. Recent developments in the non-invasive surgery field could have a strong impact on everyday hospital practice. These latest advances offer superior results and also present a significantly reduced risk to patients.

Technical Aids
The French market for medical prosthesis, 8 percent of the total medical equipment market, is characterized by a strong potential for innovative internal prosthesis such as knees, hips, ligaments, and elbows, and with a slightly decreasing market for external prosthesis. Technological evolution, especially in the field of anesthesia, offers the potential for rapid changes in this market.

Intensive Care
Intensive care equipment such as respiratory monitoring, pumps and incubators represent about 8 percent of the total medical equipment market. Intensive care equipment includes the latest technological advances. Both public and private hospitals show a rising demand for intensive care equipment and supplies.

Hygiene
The hygiene sub-sector represents approximately 6 percent of the total medical equipment sector. Patient and medical personnel safety is of growing concern to both members of the medical profession and the public. Best sales prospects will certainly focus around assuring stringent personnel safety requirements. This is especially due to the concern regarding AIDS and other contagious diseases. In the future, prevention should receive similar emphasis considering the present focus on protection.

Registration Process
All medical device sold in France have to carry the CE Mark. Registering with the French Ministry of Health is to be addressed on a case by case basis. In the very best interest of any U.S. exporter, and in the vast majority of cases, this task is handled by the importer/distributor. Indeed, a previous experience of successful registration of products with the French Ministry of Health will be a critical factor of success in order to facilitate access to end users in France.

Trade Events
Les SALONS de la SANTE et de l'AUTONOMIE
May 19–21, 2015 • Paris, France • ***salons-sante-autonomie.com***
Annual Hospital and Medical Equipment Exhibition. Largest medical trade show in France: 817 exhibitors, of over 22,000 square meters of space, 32,000 visitors from throughout Europe.

Germany

Summary

Medical technology is set to remain a German domain, at least until 2020. Germany has a long history of producing high quality medical equipment, with a particular emphasis on diagnostic imaging, dental products, and optical technologies. Not only is Germany the third largest market in the world after the United States and Japan, but also by far the largest European market—twice the size of the French market, and three times as large as those of Italy, the United Kingdom, and Spain.

Germany has a strong healthcare system in terms of infrastructure, hospital beds, and trained staff. It counts 500,000 beds in 2,017 hospitals (around 620 public hospitals; 717 non-profit, and 680 private hospitals), 2,000 medical supply stores, 1,200 rehabilitation centers, 21,000 pharmacies, and 150,000 doctors' offices. The well-established infrastructure makes the healthcare industry the largest employer in Germany with currently 5.4 million employees. Almost one in seven jobs can be found in the healthcare industry, 10 times more than in the chemical industry.

Accordingly, German healthcare expenditures are comparatively high but also increasingly cost-contained. In 2011 total expenditures increased to USD 399.5 billion, roughly 11.7 percent of GDP. In per capita terms, expenditure is estimated at USD 285, ranking fourth-highest in the world, exceeded only by Switzerland, the United States and Denmark.

Around 77 percent of healthcare spending is sourced from the public sector, mostly the statutory health insurances. As public insurance continues to record deficits and public hospitals are operating at a loss, health reforms and cost-cutting measures keep the market tight and increase pressure on prices. Although hospitals in the public sector are therefore maintaining existing equipment rather than investing in new appliances, price-competitive state-of-the-art technologies and equipment offering proven cost savings will have strong market potential.

Statistics

Capital:	Berlin
Population:	83.8 million (2013)
GDP (USD):	3.4 trillion (2013)
Currency:	Euro (EUR/€)
Language:	German

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The German healthcare industry has enormous potential to grow, and provides opportunities for U.S. medical technology exports. The Federal Ministry of Economics anticipates that by 2030 an additional two million people will be employed in the industry. Current austerity measures are likely to hit the pharmaceutical industry harder than the medical device industry, which continues to be a job engine and is expected to achieve steady growth over the next five years. In 2012 almost 60 percent of healthcare companies were reported to have created new jobs.

According to the German Medical Technology Association (BVMed), the medical devices industry employed 175,000, with a market valued at USD 33.3 billion in 2012.

German Medical Equipment Market, 2011–14

(USD Thousands)	2012	2013	2014 (estj.)	2015 (proj.)
Total Market Size	32,000,000	33,400,000	34,700,000	35,000,000
Total Local Production	33,000,000	33,400,000	34,700,000	35,000,000
Total Exports	20,000	21,000	21,840	22,000
Total Imports	20,000	21,100	21,944	22,000
Imports from the U.S.	5,625	5,906	6,142	6,201

Source: Spectaris Trade Association; BVMED Trade Association; Eucomed; Statista

For general statistical information published by the German Federal Statistics Office, please visit ***destatis.de/EN***.

Market Entry

Distribution Practices

Most medical equipment imported into Germany is either sold direct through a local subsidiary with a field sales force, through medical distributors with an established distribution network, or through appointed agents or manufacturer representatives. Local representation or market presence is essential when considering differing standards and certifications, warehousing costs, maintenance, accessibility, and local marketing/sales preferences/ discussions. An agency agreement is often a cost effective mechanism to enter the market but under German law—even if the agent's performance is not satisfactory—it can be difficult and costly to terminate the arrangement. A representation or distributorship agreement may be harder to arrange but the German associate will, in fact, purchase the product which is to be sold, thus sharing the marketing risk.

In addition to complying with standards and regulations, U.S. firms should seek to meet some additional criteria to assure product acceptance recognition and marketability when trying to enter the German market. For example, they should supply product information and trade

literature in German. At a minimum, catalog inserts should be in German. Firms should also provide operation and instruction manuals in German to insure proper understanding and usage of equipment, as well as providing reliable after-sales servicing and product support or select qualified agents or distributors who are capable of providing quality service. U.S. firms should maintain close contact and good feedback with agents in Germany in order to stay informed about market developments, trade issues, regulations, and laws concerning their products.

Product Standards

The German market for medical devices is regulated by German and European Union (EU) directives, standards, and safety regulations. The requirements are complex and based on environmental, consumer health, safety and social concerns. Not all standards and regulations are mandatory, but compliance greatly enhances a product's marketability. Advice on the requirements and compliance certification in the case of a specific product should be sought from the sources referenced below.

The German Medical Products Law (MPG) of 1995 underwent a revision in August 2013. It applies to all equipment, instruments, devices, and materials, which are used on or in the human body and is relevant when trying to get permission to enter the German market. Exceptions are those devices, which achieve their intended effect pharmacologically. About 400,000 different medical products fall under this legislation. The MPG implements EU guidelines covering medical and diagnostic products. Devices complying with the MPG or its equivalent directives in other EU countries must carry the CE mark. They have the advantage of being permitted on the market anywhere in the EU without further certification requirements.

Packaging and Labeling

The European Union does not legislate packaging and labeling requirements in general, only in very specific high-risk product related cases. In the absence of any EU-wide rules, the exporter has to consult national rules or inquire about voluntary agreements among forwarders, which affect packaging and labeling of containers and outer packaging. The importer or freight forwarder is the first point of contact for shipping documents and outer packaging/labeling. EU customs legislation only regulates administrative procedures, such as type of certificate and the mention of rule of origin on the customs forms and shipping documents.

Product specific packaging and labeling requirements applicable throughout the EU apply to food, medicines, chemicals, pharmaceuticals, and other high-risk items. The purpose of harmonizing such legislation throughout the EU is to minimize the consumer risk.

Payment and Financing Practices

In Germany the period allowed for payment, is between 30 and 60 days. Early payments are credited with a 3 percent discount, and supplier credits are common.

Practices regarding financing, availability of capital, and payment schedules are comparable to those in the United States. There are no restrictions or barriers on the movement of capital, foreign exchange earnings, or dividends. Virtually all major U.S. banks are represented in the German market, principally (but not exclusively) in the city of Frankfurt/Main, Germany's financial hub. Similarly, a large number of German banks, including some of the partially state-owned regional banks, maintain subsidiaries, branches and/or branch offices in the United States. Germany is not eligible for support from OPIC, TDA or similar agencies.

Tariffs and Import Regulation

There is an import duty of 5.1 percent to 5.3 percent of the import product value along with a 19 percent import turnover tax payable at the port entry. For customs clearance, a product description is required describing the use, origin and value of the product. The cost of the import-turnover tax is usually offset by ultimately passing it on to the end-user in later distribution stages in the form of a Value-Added-Tax (VAT), known in Germany as Mehrwertsteuer (MwSt).

Current Market Trends

The German medical technology market grew by 2.6 percent in 2013. This makes Germany an attractive market in the Eurozone. Globally Germany still ranks outside the top 60 in terms of market growth, because of lower economic growth and the launch of a restrictive reform program within the statutory health insurance system. Demand for medical supply will mainly be driven by demographics and a substantial increase in the number of patients. Germany's population still accounts for 20 percent of the total population in Western Europe and is increasingly aging. By 2050 the 65 and over age group is forecast to expand to 23 million, up from an estimated 17 million in 2012.

The German medical technology industry is a highly innovative and dynamic sector. One third of sales are generated by devices that are less than three years old and approximately 9 percent of all sales are reinvested in research. The German healthcare system is also among the best in the world regarding the uptake of new technologies. More than two thirds of German physicians are seeing innovation as the key element in maintaining the high standards of the German healthcare system. Hospitals are allowed to introduce innovative technologies. The German medical device sector, therefore, remains highly attractive for investors and continues to provide excellent potential for U.S. suppliers of innovative and price-competitive products, particularly in high tech imaging; minimally invasive surgery; big data management, and other key areas.

The economic situation of German hospitals worsened in 2012 due to poor investment abilities and an investment bottleneck. A recent market study by Accenture estimates that 16 percent of German hospitals have a high risk of default and 13 percent could drop out of the market until 2020. At the same time, the government coalition agreed on an investment fund for hospitals in their coalition contract of 2013. The injection of capital led to an easing of financial

tension in 2013 and this is expected to continue throughout 2014 and 2015. Investment backlog is estimated at 15 billion Euros in 2014, according to the Accenture study.

Main Competitors

The German market for medical devices is sophisticated and well served. Germany has a handful of large producers, headed by Siemens, B. Braun and Fresenius. 95 percent of the German medical technology industry is characterized by small and heterogeneous companies or sub-groups of larger companies. Almost 1,250 SME businesses (more than 20 employees) employ over 100,000 people and 10,000 smaller businesses employ around 75,000 people. 95 percent of all companies employ less than 250 employees and rarely does one company represent more than 2 percent of the entire sector. In addition, foreign industry giants such as Philips (NL), Hitachi (Japan) and Toshiba (Japan) are well entrenched. GE Medical, Medtronic, Agilent, 3M Healthcare, Hollister, and Johnson & Johnson are only a few of the many German subsidiaries of U.S. medical device suppliers.

As a result of a low-growth domestic market, the German medical technology industry has to rely heavily on export markets for continued growth. On average, German medical technology companies export between 60 percent and 65 percent of their products. In 2012 foreign sales rose by 6 percent and the export rate reached 66 percent of local production. Around one-fifth of these exports went to the United States. Next to a strong German manufacturing base, imports supply around three-quarters of the German medical market (USD 16.7 billion). Between 2007 and 2011 medical device imports recorded a CAGR of 6.6 percent (EUR) and 7.0 percent (USD). U.S. medical device exporters to Germany continue to hold a 27–30 percent import market share, depending on product. U.S. suppliers of innovative and price-competitive products especially can compete strongly on the German market.

Current Demand

There is a stable demand for high-quality advanced diagnostic and therapeutic equipment, innovative technologies and minimally invasive equipment, in vascular surgery, urology, gastrology sand gastro-enterology sand gastro-enterology, dermatology, and neuro-surgery. Future mega trends are predicted to be wearable and wireless medical technologies. At the same time, the demand for specialized software to secure wireless medical devices against cybercrime and malware is expected to increase. Furthermore, the German medical market experiences a clear trend towards personalized medicine based on individual patient requirements. This reflects on medical packaging with increased demand for flexible and compact packaging machines.

The trend is toward miniaturization of electro-medical equipment and nanotechnology products. New technologies in emergency and first responder care along with computer-assisted surgery are widely discussed among the German medical community. Germany is also proactive in coming up with solutions to address the aging population. Therefore, there will be

an uptake in demand for diagnostic equipment to detect chronic diseases in their early stages in order to prevent higher costs. It will also spur the demand for specialized wound care and easy-to-use home care products for diabetes, orthopedic appliances, and dialysis equipment. Third, big data technology is in high demand in all segments and in the context of evaluating data for new therapies and cost-containment measures.

Registration Process

In 2013, the EU Commission was considering a fundamental revision of the regulatory framework for medical devices, including a central premarket authorization (PMA) system for implantable devices, and randomized clinical trials. On September 09, 2013, the EU Parliament took vote on the draft regulation and rejected it. Representatives of German industry and government were concerned that the comparative advantage of European medical manufacturers would be lost, and investment would decrease, if the new rules were to be approved.

The CE Mark signifies that a product fulfills all necessary EU requirements. CE marking is now a legal requirement for a wide range of equipment manufacturers in Germany. Certification requirements for use of the CE mark vary depending on the product. For some, such as those in the MPG low risk class I, the manufacturers (or importer/authorized representative, if the product is manufactured outside the EU) may self-certify compliance with EU requirements and affix the mark; for others the certification of a "notified body" (an accredited certification agency such as the TUEV) will be required. For the medical aids sector, the workability and safety of a product is now considered satisfied by CE marking. The CE mark is a visible indication that the manufacturer signed a "Declaration of Conformity" prior to affixing the CE mark, claiming compliance with all relevant CE marking directives in force.

All electro-medical equipment in Germany must be suitable for use with 220 Volt, 50 cycle electrical current, and should have VDE or TUEV approval. A UL approval is not a substitute but is helpful to obtain "GS/VDE," or GS/TUEV" approval in Germany. "GS" stands for "gepruefte Sicherheit" (safety tested). Although "GS" and the "VDE" (or "GS and TUV") marks are not required by law, they are highly recommended for marketing electro-medical goods in Germany. These labels denote high product safety; German consumers look for these labels as Americans do for the "UL" mark.

The U.S. Product Safety Testing Institute, Underwriters Laboratories (UL), the VDE Testing and Certification Institute, and the TUEV Product Service, have formed a strategic alliance for testing of electromagnetic compatibility (EMC) which has resulted in globally recognized EMC test mark. For manufacturers of electrical and electronic products, this cooperation has led to a substantive simplification of EMC testing. Through a single test carried out by one of these three partners, a product can now be awarded an international EMC mark, which replaces the national test marks in the major world markets of Europe, the USA and Japan.

Barriers

Firms exporting medical devices to Germany will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers could include the complex German reimbursement system, the need for additional registration procedures in the case of medical assistive technologies, for example, or products sold in pharmacies, with the requirement to apply for HMV or PZN codes, respectively. For Class 2 medical products, the German medical products law requires manufacturing and distribution control/quality control documentation.

Trade Events

MEDICA with Compamed

November 12–14, 2014; November 16–19, 2015 • Düsseldorf, Germany
medica.de • ***compamed-tradefair.com***
Considered the world's most important and largest international fair for medical equipment. Medica attracts 147,000 trade visitors from more than 70 countries and over 4,500 exhibitors from 80 countries. Compamed, the marketplace for suppliers to the medical manufacturing industry, attracts 600 exhibitors from 40 countries.

BIO-Europe Spring 2015

March 9–11, 2015 • Paris, France • ***ebdgroup.com/bes***
Europe's largest biotechnology partnering conference. Nearly to 3,000 global decision makers from biotechnology, pharmacology, and finance attend annually.

IDS (International Dental Show)

March 10–14, 2015 • Cologne, Germany • ***english.ids-cologne.de***
The world's leading trade show for the dental industry including dental practices, dental labs, the specialist dental trade. More than 125,000 visitors from 150 countries; more than 2,000 exhibitors from 56 countries.

FIBO 2015

April 9–12, 2015 • Cologne, Germany • ***fibo.de***
The world's leading trade show for fitness, wellness, and health. More than 80,000 visitors from 100 countries and more than 650 exhibitors from 38 countries.

BIOTECHNICA

October 6–8, 2015 • Hanover, Germany • ***biotechnica.de***
Europe's leading trade fair for biotechnology, life sciences, and laboratory equipment. More than 600 exhibitors.

REHACARE

October 14–17, 2015 • Düsseldorf, Germany • ***rehacare.de***

Europe's premier rehabilitation and care event; open to the public. 50,000 visitors and 805 exhibitors from 32 countries.

A+A 2015 (Safety + Health at the Workplace)

October 27–30, 2015 • Düsseldorf, Germany • ***aplusa-online.de***

The world's largest and most important specialist trade fair for all aspects of safety and security. Includes safety, security, and health management, including prevention and therapy of work-related illnesses. More than 55,000 visitors and more than 1,600 exhibitors.

BIO-Europe 2015

November 2–4, 2015 • Munich, Germany • ***ebdgroup.com/bioeurope***

Europe's largest biotechnology partnering conference. Nearly to 3,000 global decision makers from biotechnology, pharmacology, and finance attend annually.

OTWorld

May 3–6, 2016 • Leipzig, Germany • ***ot-leipzig.de***

Innovative technology, new products, and high-quality professional training. The orthopedic and rehabilitation industry's leading event worldwide. More than 19,500 international visitors and 537 exhibitors.

Available Market Research

- Pharma Data (2013)
- Pharmaceuticals (2010)
- Biotechnology
- BVMED Annual Report (2013/2014)
- Ernst & Young
- Customized Market Analysis available upon request (requires fee)

Ghana

Summary

Ghana is one of the most attractive markets in Sub-Sahara Africa for U.S. products and investment. The country has demonstrated remarkable stability and legal transparency, particularly in comparison to its neighbors in Africa. Ghana has a vibrant democratic government and has witnessed strong economic growth over the last 20 years. Health is one of the central pillars of the government of Ghana's human development agenda and is an underlying factor in the government's overall strategy for accelerated growth in the country. Ghana's demographics remain reflective of its lower-middle income status: the average life expectancy is 60.9 years and infant mortality remains far above the world average (40 deaths per 1,000 live births in 2013). Ghana has a full range of diseases endemic to Sub-Sahara Africa: cholera, typhoid, pulmonary tuberculosis, chicken pox, yellow fever, measles, infectious hepatitis, malaria, and schistosomiasis are all endemic in Ghana. Despite these challenges, the country does have a strong and growing middle class and a large number of expatriate Ghanaians are choosing to return to participate in one of Africa's fastest growing economies.

Market Entry

U.S. companies should consider partnering with an appropriate local company to most effectively enter the market. Many Ghanaian companies are qualified to represent manufacturers of U.S. pharmaceutical and medical device and equipment in the market. Ghana's market for U.S. healthcare products is primarily focused on the country's largest cities: Accra, Tema, Kumasi Takoradi, and Tamale.

The U.S. Commercial Service can assist interested U.S. companies to identify appropriate partners.

Statistics

Capital:	Accra
Population:	25.4 million
GDP (USD):	40.7 billion (2012)
Currency:	cedi (GHS)
Language:	English, others

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Current Market Trends

Ghana has very limited local production of pharmaceuticals and even less manufacturing of equipment and devices; the country relies on imports for approximately 80 percent of its total health care consumption. In 2005 Ghana moved from a 'pay as you go' system, where individual health expenditures were paid in cash prior to treatment, covered entirely by patients. The National Health Insurance Scheme now provides wide coverage for a limited scope of health issues, primarily insuring for treatment against the most prevalent diseases (malaria and others). Ghana has sought to introduce more private sector participation into the health care sector and the most dynamic growth and most exciting opportunities will be found in privately invested hospitals and clinics and in the non-state controlled portion of the pharmaceutical sector.

Main Competitors

Ghana's colonial history still impacts the presence of competitors in the market—European, and particularly British, brands have a distinct advantage with Ghanaian consumers. Ghana's standards generally follow European standards, providing an additional advantage to those companies. In the last 20 years there has been a growing presence in Ghana by Indian and Chinese companies selling into the health care sector. Chinese companies in particular are aggressively pursuing opportunities in West Africa and seeking partners to manufacture or assemble products in Ghana.

As both Indian and Chinese companies have become more active in Ghana's market there has been a corresponding rise in the amount of counterfeit pharmaceutical products. The wide availability of counterfeit (and ineffective) malaria medications has caused particular concern. In response, the United States Pharmacopoea Commission (USP) established a presence in Ghana to provide assistance in the identification of counterfeit and substandard medicines. USP now has an active clinical lab in Accra working to build local capacity within Ghana's healthcare industry.

Current Demand

Ghana's per-capita health expenditures are low, less than USD 85/year (compared to South Africa at USD 655/year and the U.S. at USD 8,500/year). Most coverage is focused on basic treatments of commonly occurring illnesses. Under publicly funded health care outreach programs (often funded through grants or loans by multinational development agencies) there is a strong focus on driving basic health care services to smaller towns and villages in rural Ghana. U.S. companies have profited in the Ghana market by providing mobile health equipment that can be used in rural settings, often in regions that are off the power grid. Outside of the mainstream healthcare market, significant opportunities are available in serving the higher-end needs of Ghana's middle and upper class and the growing expat community in Accra. Ghanaian government authorities have discussed their intentions to attract private

investment to establish a medical tourism sector in Accra; companies should keep an eye on these developments but understand real opportunities will be years down the line.

Registration Process

The Food and Drugs Authority (FDA) is the registering body in Ghana for pharmaceuticals, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products. Ghana's Standards Board develops and regulates standards used in the health care sector in the country. Both organizations have a reputation for relative transparency and work closely with certifying bodies around the world, including the U.S. FDA and the National Institute for Standards and Technology. It is important to note that Ghanaian government agencies are typically not responsive, management of the registration process requires a significant amount of hands-on effort by the applicant.

Barriers

There are no significant trade barriers or quotas for U.S. health-care companies operating in Ghana. The country has a well-deserved reputation for being friendly to both foreign investment and foreign imports. Companies interested in the Ghana market should note that European standards are widely adopted in the country. Electricity in Ghana is 220V/50 MHz.

Trade Events

Ghana hosts no significant health care trade events of its own. Companies interested in accessing the market should consider participating in major healthcare trade events in the U.S.; CS staff can facilitate discussion with visiting potential Ghanaian partners.

Regionally, South Africa's Africa Health is well-attended by Ghanaian buyers:

Africa Health

May 5–7, 2015 • Johannesburg, South Africa • ***africahealthexhibition.com***
Over 4,000 attendees; approximately 450 exhibitors; 17 country pavilions and 14 accredited conferences.

Greece

Summary

Greece finds itself in one of its most challenging periods in its post-war history. The economic developments in Greece, triggered by the recent financial crisis, have created a new environment for all sectors. The government has made progress in carrying out widespread economic reforms. Many of these reforms aim to simplify the investment framework, and the government is aggressively seeking to attract foreign investment to drive the country's long-term economic recovery.

After six years of recession, Greece is expected to return to positive growth rates (+0.6 percent) in 2014. Business confidence dropped sharply through the crisis, but after Greece and its international creditors reached agreement on a large disbursement of assistance (over €50 billion) for the country in early 2013, sentiment along with several economic indexes improved and this trend continues in 2014 to date. Access to the international capital markets has improved, as demonstrated by two successful senior bank bond issuances for the first time since 2009 and the successful share capital increases by all four core banks, validating investors' renewed trust in the Greek economy.

Amidst the above developments, Greece's geographic location continues to make the country an excellent business gateway into Southeastern Europe. The continuously growing demand for medical equipment in Greece, as well as in many of the developing Balkan states, provides strong prospects for companies in the medical equipment field in Greece and neighboring Balkan countries. The Greek market for medical equipment had experienced stable annual growth of 12.7 percent in the previous years, which is expected to resume, following the expected overall market recovery. One of the prime characteristics of this market is its high level of imports.

Spending in 2011 of 21.80 billion euros (USD 30.31 billion) was reduced to 20.34 billion euros (USD 25.83 billion) in 2012 in both the public and private healthcare sectors. The government is finalizing the merger of many hospital units and

Statistics

Capital:	Athens
Population:	10.8 million (est. 2013)
GDP (USD):	241.8 billion (2013)
Currency:	Euro (EUR/€)
Language:	Greek

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attempting a twenty-four hour operation standard within all public hospitals, with a greater level of transparency in hospital financial transactions and hospital procurement. Healthcare expenditures as a share of GDP in Greece have been reduced to 6.3 percent annually in 2012. This expenditure is comprised of approximately 60 percent government–provided care and 40 percent private care. Preference for private healthcare has been higher in Greece than in most E.U. countries during the recent years, although this is changing, given the economic situation and Greek citizens' ability to pay for private care. Still, healthcare is the number one concern since more than 25 percent of the population is over 60 years old.

Market Entry

General

As a member of the E.U., Greece applies the E.U. common tariff schedule on products imported from non-E.U. countries. All products, regardless of origin, are subject to the value-added tax (VAT) which is 23 percent for most products and 11 percent for pharmaceutical products. A further increase is under debate, as a result of the government's intention to raise more funds to fight the budget deficit. According to sources*, the projected expenditure on Pharmaceuticals for Q4 in 2012 was USD 7.5 billion, on Healthcare USD 26 billion and finally on Medical Devices USD 775 million.

Medical Equipment and Devices

While duties are applied to parts of medical products and disposables, U.S. medical equipment receive duty-free treatment. Within the E.U., medical device legislation has been harmonized through the European Union's Medical Devices Directive 93/42/EEC. This enables a manufacturer who has approval in one E.U. country, to gain access to Europe's entire market without having to obtain approvals from each additional country. All low risk devices, which are in conformity with the requirements of the directive, must carry a CE mark. Higher risk classified products, in addition to the CE mark, must carry the identification number of the certifying organization that performed the conformity assessment and issued the approval. National implementation of the Medical Device Directive requires instructions for use in the national language. However, technical manuals and promotional material may be in English, French or German. Representatives in Greece can assist U.S. companies to meet these standards, if the U.S. firms have not already done so, in an effort to enable them to gain access to E.U.'s entire market. Other Directives they follow under the European Legislation are Data Protection Directive (95/46/EC), Electronic Signatures (1999/93/EC), Patient Rights in Cross border healthcare (2011/24/EU), Medical Device (90/385/EEC),(93/42/EEC),(98/79/EC), Electronic Commerce (2000/31/EC).

Over-the-Counter Medicines and Dietary Supplements

All the details pertaining to the introduction of a new food supplement to the Greek market are outlined in the Greek Government Gazette #935 of November 13, 1995 and in the E.U. Directive 2002/46/EC of the European Parliament. A U.S. company interested in entering

the Greek market is advised to find a local agent/distributor in order to expedite procedure normally encountered during the registration–approval process. The National Organization for Medicines (EOF) is the official authority for granting authorization to the sale of medicines and drugs in Greece.

In 2012, a plan to merge the National Organization for Medicines with the Hellenic Food Authority and other similar organizations was proposed to the Greek government by appointed consultants. With this merger, the new centralized agency would resemble the U.S. FDA and contribute towards a more immediate regulatory process.

Current Market Trends

Medical Equipment and Devices

The Greek market for medical equipment was estimated in 2010 to have increased by 5.4 percent compared to the previous year. It is estimated that the Greek market for medical equipment in 2010 reached USD 1.569 billion, out of which around 95 percent was supplied by imports. The greater share of the companies' revenues is recorded in their business with the public sector (at around 80 percent) but this slightly changed due to the revised company focus toward the private healthcare sector, given its ability to pay for the products it buys in a reasonable time frame. As of 2012, approximately 13,000 individuals are employed in the Greek pharmaceutical and medical supplies fields. Medical Devices and Diagnostics total market value reached 1.2 million euro in 2012 and faced a decline of approximately 10 percent from 2011 as a repercussion of the economic crisis. However, for 2013 onwards this decline has been stabilized from 10 percent reduction with signs of positive prospects thereafter.

Health IT

Health Information Technologies (e-Health) consists of hardware and software systems used by healthcare professionals to gather, file, classify, have access to, and electronically exchange healthcare information including administrative, clinical and other supportive systems. eHealth is one of six prioritized markets in the European Commission's Lead Market Initiative, a public-private dialogue to promote innovation and an open market. The Commission's eHealth Action Plan 2012–20 sets out the following goals and asks member states to work closely together with EU institutions to:

- Achieve wider interoperability of eHealth services.
- Support research, development and innovation in eHealth.
- Facilitate uptake and ensure wider deployment
- Promote policy dialogue and international cooperation on eHealth at global level.
- Improve legal and market conditions for developing eHealth products and services.

As stated in the European Action Plan, the development of e-Health aims to improve the implementation of digital systems for monitoring and home care for the elderly and chronically ill, in disseminating the use of telemedicine technology for diagnostic and therapeutic purposes, to enhance the safety and quality of cross-border health services, promoting innovation to create new products and services that can contribute to the sustainability and efficiency of health systems, and generally improve the quality of life of Europeans citizens. In addition, the development of e-health services can contribute decisively as a major engine of growth and competitiveness in European industry and technology.

In terms of e-Health, Greece scores below the E.U. 27 average regarding availability of Information and Communication Technology (ICT) infrastructure (computers and Internet) and the use of ICT for e-Health purposes. Although Greece was lagging behind the E.U. in internet penetration and broadband, the aim of the National Digital Strategy was to reach the E.U. average by 2010, and the recent government efforts through its National Digital Strategy (2007–13), including related investments of over USD 665 million have already led to considerable improvement. In particular, Greece is quickly catching up to the above-mentioned E.U. average (20 percent). According to the National Telecommunications and Post Commission, by the end of March 2012, the market grew by 8.1 percent year-on-year.

Although the use of ICT technology for use in healthcare appeared in the 1980's, ICT solutions have not yet been strongly adopted in healthcare practice in Greece. This is mainly due to the rather late development of an e-Health strategy. However, the successful Conference under the Greek Presidency [E-Health Forum 2014] shows that e-governance together with private business initiatives may change the scenery, This moves Greece towards the real development of the Greek eHealth ecosystem that will bring the country closer to the goals of the EU Action Plan 2012–20 for eHealth while at the same time it attracts the interest of the industry and other stakeholders. The eHealth Forum 2014 served as the meeting point for the six Actions Groups of the European Innovation Partnership on Active and Healthy Aging (EIP on AHA). The Forum brought together the High Level eHealth Conference and Exhibition, the eHealth Network Meeting and many more events, and become a true forum for the exchange of experience, mutual support, good practices and innovation.

The first preparatory meeting for the eHealth and the Greek eHealth Ecosystem took place in July 20, 2013, thus reinforcing the strong commitment and investment in the deployment of eHealth solutions and the dissemination of good practices. Therefore, the required infrastructure, including standards, a national health portal, insurance smart cards, electronic information systems, etc., will start becoming available in the upcoming years. eHealth facilitates the values of equity and solidarity by enabling the access to high quality services and safer care for all, including numerous groups of citizens with chronic diseases and the elderly. At the same time it serves as the backbone for necessary structural and functional reform and for addressing the issue of shortage of financial resources.

Greece considers that ICT solutions and eHealth could lead to valuable, sustainable outcomes for the society, promote the wellbeing of the European Union citizens and build a solid base for the delivery of cross-border healthcare through interoperable services. Regardless of the recession, Greece aims at driving eHealth forward. The Greek Presidency through the eHealth Forumencouraged the development of visionary policies and looked into maximizing health and economic benefits and the potential for employment through new technologies.

Best prospects include:

- Hospital procurement based on Electronic Data Interchange Systems (EDI)
- Information systems for transactions between hospitals and insurance companies
- Smart health insurance cards
- Information system for the national ambulance service
- Information system for organ transplantation coordination and control
- National blood-bank information system
- Primary care information system
- Medical libraries information system
- Clinical information systems such as radiology information system; Nursing information system; Computer assisted diagnosis; Surgery training and planning system
- E-care and telemedicine such as disease management, and remote patient monitoring,
- Development of information systems to improve the services provided by welfare and mental health providers to the elderly and people with special needs.
- e-Prescription and e-Referral, e-Labs systems(inclusive of provisions for appropriate accreditation, testing and certification).

Over-the-Counter Medicines and Dietary Supplements

The regime for over-the-counter medicines (OTCs) and dietary supplements, including vitamins is highly restrictive. Greece is among the few EU countries that both set prices throughout the vertical production chain for OTCs (ex-factory, wholesale and retail prices) and restrict their distribution to licensed pharmacies only. The joint restriction severely limits competition in the market, leading to under-investment in the sector and poor availability of OTCs and dietary supplements for consumers. The OTC healthcare market in Greece is characterized by consolidation of global supplies, with multiple foreign brands active in the market. This market condition does not seem likely to change, as multinationals are only becoming stronger and traditional Greek firms are moving towards importing rather than manufacturing medicines. The trend of health and wellness in Greece has favored companies in nutritionals, herbal/traditional products and in OTC healthcare, for example vitamins and dietary supplements.

A recent contributor to the sector's positive growth is the ongoing trend towards self-medication as many Greek people are now avoiding a visit to the doctor for economic reasons. Also, further to the recent removal of non-prescription products from the public reimbursement plan, and their relevant transfer to official OTC status, there is opportunity for OTC market development in the future. Availability without prescription from the Greek public reimbursement scheme, supports the development of a real OTC market in the longer term.

During the past couple of years, weight management in Greece encompassed a shift away from meal replacement slimming and move towards weight loss supplements and OTC. Dynamic new product launches within weight loss supplements and the positive performance of GlaxoSmithKline's Alli (example of an OTC obesity brand) were the main reasons for the shift towards weight loss supplements and OTC respectively. Weight loss supplements recorded the fastest value growth in weight management in Greece during the past couple of years, increasing in value by 13 percent.

The Greek vitamin and dietary supplement market has grown significantly during the last decade, creating investment opportunities. Consumption of vitamins and dietary supplements has increased as people learn of potential beneficial effects through advertisements and their doctors. Vitamins and dietary supplements increased in value by 2 percent in 2011 and onwards, including those which are normally associated with health and beauty and skin health as well as anti-ageing and anti-stress products and products which boost immunity and energy levels.

Dietary supplements and herbal/nutritional products remain under the supervision and control of the National Drug Administration (EOF) with very few exceptions (e.g. herbal nutritional supplements). Consequently, the majority of these products can only be sold through pharmacies, are not eligible for reimbursement and their prices are set according to a reference price system. Cosmetics also fall under the supervision of the EOF following the European Regulation No. 1223/2009, which is common for 31 European countries, as well as the REACH regulation on chemicals No. 1907/2006.

Main Competitors

In the Greek market, there are approximately 300 active companies in the medical device field. These companies are mainly importers and distributors of scientific and medical equipment which also provide after-sales services. Key suppliers of medical equipment to Greece are the United States, Germany, and Italy, and to a smaller degree, the Netherlands, France, United Kingdom, and Luxemburg. The E.U. has acquired a major share of the Greek market due to geographic proximity, product quality, established marketing arrangements and favorable tariff treatments. Domestic manufacturing in this sector is not highly developed. Consequently, the supply capability of Greek companies is largely limited to low-value products such as syringes, bandages, gauze and various small medical devices. The medical equipment market in Greece is highly competitive because of the number of diverse importers.

The structure of the public healthcare sector and especially the bureaucratic process of the existing tender system make it imperative for U.S. suppliers to have local partners. Competitive strategies focus mostly on pricing, exchange rates, and payment terms, particularly when dealing with the public hospitals. Leasing is also an option, especially for large, high-tech, expensive equipment. The most active and profitable subsectors for foreign suppliers include surgical equipment and supplies, electro medical equipment, IT healthcare systems and telemedicine technology. Specifically for IT healthcare, there is significant demand for products that increase the patient's safety through reduction of medical errors, while improving health information management.

Relevant U.S. company presence in the Greek market includes: 3M, Abbott, Alcon, Bard, Baxter, Boston Scientific Hellas, Carestream, Edwards Lifesciences, GE Medical Systems, Johnson & Johnson, Medtronic, Stryker, and Teleflex Medical. It should be noted that the actual share of U.S. imports was much higher than the estimated 18 percent because a large amount of the medical equipment was produced by the European subsidiaries of U.S. firms and are registered as having originated in the EU.

Current Demand

There are two major sources of demand for medical devices:

- Public Health Institutions (hospitals, health centers, and regional clinics)
- Private Health Institutions (hospitals, clinics, diagnostic centers, and professionals)

Demand from consumers represents a small but increasing segment of the market. Research shows that demand for medical equipment from public hospitals represents approximately 80 percent of the total demand, making public sector hospital payment delays a serious concern. There are ongoing public and private initiatives to reduce the mismanagement of public capital and delay of payments, which the new government claims is at the top of its agenda. Additionally, the Greek government has agreed to start paying off debt to hospital suppliers and to maintain the uninterrupted flow of medical supplies and consumables to the public hospitals.

During the past year, progress has been made in the electronic processing of prescriptions which leads to better drug control within the public sector. Doctors are now required to electronically prescribe medication. With this change the government has started to regulate the budget for pharmaceuticals accordingly.

The challenges within the public sector have created an opportunity for the private sector to grow in importance. The involvement of the private sector in health care delivery is extensive and has been growing rapidly since the early 1990s. The current number of private hospitals is 146 with a total capacity of 38,628 beds and 140 hospitals in the public sector with 37,027 beds accounts for 95.9 percent of the total healthcare infrastructure. Most of these facilities are general and maternity hospitals. There are also 170 private clinics in the country

with another 15,028 beds. (BMI, source 6) The private hospital sector accounts for 39 percent of all health services provided in Greece, trying to capture opportunities in new areas, such as Medical Tourism.

The market leaders in the private Healthcare Sector in Greece are the Athens Medical Group, Euromedica, Hygeia Group, and IASO Group. These medical business groups have grown tremendously from the past decade. These companies continuously seek to increase their stake in the market, however, because of the current economic situation, operate under financial pressure. Already, they have established facilities in Greece, and some neighboring countries such as Albania and Cyprus. The private health care sector is averaging an annual growth of 13–15 percent. General and diagnostic clinics have averaged 16.8 percent and 8.4 percent annual growth, respectively. In terms of primary health care, there are more than 25,000 private practitioners and laboratories, and approximately 250 diagnostic centers in Greece, most of which are equipped with, "big ticket" medical technology. Private practices, labs and diagnostic centers are also contracted through social insurance funds to provide health care services to their beneficiaries. Remuneration is on a fee-for-service basis. Rehabilitation services and services for the elderly (geriatric homes, etc.) are predominantly offered through the private sector. Finally, the private sector through its digital strategy, together with the Ministry of Health are following an ongoing development/adaptation of Hospital Information Systems applications, to comply with the newly introduced and evolving, requirements on DRGs, billing, and reporting.

Registration Process

There is no requirement for an FDA certification since it is not accepted by the EU legal framework. Every product even if it has an FDA Certification should comply with the European standards. More particularly, companies interested in exporting to Greece should apply through the importing company to the National Organization for Medicines (EOF), indicating the country and the laboratory that produced the pharmaceutical as well as precise details about its active ingredient, etc. The company importing the U.S. pharmaceuticals should also have a specialized license to import pharmaceuticals obtained by EOF. The exporter and/or the product should also comply and be certified with the Good Manufacturing Practice (GMP) by a member state of the EU. This can be based on the Compilation of Community Procedures on Inspections and Exchange guidelines as described in the Outline of a Procedure for Coordinating the Verification of the GMP Status of Manufacturers in Third Countries. Additional documentation, such as the license to produce the pharmaceutical product by the FDA should be provided. Finally, relevant fees will be applied for the procedure.

There are no import restrictions for medical devices. However, there is a requirement for CE Certification (European Conformity) according to the European Law which can be provided by the authorities of any EU country and is accepted by the member countries of the EU. According to the Council Directive 93/42/EEC as amended by Directive 2007/47/EC, a

manufacturer from a third country, who does not have a registered place of business in EU seeking a CE Certification should designate a single authorized representative in the EU.

Barriers

There are no real barriers for entry in the Greek market. However, the situation with public sector hospital payment arrears has been an issue, particularly amidst the Greek economic crisis. Many companies have witnessed long delays in the payment of accumulated debts by the Greek public sector. However, the DIRECTIVE 2011/7/E.U. of the European Parliament and of the Council of 16 February 2011 on combating late payment in commercial transactions has placed some increased pressure on the Greek government in proceeding with the normalization of payments in the future. Despite this directive and given the financial crisis, there continues to be public sector debt.

Trade Events

Medpoint Hygeia by Helexpo

February 7–8, 2015 • Athens, Greece • ***www.helexpo.gr***

Medic Expo 2015

February 22–24, 2015 • Athens, Greece • ***medicexpo.com***

Available Market Research

- Euromonitor International
- Business Monitor International
- Hellenic Republic Ministry of Health
- Morgan Stanley Risk Analysis
- ***Iatrikesexelixeis.gr***
- European Commission

Guatemala

Summary

The United States and Guatemala enjoy a strong and growing trade relationship, especially under the U.S.-Central America-Dominican Republic Free Trade Agreement (CAFTA-DR). The United States is Guatemala's largest trading partner accounting for nearly 40 percent of Guatemala's trade.

Guatemala is a country of over 15 million inhabitants with high levels of poverty that require assistance by the public sector for its health care needs and also a large number of inhabitants that do not use public services because they can afford a private hospital or clinic. The market of medical services is divided in two segment, the private and public sectors.

- The private sector as a common rule purchases only well-known brands of medical equipment. Because of their appreciation of high quality products and a total customer support from the distributor in any emergency. Investments in new medical equipment within the private health care sector are expected to continue as new clinics and current hospitals buy periodically their equipment needs and continue to invest strongly in new technology diagnostic and treatment equipment.
- The government, in contrast, is price-driven and will purchase the lowest bidder via public tenders. All medical services in public hospitals and clinics are free of charge to any patient. This means major hospitals are replacing older equipment and buying new equipment that can meet the demand of free medical services for all the population. The public sector consists of hospitals and clinics operated by the ministry of health through the social security institute and the armed forces.

Statistics

Capital:	Guatemala City
Population:	15.5 million (est.)
GDP (USD):	53.7 billion
Currency:	Quetzal (GTQ)
Language:	Spanish

Contact

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Market Entry

The most important decision a U.S. company has to make is to choose a local representative. The best strategy is to screen potential importer-distributors, and select the most qualified.

The chosen importer should be a company that is registered to sell to the government and can participate in official tenders and bids. Also this company needs to know the private market and have constant communication with the purchase manager of Hospitals, clinics and medical doctors with practices that use machinery.

Once the exclusive representation is given to a Guatemalan importer it is difficult to take it back because of the representation law in Guatemala, so it is necessary to have a good relationship and chose the correct representative. The legal system can be slow and the law, under certain conditions, offers local agents a great deal of protection.

Formal agency or distribution agreements should be reviewed by a Guatemalan attorney hired by the U.S. exporter (independent of the Guatemalan party with which the agreement is being established).

Current Market Trends

Consumer Preference

Hospital and clinic medical equipment is based mostly on:

- Brand name
- Specifications of the equipment
- After sales and training of the end user
- Latest technology or world trend

Differentiated Market

The final consumers or end users of the medical equipment are all the private and public hospitals and clinics in Guatemala. The difference between both markets is that private customers buy immediately and often look for the best brand of equipment meanwhile public purchases are made by bids all year long and are informed by the government via their procurement website, ***guatecompras.gt***.

Main Competitors

Many countries compete in Guatemala; competitors vary depending on the specifications and purpose of equipment, but in general the U.S. is the most important exporter of medical equipment to Guatemala. Germany is the second major exporter to Guatemala, but is showing a decrease in almost all the categories of HS code due to the high prices of the German brands and because they export their medical equipment directly from USA because it is more convenient for delivery time. Japan and China are in third place depending on the HS code and each one with different features of price and quality in their products.

Current Demand

The total of hospitals in Guatemala is approximately 195 and the total of clinics 2,502 there is no exact number for the private sector because there is no record of it, the ministry of health only keeps record of the public sector.

All of the hospitals will need to purchase equipment in the future it is a constant procedure in the medical field so medical equipment like radiology, mammography, IMR, scanners, patient monitoring systems, digital image processing clinical laboratory equipment and dialysis equipment are going to be purchased periodically by all the hospitals and clinics in Guatemala depending on each necessity.

Medical equipment is constantly evolving and utilizing sophisticated products and most end users are looking for new technologies as well as to prefer user-friendly features in the medical machines. Also recently end users have requested companies to provide with manuals, buttons in the machines and instructions in Spanish of their equipment.

Registration Process

Most medical devices require sanitary registration at the registration office of the Ministry of Health. Some of those devices also require lab analysis from the National Health Laboratory. The requirements for both procedures and the requirements for packing are listed under Technical Regulation No. 37-2003 of the Ministry of Health's Department for the Regulation and Control of Pharmaceutical and Related Products.

This technical regulation also provides a classified guide/list of medical devices that require sanitary registration and lab analysis. According to the head of the Department for the Regulation and Control of Pharmaceutical and Related Products, the National Health Laboratory conducts microbiological tests on sterile products only and does not evaluate functionality/effectiveness of devices. Sanitary registration processes are usually completed in about one week when lab tests are not required and in about six weeks when lab tests are necessary.

Sanitary registrations need to be renewed every five years. Devices such as anesthetics and asthmatic inhalers, high pressure measuring apparatus, laser-guided apparatus do not require sanitary registration at the Ministry of Health.

Trade Events

No local medical trade fairs, but most Guatemalan importers attend Miami's FIME International Medical Exposition (***fimeshow.com***).

Hong Kong Special Administrative Region

Summary

Hong Kong relies heavily on imports to satisfy its medical equipment needs. Total medical equipment imports in 2013 amounted to USD 1.67 billion. The United States was the market leader in the high-end market segment, capturing about 20 percent of the total import market in 2013.

Hong Kong is also a sourcing point for medical products for mainland China. In 2013, transshipment of medical equipment to China through Hong Kong amounted to USD 0.8 billion; accounting for approximately 47 percent of Hong Kong's medical equipment re-exports to all destinations.

Market Entry

One of the best ways to sell healthcare devices, equipment and products in the Hong Kong market is through the use of agents or distributors. It is also an excellent way of minimizing the initial investment in the market. Working with agents and distributors in Hong Kong is very much like working with an agent in the United States. Hong Kong has no special legislation regarding agents and distributors. Virtually anything that both sides can agree to and put into a written contract is acceptable and enforceable, including restrictions on territory and a grace period for termination of the agreement.

Current Market Trends

The top deadly diseases in Hong Kong are cancer, pneumonia, heart and cerebrovascular diseases, which together accounted for about 67.5 percent of all registered deaths in 2013. Elderly people are the major victims of these chronic non-communicable diseases. As Hong Kong's aging population grows, opportunities exist for technologies that prevent and treat these diseases or reduce disability caused by them.

Statistics

Population:	7.21 million
GDP (USD):	273.658 billion
Currency:	Hong Kong dollar (HKD)
Language:	Cantonese, English, Mandarin Chinese

Contact

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Main Competitors

U.S. healthcare technology is widely recognized as some of the most advanced available in the market today. The United States was the market leader in the high-end market segment. European, especially German, and Japanese companies are strong competitors for U.S. medical equipment and products. European medical equipment has a long record of product reliability and Japanese suppliers attend to the needs of their customers, as reflected in their product designs. Also, the recent depreciation of the Japanese yen makes Japanese products more price-competitive.

Current Demand

Hong Kong's population aged 65 or above is expected to surge from the current 980,000 to 2.6 million by 2041. The rapidly aging population will need elder care facilities, such as nursing homes and rehabilitation centers, as well as products for the elderly.

The people of Hong Kong are becoming more health conscious and focused on preventive care, which increasingly includes routine vaccinations, screening for various cancer, high cholesterol, high blood pressure and diabetes, prenatal care and regular wellness visits.

Owing to various government campaigns, the Hong Kong public is becoming more aware of oral health. Cosmetic dentistry has also become very popular in the last several years.

Registration Process

Medical Devices

Currently, there is no specific legislative control over the importation and sale of medical devices. A framework for regulating the supply of medical devices was proposed in July 2003. It is largely in line with that recommended by the Global Harmonization Task Force. Until the enactment of such legislation, the Medical Device Administrative Control System will continue to take effect. The Medical Device Administrative Control System features:

- A listing system for medical devices, under which manufacturers and importers of medical devices could voluntarily list their medical devices with the Department of Health; and
- An adverse incident reporting system, through which the manufacturers, importers, users, and the general public could report adverse incidents to the Department of Health.

Pharmaceutical Products

Medicines to be applied on human or animal bodies for diagnosis, treatment, relief or prevention of diseases must be registered with the Hong Kong Pharmacy and Poisons Board (PBB) prior to their sale in the Hong Kong market. Pharmaceutical products are required to conform to the standards on safety, efficacy and quality before they can obtain registration. Detailed information on the registration process is available at ***bit.ly/1bIVrlu***.

Barriers

Hong Kong is a duty free port. There are no barriers or limitations to the import of U.S. medical equipment, devices, and products.

Trade Events

Hong Kong International Medical Devices and Supplies Fair

May 18–20, 2015 • Hong Kong • ***bit.ly/1bIVvl0***

Showcases a wide variety of medical devices, supplies, and concepts. Organized by the Hong Kong Trade Development Council. Co-organized by the Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA).

Resources

- Available at ***go.usa.gov/DfVF***

Hungary

Summary

The Hungarian healthcare providers sector is expected to generate total revenues of USD 9.9 billion in 2014, representing an annual growth rate of 0.8 percent between 2010 and 2014. The medical instruments segment has been the most lucrative over the past two years and will remain so in 2014, with total revenues of USD 3.3 billion, equivalent to 32.7 percent of the sector's overall value. The outpatient care segment will contribute revenues of USD 2.8 billion in 2014. The annual growth rate of the sector in the period 2012–17 is predicted to be 3.1 percent.

Hungary's health care system is mostly state-funded and its long-term policy focuses on maintaining public health care service by offering optional services through privately-operated healthcare clinics and centers. The public sector accounts for about 75 percent of the total health expenditure. In 2013, Hungary spent 6.8 percent of its GDP on public healthcare, representing about USD 85 billion. Restructuring of the healthcare systems started in 2011 when the government of Hungary came up with reform plans for renationalizing Hungarian hospitals that were maintained by the local government. The restructuring process was completed last year with a significant delay.

Market Entry

Medical devices

Medical devices represent the largest segment of the healthcare sector in Hungary, accounting for 32.7 percent of the sector's total value. The outpatient care segment accounts for a further 27.7 percent of the sector. Hungary is part of the EU External Tariff System. According to Hungarian tax regulations, all products, regardless of origin are subject to an extremely high (27 percent) value added tax which is borne by the final customer (by the hospital or by the patients). The EU directives on Medical products have been integrated into Hungarian legislation.

Statistics

Capital:	Budapest
Population:	9.9 million
GDP (USD):	125 million (2013)
Currency:	Hungarian Forint (HUF)
Language:	Hungarian

Contact

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Generally, there must be one Authorized Representative in one of the EU countries, who is responsible for the EU-wide CE mark. Prior to entering the Hungarian market, medical products must have the CE mark. If a medical product has the CE mark issued by an eligible notified body, no further testing is required by any Hungarian authority. If the product has no CE mark, a Hungarian notified body can issue it. According to Hungarian regulations, foreign suppliers are required to have a Resident Representative in the country responsible for the foreign product. The Hungarian partner is required to registers the product with the Authority for Medical Devices (c/o Ministry of National Resources) and provide the necessary information including directions for use and labeling in Hungarian. The resident representative keeps the technical files and is the point of contact for market surveillance. The Hungarian market is receptive to high quality, innovative U.S. medical devices and diagnostic instruments.

As Hungarian health care system is widely felt to be under-financed, foreign companies have a competitive edge if they offer financing. The number of clinical trials in Hungary has been on the rise over the recent years. Medical products are marketed in Hungary through authorized and exclusive distributors. Major foreign companies either have their own subsidiaries or operate through local distributors. Most distributors handle several brands of similar equipment or several lines. Pricing is a key factor in selling medical products in Hungary, as the market is very price sensitive. When purchasing medical equipment, end-users also look for established companies with reliable and efficient after-sales service and customer support.

Drugs

Registration of all medicines intended for human use including homeopathic preparations, preparations marked with isotopes and immune-biological preparations, vaccines, and blood products is carried out by the National Institute for Quality and Organizational Development in Healthcare and Medicines (GYEMSZI, ***gyemszi.hu***).

Current Market Trends

Imports dominate the very competitive Hungarian market for medical supplies and equipment. Over 80 percent of an estimated USD 801 million (2013) is spent on foreign products. According to industry estimates of the Association of Medical Technology in Hungary, roughly and only 23 percent is spent on high-value devices, another 29 percent for rehabilitation products and the rest for medical equipment and hospital supplies. Hungarian companies supply local products for about 15–18 percent of the medical equipment and supply market. There are about 150–160 small and medium-sized medical companies in Hungary, most of them specialized in high-tech products for export markets and in Research and development activities with a staff of less than 20 people. Electro-medical devices, blood sugar meters, urine analyzers, neonate therapeutic devices are the largest products by export value. U.S. products account for approximately 15–17 percent of total medical technologies imports. In addition to the official statistics, a number of European subsidiaries of U.S. companies are shipping products to Hungary registered as goods from Germany, England,

the Netherlands, and the Scandinavian countries. A few U.S. companies have their own representative, sales offices or even manufacturing and Research and development centers in Hungary like GE Healthcare, Varian or Fluke, while most distribute their products through local firms. Medical products imported from the U.S. in significant amounts include electro-medical instruments; disposables like catheters; ultrasound machines; diagnostic equipment and instruments; orthopedic appliances and implants, hearing aids and pacemakers.

Main Competitors

The import of medical products is fully liberalized. U.S. companies face stiff competition from West European and Japanese companies in Hungary. German, Austrian, Italian and British firms have been present for many years in the market. Germany has been the sales leader for decades with over 20 percent market share in the overall medical market. The proximity of the European firms to the Hungarian market allows them frequent visits to meet end users, to participate in exhibitions and scientific meetings, and to provide prompt after-sales services to buyers. Some of them have established manufacturing units in Hungary for serving their Central-Eastern European markets.

Current Demand

Medical Devices

Funding from the EU structural fund has been used for priority healthcare development projects, including development of outpatient clinics (funds for 19 regional outpatient clinics has been approved), development of one-day surgery, development of high-priority hospitals for the regions, and upgrade of emergency care. Opportunities for U.S. medical equipment suppliers include ultrasound equipment, digital X-ray, monitoring equipment, MR, CT, nuclear imaging (PET, Gamma camera), laboratory diagnostics, and clinical chemistry.

Dental Equipment and Supplies

With close to 5,800 practicing dentists (out of 6,000 registered), Hungary is a market leader in providing dental services for dental tourists. It has a market share of 42 percent, closely followed by Poland (31 percent), Turkey (15 percent), Spain and Bulgaria with 7 percent. The size of the Hungarian dental equipment and supply market is estimated to reach about USD 34 million. It has grown significantly and the dental tourism is 15 years ahead in Hungary compared to other countries in Europe. Hungary is the third country in the world in the dental tourism after Mexico and India preceding Poland, Thailand and Turkey. Most dental tourists come from Germany, Great Britain, the Scandinavian countries, Italy and France. In terms of imports the market is dominated by Austrian, German, British, Scandinavian, Italian, French and Japanese suppliers however it provides market potential for U.S. suppliers of teeth whitening systems, lasers, optical instruments, implant instruments, root canal treatment, computer-controlled injection devices for anesthetization, and orthodontics devices. The

dental tourism has been contributing to the Hungarian economy growth and resulted in HUF 90 billion revenue in 2013.

E-Health

In the framework of the National Development Plan, European Funds are allocated to various healthcare expenditures including specific IT related projects. Best prospects include the E-Health Card, E-Patient Registration system project that will require the supply of about 40,000 card readers, a card management system, card application and authentication solutions etc. and the Electronic authentication database and healthcare portal project requiring security and authentication solutions.

Drugs and Pharmaceuticals

Drug sales amounted to USD 2.4 billion in 2013. Imported medicines accounted for 64 percent of sales, worth USD 1.7 billion. As of December 2013, there were 5,118 registered drugs on the Hungarian market, out of which 3,380 were prescription medications. In 2013, the number of subsidized drugs reached 4,800. The number of over-the-counter (OTC) medications rose to 1,870 in 2012. In terms of total sales, prescription drugs dominate the market with approximately 72 percent of the market share. Roughly four-hundred OTC products can be sold outside pharmacies in drug stores and large hypermarkets as well. There is no import duty levied on pharmaceutical products, and a 5 percent VAT must be paid by consumers.

Barriers

Firms exporting medical devices to Hungary will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers, however, affect the pharmaceutical manufacturers including a 20 percent tax on reimbursed sales of pharmaceutical products, a non-proportional annual fee of HUF 10 million (about USD 54,000) for every pharmaceutical sales representative, and a claw-back, mandating that pharmaceutical manufacturers repay the government for up to 100 percent of pharmaceutical over-expenditures by the National Health Insurance Fund (NHIF). In order to meet the requirement of the convergence plan and keep the budget deficit under 3 percent, the government plans a HUF 150 billion (USD 750 million) cut in the Pharmaceutical Fund over the past four years that seriously affects innovative pharmaceutical manufacturers in the market.

If there is an overspending in the pharmaceutical budget, the NHIF determines which pharmaceutical manufacturer's market share has increased compared to the base year. Any company whose turnover has exceeded the market share of the baseline year has to pay this claw-back on the basis of a complicated formula.

Trade Events

Dental World 2014 Budapest

October 16–18, 2014 • Budapest, Hungary • ***dentalworld.hu***

India

Summary

The Indian healthcare sector has been undergoing rapid change for many years, but it has become significantly more apparent in the last decade, with a renewed thrust from both the government and a growing market for healthcare services and products. Rapid economic growth, rising middle class incomes and a surge in lifestyle diseases have created a booming life science market.

The Indian Healthcare industry (including hospitals, medical infrastructure, medical devices, clinical trials, outsourcing, telemedicine, health insurance, and medical equipment) was valued at USD 78 billion in 2012, and is expected to reach USD 280 billion by 2020, due to increasing demand for specialized and quality healthcare facilities. The market is dominated by private players. The industry is rapidly developing and is being fueled by large investments from existing corporate hospital chains and new entrants backed by private equity investors. Growth will be driven by healthcare facilities, private-public projects, medical diagnostic and pathological laboratories, and the health insurance sector. In addition, changing demographics and disease profiles and the shift from chronic to lifestyle diseases has led to increased spending on healthcare delivery.

Indian Medical Devices and Equipment Market, 2012–15

(USD Millions)	2012	2013	2014 (est.)	2015 (proj.)
Total Market Size	5189	5812	7290	7719
Total Local Production	2670	2767	3800	534
Total Exports	75	91	155	110
Total Imports	2594	3136	3645	7295
Imports from the U.S.	496	509	535	604

Source: Unofficial estimates from trade sources and industry; as this industry has not been well documented, estimates vary significantly across different sources. Additional information from the U.S. Census Bureau

Statistics

Capital: New Delhi
Population: 1.22 billion
GDP (USD): 5.07 trillion
Currency: Indian rupee (INR)
Language: Hindi, English

Contact

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Market Entry

In India, healthcare is delivered through both the public sector and private sector. The private sector's contribution to healthcare has been growing at a faster pace than government. There are no restrictions on foreign direct investment in healthcare services. Import of medical equipment is allowed under the "Open General" category of the Import regulations, except for nuclear medicine. Customs duty levied on imported products depends on the product classification, for some devices the duty has been brought down from 25 to 5 percent. Products classified as "life saving equipment" have reduced duty applicable on them to encourage hospitals to import latest equipment.

Price, quality and after-sales service support are major factors in medical equipment purchase decisions. Letter of credit is usual the mode of payment for imports. Purchase decision in government follow a tendering process and is time consuming, while it is faster in the private hospitals.

Current Market Trends

India's population of over one billion people is growing at a rate of 1.6 percent per year. An ageing population of over 100 million, with rising incidence of lifestyle diseases, which combined with rising incomes and increased penetration of health insurance are fuelling growth of the industry. Considerable challenges exist in terms of service accessibility and patient care quality. As such, government support would inherently play a significant role in the overall development and growth of the sector.

High upfront investments, long gestation periods, and rising real estate costs are compelling private players to innovate with business models and expand into under penetrated tier II and III cities. As a result, these private players can capitalize on the opportunity to expand. The private sector is likely to contribute 80–85 percent of the USD 86 billion healthcare investment required until 2025.

The Indian medical device market is worth an estimated USD 3.2 billion and expected to reach USD 5 billion by 2015. Medical device industry is a very attractive export sector for U.S. firms, which account for one quarter of exports to India. India imports nearly 80 percent of its medical devices and barriers to entry are low compared to other industries, despite a 4 percent additive import tax placed on most categories of devices in 2007. India remains highly dependent on imports for many types of medical devices, particularly higher end products that include cancer diagnostics, medical imaging, ultrasonic scans, PCR technologies.

Health insurance is gaining high momentum in India. It is one of the fastest growing segments in the non-life insurance industry with 30 percent growth in 2010–11 and is expected to grow significantly in the next few years. For the purpose of regulation, health insurance companies are classified as non-life companies. This penetration of health insurance will significantly increase the affordability of healthcare services for the population. Several private insurance

companies have entered the market and have empanelled hospitals to provide cashless treatment to subscribers of insurance companies.

In India, healthcare is provided through primary, secondary and tertiary care hospitals. The first two categories are fully managed by the government. While the tertiary care hospitals are owned and managed by either government or private sector, the private sector's contribution to healthcare has been growing at a faster pace than government. The medical infrastructure market is estimated to have a growth rate of 15 percent. Both the government and private sector are planning several new specialty and super-specialty hospital facilities, modernization of existing hospitals. India currently faces a chronic shortage of healthcare infrastructure, especially in rural areas and Tier II and Tier III cities, and it is expected that India will have potential requirement of 1.75 million new beds by the end of 2025. The opportunity also exists for overseas organizations to set up hospitals in India through the Foreign Direct Investments. The hospital services market, which represents one of the most important segments of the Indian healthcare industry, is expected to be worth USD 80 billion by 2015.

The new specialty and super-specialty hospital facilities depend on the import of high-end medical equipment, accounting for over 65 percent of the entire market. There is a need for sophisticated hospital equipment, especially operation theatre products and training through simulation labs. In view of the relatively low customs duty rates (9.2–15 percent) combined with an increasing number of healthcare centers specializing in advance surgery, India offers opportunities for the direct supply of high-technology, specialized medical equipment, products and systems.

Biotech is one of the fastest growing segments of the life sciences sector. The market currently stands at USD 3.2 billion and is growing over 20 percent per year. If the current trends continue, the biotech market could reach USD 8 billion by 2015. The biotech sector represents a diverse opportunity for international firms.

The boom in medical tourism in the Indian healthcare sector is encouraging hospitals and hoteliers to strike alliances with each other. Presence of world-class hospitals and skilled medical professionals has strengthened India's position as a preferred destination for medical tourism. According to the industry estimates, Medical tourism market is expected to expand at a CAGR of 27 percent to reach USD 3.9 billion in 2014 from USD 1.9 billion in 2011.

E-healthcare/Telemedicine, though in its infancy in India, is beginning to take root. Most public hospitals (funded by State governments) and private single and multi-super specialty hospitals have gone in for customized Hospital Management Systems and other medical based IT products. Given the poor availability of quality healthcare facilities outside the large and second tier cities, telemedicine is expected to become viable business proposition. Several major private players like Apollo, AIIMS, and Narayan Hrudalaya have adopted telemedicine services.

Main Competitors

The large private healthcare services providers are actively seeking growth by enhancing their reach across the country through the building new hospitals and acquiring and upgrading existing hospitals. There are several groups operating hospital chains including Apollo Group, Fortis Healthcare, Manipal Group, Max Healthcare, Medanta-Medicity, and Wockhardt Hospitals. In the medical equipment segment competition is from the imports from European companies and Japan. India being a price sensitive market there is competition from low priced Chinese products.

Current Demand

The growing demand for quality healthcare and the absence of matching delivery mechanisms pose a challenge and certainly a great opportunity. In Infrastructure—building, equipping, managing and financing the super specialty hospitals in India through the FDI route is another areas for future growth. Some best sales prospects in the medical equipment market include medical and surgical instruments, medical imaging, electro medical equipment, orthopedic and prosthetic appliances, cancer diagnostic, orthodontic and dental implants equipment, ophthalmic instruments and appliances.

A proper supply of equipment and medical consumables will also be an area with significant for U.S. companies. Several leading U.S. purveyors of hospital equipment and supplies have opened Indian operations to cater to this growing market.

Health insurance and hospital administration is another area in which U.S. companies can make a difference. This opportunity includes introducing and maintaining industry standards, and also classifying and certifying healthcare centers.

Other growth areas include diagnostic kits, reagents, hand-held equipment and stimulation for operation rooms. Imports constitute 50 percent of this market. Hand-held/portable diagnostic equipment (e.g. for blood sugar, blood pressure testing etc) is also a fast growing segment since India has around 46 million diabetics, which is expected to swell to 70 million by 2025.

Registration Process

The Central Drugs Standard Control Organization (CDSCO) is the key regulatory organization in India. Import of medical devices into India still remains largely unregulated, though the Indian government has adopted some measures in recent years to change that. With the final procedures and guidelines not being laid down as yet, things are actually pretty confusing at this stage. Currently, the Ministry of Health and Family Welfare has notified only 14 devices that are regulated: ***bit.ly/1b88V6e***.

Visit ***bit.ly/18DlOGI*** for more information on import regulations and the registration process.

The CDSCO drug controller provides detailed information on medical device import regulations and registration requirements. Please e-mail ***dci@nb.nic.in***, call +91-11-2323 6965, or visit ***cdsco.nic.in*** for more information.

Barriers

To ensure quality healthcare, in October 2005 the government of India increased a list of medical devices covered under the Drugs and Cosmetics Act of 1940, bringing fourteen categories of implantable devices under regulatory control. These include:

- Cardiac stents
- Drug eluting stents
- Heart valves
- Catheters
- Intra-ocular lenses
- Hip and knee implants and bone cements
- Intravenous cannulae
- Scalp vein set
- In-vitro diagnostic devices

An improved central licensing authority must license these devices for manufacture, sale, or distribution.

Hospitals are also seeking quality accreditations such as JCI, NABH and ISO.

Trade Events

Medical Fair India

March 21–23, 2015 • New Delhi, India • ***medicalfair-india.com***

Medicall

July 31–August 2, 2015 • Chennai, India • ***medicall.in***

Indonesia

Summary

As the fourth most populous country in the world, Indonesia offers great potential for the medical equipment and supplies market. The market is estimated at USD 593.8 million in 2013. The market shows consistent growth and is expected to reach over USD 650 million in 2015. About 97 percent of the Indonesian medical device market is made up of imports. Healthcare is a top priority in Indonesian's national development agenda. The central and regional governments continue to build and upgrade healthcare facilities. They are planning to equip community health centers with inpatient facilities and improve their quality of service in the 33 provinces. The government continues to encourage private sector involvement in developing hospitals. In the next five years, the private sector plans to develop over 30 hospitals. Indonesia began implementing its National Health Insurance Plan this year with the goal of universal coverage of the country's population of 254 million people by 2019. Given the large population and the implementation of the universal social health insurance coverage, Indonesia is potentially a good market for healthcare products.

Market Entry

U.S. companies must either establish a foreign investment company in the form of a PT (limited liability company) or appoint one or more Indonesian agents/distributors to market and sell their medical equipment and supplies in Indonesia. Local agents/distributors handle registration for the products and play an important role in developing the market and providing after-sales services.

Current Market Trends

Healthcare providers show a growing interest in high technology equipment to improve the delivery and quality of their services. The government is encouraging more private sector involvement. Major property developer Ciputra Group plans

Statistics

Capital:	Jakarta
Population:	253.6 million (est. 2014)
GDP (USD):	867.5 billion (est. 2013)
Currency:	Indonesian Rupiah (IDR)
Language:	Indonesian

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to build up to 10 hospitals within the next five years with an estimated investment of USD 130 million. In September 2013, the Siloam Hospital Group announced that they plan to spend USD 400 million through 2017 to develop new hospitals and buy medical equipment. The group will open six new hospitals by the end of 2014, adding to its existing 14 hospitals. In October 2008, an official ground-breaking ceremony for the construction of a USD 700 million Jababeka Medical City project took place. The city will consist of world-class healthcare facilities, a hotel and apartments, research centers, and shopping center. The city is scheduled for completion by 2015.

Main Competitors

The market for medical equipment and supplies is highly competitive. U.S. exports account for 10 percent of this market. Other countries vying for market share of medical equipment and supplies in Indonesia include Singapore, Japan, Germany, China, and Korea. Companies from China and Korea provide the greatest challenge to U.S. firms as they offer low-priced equipment. Therefore, while quality and after-sales service are essential elements, it is also important to price products competitively.

Current Demand

Best prospects include:

- Diagnostics and laboratory reagents
- Compact/modular laboratory automation for clinical chemistry
- Electro-diagnostic equipment, ultrasonic scanning machines, and x-ray units
- Rapid tests for HIV, TB, and other infectious diseases
- ICU, ICCU, and life support equipment such as ventilators, anesthesia and patient monitoring equipment

Registration Process

Foreign companies must be prepared to operate in an often uncertain regulatory environment. Product registration can be lengthy, and new and changing requirements can hamper market entry, such as labeling and local content requirements. A strong local distributor or partner is critical to help navigate the product registration process and stay abreast of changing regulations.

The Indonesian Ministry of Health (MOH) controls the registration of medical devices and household health supplies in Indonesia. In general, products that are FDA-approved and sold in the U.S. will be approved to enter the market in Indonesia. The process to obtain the license may take over six months. Imported medical devices and supplies must be registered with the MOH before clearance through Customs.

Medical equipment importers must submit a registration application to the Ministry of Health which includes all of the following documents that the U.S. company should supply:

- Letter of Authorization issued by the manufacturer, legalized by the Indonesian Embassy and a notary public in the U.S.
- Certificate of Free Sales from the authorized institution.
- Certificate of CE for 'CE' mark products or Certificate of ISO for 'ISO' mark products, if any
- Product Information
- Formula/component/raw materials
- Brief manufacturing process flow chart
- Finished product specifications
- Safety and Efficacy Data
- Manual Book (instruction for use), which will be translated into the Indonesian language

Barriers

There are no restrictions on imports of medical equipment; however, imports of used equipment are prohibited. Medical equipment is subject to a 0–5 percent import tax and a value-added tax of 10 percent. The Ministry of Health controls the registration of medical equipment in Indonesia. In general, products that are FDA-approved and sold in the U.S. will be approved to enter the market in Indonesia.

Trade Events

Hospital Expo 2015 Medan

February 25–27, 2015 • Medan, Indonesia • ***hospital-expo.com***

Hospital Expo 2015 Surabaya

April 22–24, 2015 • Surabaya, Indonesia • ***hospital-expo.com***

Hospital Expo 2015 Jakarta

October 21–24, 2015 • Jakarta, Indonesia • ***hospital-expo.com***

Ireland

Summary

Ireland is ranked as having the 13th most consumer-friendly healthcare system in Europe. The market offers U.S. manufacturers of medical equipment and services an opportunity to take advantage of mutual language, business and cultural links and to use the market as a springboard for Europe.

The country has a dual healthcare system, consisting of both private and public healthcare options. The public healthcare system is regulated by the Irish government's Health Service Executive, providing free public health coverage for 1.364 million people with low incomes and those over the age of 70. The healthcare expenditure ceiling for 2014 was decreased from USD 17.8 billion to USD 17.5 billion. A total of 45 percent of the population is covered by private health insurance.

Twenty of the world's top thirty medical technology companies are located in Ireland. The country is the second largest exporter of medical products in Europe. Over 250 medtech companies export almost USD 5 billion of medical products and equipment annually, approximately 45 percent of which is exported to the U.S.

A strong relationship is maintained between Irish and U.S. universities and hospitals, e.g. Cleveland Clinic's partnership with the Royal College of Surgeons.

Market Entry

U.S. medical device products are well regarded in Ireland, with the market being highly receptive to U.S. medical equipment/technologies. Ireland, as a member of the Euro-zone, serves as a natural test market and location from which to begin distribution throughout Europe.

U.S. companies exporting to Ireland should obtain local representation through an agent or distributor, of which there are 100 plus qualified companies in Ireland.

Statistics

Capital:	Dublin
Population:	4.77 million
GDP (USD):	217.8 billion
Currency:	Euro (EUR/€)
Language:	Irish, English

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CE marking is a legal requirement in Ireland. Irish labeling requirements are similar to those used elsewhere in the EU, except Irish authorities require the name and the EU address of the manufacturer, distributor or packer to also appear on the label.

Ireland applies EU tariffs (customs duties) which are based on the international Harmonized System (HS) of product classification. Duty rates on manufactured goods from the United States generally range from 5–8 percent and are usually based on the c.i.f. value of the goods at the port of entry.

The standard electricity voltage in the Republic of Ireland is 230V a.c., nominal, at 50Hz, with plugs being of the three-pin IS411 (BS 1363) type. Any electrical item sold on the Irish market should include a three-pin plug attached (molded) to the power cord. Exporters selling electrical products in the EU must conform to the WEEE and RoHS directives.

Current Market Trends

Following an Irish government cabinet reshuffle in July 2014 and the subsequent appointment of a new minister at the Department of Health, ambitious plans to reform the healthcare system by introducing Universal Health Insurance have been delayed in the short-term. The government's priorities however continues to be the eradication of the dual healthcare system, provision of better access to A and E facilities, reduction of waiting lists and also to reel in extensive hospital budget overruns. The government is also in favour of primary care centers and is an advocate of preventative medicine focusing on breast, cervical and colon cancer screening.

The aim of the Health (Pricing and Supply of Medical Goods) Bill 2012 is to cut spending by increasing competition between suppliers. General cuts in healthcare expenditure have catapulted cost-efficacy and money-for-value products to center stage. Capital spend has diminished with focus primarily on the equipment replacement market. Opportunities exist for products that save time, resources, and produce cost savings in a very price sensitive market. Public tender opportunities are advertised on the eTenders Public Procurement website, ***etenders.gov.ie***.

Main Competitors

U.S. medical device companies include: 3M, Abbott, Baxter, Biomet, Boston-Scientific, Cook Medical, GE Healthcare, Hospira, Johnson & Johnson and Stryker. Foreign competitors include: B. Braun Melsungen, Philips, Siemens, and Smith & Nephew.

International brands have local sales and marketing operations or utilize an extensive network of Irish agents and distributors. U.S. Commercial Service Dublin facilitates introductions to this agent/distributor network for U.S. companies interested in serving the Irish and wider European marketplace.

Current Demand

Ireland has a population of almost 4.6 million people. There are over 11,000 in-patient beds and 1,200 day beds distributed across 51 public hospitals, 22 voluntary hospitals, and 19 private hospitals. Overall, government spend on medical devices and technology of 2.5 percent is below the EU average of 4.5 percent. Despite the spending cuts, long term demand is expected to continue to grow, with healthcare spending expected to increase to USD 50 billion in 2020. Currently 12 percent of the population is over 65. As a result of the aging population, it is expected that further increases in demand for healthcare services and the emergence of niche markets will arise.

A new children's hospital is to be tri-located at St. James Hospital in Dublin with a 445-bed hospital equipped to meet the peak in child population in 2021. Also, the National Maternity Hospital is being moved to the St. Vincent's Hospital campus. Growth in the private healthcare sector has slowed down considerably but plans are underway for a small number of primary care centres. The development of these new projects will provide opportunities for U.S. suppliers.

Distributors are eager to source new products to help them maintain their businesses in a challenging trading environment. Demand for medical equipment exists particularly across the general medical device, diagnostics, hygiene, living assisted and homecare products, bio-medical, dietary supplement, drugs/pharmaceutical, and veterinary sub-sectors.

Registration Process

The Health Products Regulatory Authority (formerly Irish Medicines Board) is the regulatory authority for medical equipment and healthcare. Detailed information on Medical devices are regulated by EU Directives that set out compliance requirements and procedures including the General Medical Devices Directive (93/42/EEC), the Active Implantable Medical Devices Directive (90/385/EEC), and the In-Vitro Diagnostic Medical Devices Directive (98/79/EC).

Barriers

There are no specific trade barriers. However, continued cuts in healthcare spending does pose a challenge for U.S. suppliers. U.S. medical device manufacturers should promote the long term cost saving, quality, safety and efficacy benefits of their products and equipment at a time when procurement managers are under pressure to achieve short term savings. U.S. companies partnering with distributors should work together to devise creative strategies to bring new products to the market.

Trade Events

Medical Devices Summit Europe

November 11–12, 2014 • Dublin, Ireland • ***bit.ly/18FLjqv***
Information on regulations and forthcoming changes.

Investment in Innovation Medical Device 360 Dublin

TBD 2015 • Dublin, Ireland • ***in3dublin.com***
A partnering event. Brings together development to commercial-stage device startups seeking funding or strategic partnerships. Designed to help facilitate growth in nontraditional markets.

MEDTEC Ireland 2014

TBD 2015 • Galway, Ireland • ***medtecireland.com***
New manufacturing technologies and techniques, commercial opportunities, and clinical and academic research in the medical devices sector.

IMSTA Annual Conference

TBD • Dublin, Ireland • ***imsta.ie***
Annual conference featuring speakers from both the public and private sector.

Additionally, many Irish distributors attend Medica (***medica-tradefair.com***).

Israel

Summary

Israel has a diversified, technologically advanced economy with a strong high-tech sector. The country's strong commitment to economic development and its talented work force have led to economic growth rates that have frequently exceeded 10 percent annually. Israel's GDP in 2013 was USD 266 billion and its per capita GDP was USD 36,200. The United States is Israel's largest single-trading partner. In 2013, bilateral trade totaled USD 36 billion. Exports of U.S. goods to Israel totaled USD 13.7 billion. With a favorable dollar exchange rate, U.S. equipment suppliers currently enjoy a price advantage over EU-based manufacturers.

Israel is a lucrative market for advanced healthcare technologies. Despite its small size and population of only 8.2 million, Israel imports medical and pharmaceutical products in the amount of USD 2 billion annually. The U.S. share is roughly 15 percent at USD 300 million. Germany and other EU countries are the major competitors, but U.S. products outranked the EU competition in imaging equipment and diagnostics. Easy market-entry conditions and receptiveness to buy U.S. technologies and services make Israel an ideal destination for U.S. healthcare exports.

Characterized by a technologically advanced market economy, Israel boasts a very high level of healthcare with an extensive infrastructure ranging from local community clinics to a world-renowned trauma centers. Israel spends 7.5 percent of its GDP on healthcare and has the largest per-capita healthcare market in the Middle East. Israel's public healthcare system ensures a universal healthcare coverage to its entire population via four health management organizations and a network of hospitals, community clinics and specialized doctors. Israeli healthcare facilities are modern and are open to adopt new, cost effective technologies and procedures. Many Israeli doctors receive training in the United States and maintain personal and professional relationships with U.S. colleagues at major medical centers.

Statistics

Capital:	Jerusalem
Population:	8.2 million
GDP (USD):	266 billion
Currency:	Shekel (ILS)
Language:	Hebrew, Arabic

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Market Entry

Under the U.S.-Israel Free Trade Area Agreement (FTAA), U.S. goods face no import duties upon entering Israel's market. Proper Shipping documents and a Certificate of Origin for Exporting to Israel are required in order to benefit from the FTAA. Every product is still subject to 18 percent Value-Added-Taxes. VAT is levied on the CIF landed cost.

Current Demand

Israel has a growing elderly population. As a result, the demand for hospital beds, nursing aids and homecare products is up. Wound care, advanced diagnostics and minimal invasive procedures continue to be a high priority in the public healthcare market. In addition, a well-developed private sector health care in the areas of dental, eye laser surgery and plastic/aesthetic surgery keep up the demand for advanced medical instruments and appliances. Israel has an excellent Ehealth tech base and is a world leader in mobile and E health implementation. Opportunities exist however, in further advancing drug monitoring and disease surveillance. Other best sales prospects include minimally invasive surgical instruments and technologies that are integrated with imaging capabilities, cardiology equipment, equipment and supplies for plastic surgery, smart implants, dental instruments, equipment and technologies for pain management, physiotherapy, ozone and oxygen therapy, operating room equipment and cost-saving single use products, point of care diagnostic kits and wound management technologies.

Registration Process

Market access is fairly clear for U.S. FDA and CE Marked medical products. U.S. companies interested in exporting to Israel need to appoint a local distributor, agent or other legal representative to register their products with the Israel Ministry of Health (MOH). The device registration should be accompanied by a 510(k), Pre-Market Approval (PMA) or an Investigational Device Exemption (IDE). The Ministry of Health has an overarching regulatory and policy making role, as well as owning half of the country's hospitals. The Ministry regulates Israel's public healthcare system that ensures a universal healthcare coverage to its entire population via four health management organizations and a network of hospitals and community clinics.

Trade Events

BioMed Israel

May 18–20, 2015 • Tel Aviv, Israel • ***mixiii.com***

Israel's latest biotechnology and medical innovations.

Italy

Summary

Italy is a mature market for medical equipment, and its high per capita income and sophisticated healthcare system translate into demand for a broad range of cutting-edge medical equipment. The Italian market for medical equipment and supplies is the fourth largest in Europe following Germany, France and the UK with about 500 producers and a 30,000 people workforce. The medical device market (including dental and optical devices) was valued at approximately USD 8.8 billion in 2013 with imports accounting for USD 5.9 billion. Aside from other medical devices, consumable products represent the largest market segment (19.7 percent) followed by diagnostic imaging (15.7 percent), patient aids (13.2 percent), dental products (13.2 percent) and orthopedic and prosthetic products. The Italian government is the primary purchaser of medical equipment. Public hospitals account for over 75 percent of medical device sales, while the remaining 25 percent of sales are made to the private sector. Despite having a considerable local manufacturing industry, the domestic market for medical equipment is highly dependent on imports. Major suppliers are Germany, France, The Netherlands, Belgium and the United States, which had an 8.5 percent share of Italian imports, valued USD 470,583 million in 2012. Major U.S. imports are in diagnostic imaging, dental and patient aids.

The budgetary pressures and escalating costs of healthcare systems are moving Italy towards value-based health care: new products need to provide better health outcomes in cost-effective ways. In fact, the public healthcare system is likely to develop value- and quality-based pricing models and request data and analytics for cost-effective evidence. Opportunities for companies with very innovative products are rising compared to traditional products. Preventive care, remote monitoring, early identification of at-risk-patients are increasingly valued.

Statistics

Capital:	Rome
Population:	61 million
GDP (USD):	1.77 trillion
Currency:	Euro (EUR/€)
Language:	Italian

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Italian Medical Devices Market, 2012–15				
(USD Millions)	2012	2013	2014 (est.)	2015 (proj.)
Total Market Size	8,417	8,833	8,950	8,980
Total Local Production	6,720	6,940	6,960	7,010
Total Exports	3,933	4,007	4,060	4,180
Total Imports	5,630	5,900	6,050	6,150
Imports from the U.S.	470	490	500	530

Source: Unofficial estimates based on reports and statistics from Assobiomedica, BMI, Espicom, U.S. Department of Commerce Bureau of Census, and Eurostat.

Market Entry

The Italian government has implemented various European Union (EU) directives related to medical devices, and U.S. companies must be prepared to comply with Italian and EU legislation.

U.S. companies interested in entering the Italian market should carefully select their potential distributors or agents and should also consider cooperative arrangements or joint venture/licensing agreements with Italian partners.

It is up to the regional governments to issue specific regulations governing procurement of medical equipment. Most purchases are made by public tenders open to both domestic and foreign companies. Announcements of tenders on public procurements are monitored by the U.S. Mission to the European Union and are available at ***buyusa.gov/europeanunion***.

All medical devices marketed in the EU must bear the CE mark to certify conformity with EU legislation. Member States have appointed certification authorities or "notified" bodies to grant these compliance certificates. Award criteria are normally based either on the lowest price or on the most economically advantageous quotations.

Current Market Trends

The Italian domestic medical market (including dental and optical medical devices) was estimated at approximately USD 8.8 billion in 2013. Major constraints to the sector development are the healthcare cost-containment measures together with the late payment of public hospitals counting for 70 percent of the medical devices sales. Italy imports primarily from The Netherlands (20.4 percent), Germany (19.5 percent), and France (11.4 percent) Belgium (9.5 percent) and the United States (8.5 percent). Major subsectors, in which Italy has gained a good position, are biomedical instruments and electro medical diagnostics. Regions with the highest concentration of medical devices companies are in Northern Italy.

Main Competitors

Foreign companies represent the 8.2 percent of the total number of companies producing medical devices. Industry giants such Siemens, Philips, Hitachi and Toshiba are well present in the market. A significant number of U.S. manufacturers of medical equipment are also present in the Italian healthcare market (about 60 companies with 5,700 employees and USD 2.7 billion domestic revenue). Some U.S. suppliers maintain wholly owned subsidiaries in Italy and sell equipment imported from the United States or from plants in other foreign countries, such as Johnson & Johnson, Medtronic, and GE Healthcare.

Italian companies are small or medium size and they are mainly concentrating in six Regions: Lombardy, Emilia Romagna, Veneto, Lazio, Toscana and Piemonte. The sector is highly innovative and there are about 214 start-ups among which 67 percent received public financing.

Current Demand

Medical Devices

The best sales potential for U.S. manufactured medical equipment is in the following areas: home care equipment, remote monitoring equipment, high frequency medical lasers (for multiple applications), endoscopes and diagnostic imaging equipment non-invasive and micro-surgery devices and equipment, anesthesiology equipment, EKG, stimulators and defibrillators, ophthalmic equipment, monitoring equipment, telemedicine equipment and services. The Italian market is receptive to high quality and technologically advanced diagnostics and therapeutic equipment and products.

With an increasing attention to reforming and improving healthcare management, medical devices companies providing also services and solutions as add-ons to their products will also have opportunities in the Italian market. The services will enhance the value proposition of existing products for patients (e.g. services to identify the appropriate patients for the use of a device, training for nurses on new procedures and products, partnership with hospitals to increase efficiency).

E-Health

The European e-Health market has an estimated annual value of around USD 20 billion with an annual growth of 3 percent. Considering that the demand for healthcare products and services will rise significantly in coming years, the information technology applied to the healthcare systems is a key enabler for delivering more effective and efficient health care. In Italy the ICT expenditure in healthcare is estimated at USD 1.7 billion corresponding to 1.1 percent of the total healthcare expenditures, very limited compared to other countries (2.5 percent to 3 percent). However, growing attention has been dedicated to this subsector in order to accelerate the use of ICT and stimulate the innovation process and when adequate resources will be allocated to this area, the market will growth.

Strategic areas (in which there will be investments over the next three years) include electronic health records, cloud computing, administrative management, digital management of drugs, ePrescription, Mobile Health and business intelligence and clinical governance.

Other Sectors

Areas anticipated to see investment over the next three years include:

- Electronic health records
- Cloud computing
- Administrative management
- Digital drug management
- ePrescriptions
- Mobile health and business intelligence
- Clinical governance.

Registration Process

All medical products and equipment imported into Italy require a notification to the Italian Ministry of Health (MOH). All new–to-market medical devices must go through an on-line device registration process with the Italian Ministry of Health to be placed in the Italian market. Information on registration procedures is available at ***bit.ly/1eKoBBY***.

Barriers

There are no other significant trade barriers or limitations on imports of U.S. goods. Technical specifications are essentially those established by the EU, which have been incorporated into Italian law. Official technical norms are issued by UNI, the Italian Standards Institute, and electrical norms are from CEI, the Italian Electro technical Standards Institute. Information on EU standards is available from the U.S. Commercial Service.

Trade Events

EXPOSANITÀ

2016 • Bologna, Italy • ***www.senaf.it/Expo-Sanita/107/en***

Italy's only and Europe's second-largest event dedicated to healthcare. Held biannually. Attracts over 27,000 visitors and features over 1,000 exhibitors.

Japan

Summary

Japan's market for medical devices and materials continues to be one of the world's largest. According to the latest official figures from the Ministry of Health, Labour and Welfare (MHLW) found in the Annual Pharmaceutical Production Statistics, the Japanese market for medical devices and materials in 2012 was approximately USD 32.5 billion (up 8.7 percent from 2011 in yen terms). Japan's total imports of U.S. medical devices were approximately USD 7.4 billion in 2012. The market remains heavily dependent on imports, especially sophisticated medical technologies. U.S. exports to Japan were limited to a 23 percent market share according to the official figures. However, when including local and third country productions, U.S. firms have achieved a much higher market share than the official statistics. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the market such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. In the near term, the market is expected to increase in a measured fashion. Japan's aging population, continued demand for advanced medical technologies and the government of Japan's measures to promote healthcare industry will sustain growth. Espicom Business Intelligence estimated that Japan's medical device market will exhibit a compound annual growth rate (CAGR) of 2.5 percent from 2013 to 2018.

Market Entry

Japan does not levy customs duties on medical devices. However, medical devices are heavily regulated under the Pharmaceutical Affairs Law (PAL). A Japanese company that intends to market a U.S. medical device needs to receive a "license for manufacturing/marketing business" (seizo hanbai gyo kyoka). The company holding this license is called a "Marketing Authorization Holder (MAH)." An MAH must be physically located in Japan. The MAH must obtain marketing approval

Statistics

Capital:	Tokyo
Population:	127,103,388 (est. 2014)
GDP (USD):	4.729 trillion (est. 2013)
Currency:	Yen (JPY/¥)
Language:	Japanese

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(hanbai shonin) for each product. A U.S. manufacturer intending to manufacture medical devices in the United States and export them to Japan is required to be accredited by the MHLW as an "Accredited Foreign Manufacturer" in the same way that a Japanese manufacturer is licensed. Typically, an MAH can make an accreditation application on behalf of a U.S. manufacturer. A U.S. manufacturer that lacks a Japanese subsidiary can receive and maintain the marketing approval under its own name. However, the U.S. firm will need to designate an MAH when applying for product approval. This Designated MAH (D-MAH) will have to assume the same responsibilities as an MAH. A D-MAH can be a regulatory consulting company or an importer/distributor that holds an MAH license. When a regulatory consultant is designated as an MAH, a U.S. company will need to have a Japanese distribution partner since a regulatory consulting company will not act as a distributor. If a U.S. firm has a subsidiary in Japan, that subsidiary can become an MAH and then obtain the marketing approval for each product. If a U.S. firm does not have a subsidiary in Japan, the company has three options to consider in order to conduct business in Japan:

- The U.S. firm can ask their importer/distributor to obtain the marketing approval under the name of the importer/distributor. In this case, the importer/distributor will have complete control of the U.S. firm's products when the products are marketed in Japan.
- The U.S. firm can obtain the marketing approval under their own name by designating their importer/distributor as a D-MAH.
- The U.S. firm can obtain the marketing approval under their own name via a neutral third party (formally known as an "In-Country Caretaker") by designating them as a D-MAH.

Current Market Trends

Japan has a fast-aging demographic profile, with relatively prosperous seniors holding increasing expectations for improved quality of life in their late years. The Japanese health care system places increasing emphasis on improved treatment and health maintenance. This will generate further opportunity for the types of innovative solutions at which U.S. industry excels. Sophisticated, new medical devices, regenerative medicine and Health IT are sub-sectors that are particularly suited to meeting Japan's healthcare needs. The Japanese market for medical devices is large and established reaching USD 32.5 billion in 2012. The official figures for U.S. exports to Japan were limited to a 23 percent market share; however, according to the AMDD, an industry organization that represents the Japanese operations of 67 U.S.-based companies, approximately 60 percent of "new medical devices" approved in Japan were from AMDD member companies. Espicom Business Intelligence estimated that Japan's medical device market will exhibit a compound annual growth rate (CAGR) of 2.5 percent from 2013 to 2018, and also the firm estimated that all individual product categories should experience positive growth with the top performers being orthopaedics and prosthetics (4.7 percent CAGR in local currency terms) and patient aids (4.0 percent CAGR).

On top of this quantitative base and qualitative demand, Prime Minister Abe's growth strategy calls for promotion of the pharmaceutical, medical device and biotechnology industries. The strategy includes measures such as accelerating regulatory approvals and eliminating so-called "medical device lags" and "drug lags" in market introduction as well as rewarding innovative medical devices and pharmaceuticals among other measures. Although the GOJ's policy programs are basically targeted to enhance the international competitiveness of Japanese industries, these programs should also benefit U.S. medical companies that can offer innovative products to Japanese patients. As a part of the strategy, the government obtained Diet approval in November 2013 of amendments to the Pharmaceutical Affairs Law (PAL). The Diet revised the law to reflect the characteristics of medical devices separately from pharmaceuticals, and the medical review process is expected to be further improved through the revised PAL and related regulations.

Main Competitors

The major product categories comprising Japan's domestic medical device production include: diagnostic imaging equipment; therapeutic and surgical equipment; biophenomena measuring and monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Japanese medical device companies maintain high market share in those product segments. Top Japanese medical device companies, in terms of sales, include Terumo, NIPRO, Olympus Medical Systems, Toshiba Medical Systems, Hitachi Medico, Nihon Koden, and Fukuda Denshi. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the medical market such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. Most major U.S. and foreign medical device firms have either a Japan office or a Japanese partner. As such, new-to-market U.S. companies will face strong competition not only from Japanese companies but also from U.S. and multinational firms already in the market. In April 2009, Japan based U.S. medical device manufacturers launched a new association called the American Medical Devices and Diagnostics Manufacturers Association (AMDD, ***amdd.jp/en***). The AMDD currently has more than 65 member companies.

Current Demand

Given Japan's aging population and the increasing number of patients with chronic and life-style diseases, medical devices that alleviate pain, complement lost functions, and improve the quality of life should show steady growth in demand. Also, the market for in-home care devices, technologies, and health IT related products is expected to grow as the number of people in out-patient care increases. Due to stronger consumer health concerns, other promising growth areas include self-care and preventive care medical devices and products.

Registration Process

Japan's medical device classification system is based on the Japanese Medical Device Nomenclature (JMDN) codes which are different from U.S. and European classifications. Review processes for medical devices differ depending on the classification. Medical devices are classified by risk level into four classes (Class 1, Class 2, Class 3 and Class 4). Class 1 (lowest risk) is defined as general medical devices; Class 2 (relatively low risk) is defined as controlled medical devices; Class 3 (relatively high risk) and Class 4 (highest risk) are defined as specifically controlled devices. General medical devices can be marketed by submitting a notification to the Pharmaceutical and Medical Device Agency (PMDA). Controlled medical devices, with established certification standards, can be reviewed by third-party certification bodies. Controlled medical devices without certification standards and specifically controlled devices must be reviewed by PMDA and approved by MHLW.

Barriers

While the regulatory environment is expected to continue improving and the market for U.S. medical equipment in Japan remains strong, U.S. firms face challenges with pricing and reimbursement due to the GOJ's efforts to contain overall healthcare costs as a result of Japan's aging population. The GOJ implemented pricing policies, such as Foreign Average Price (FAP), to cut medical device reimbursement rates. In 2014 reimbursement revisions, the GOJ again changed the FAP rule by excluding the highest price under certain conditions in the foreign average price calculation method. GOJ also changed the recalculation rule by reducing the foreign average price multiplier of 1.5 times to 1.3 times under certain conditions. Despite the fact that the FAP rule has substantially narrowed foreign price differentials between Japan and overseas markets through the past seven reimbursement revisions, the price differential still remains as an issue to be solved within the GOJ. Also, as national health expenditures are expected to increase further in coming years, the GOJ will continue considering measures to contain overall healthcare costs such as the frequency of the price revisions (currently once every two years) and the use of health technology assessment (HTA) in the pricing decisions.

Trade Events

MEDICAL Japan 2015 (International Medical Expo and Conference)

February 2015 • Osaka, Japan • ***bit.ly/UGgnmQ***

Medical devices, in-vitro diagnostics, regenerative medicine, pharmaceutical manufacturing, and ingredients. Expected attendance of 25,000 visitors and 660 exhibitors.

International Technical Exhibition of Medical Imaging (ITEM)

April 2015 • Yokohama, Japan • ***jira-net.or.jp/e***

A comprehensive academic exhibition for the latest medical imaging systems and peripheral devices.

MEDTEC Japan

April 2015 • Tokyo, Japan • ***medtecjapan.com/en***

Japan's only trade show designed for technical and engineering professionals from medical device manufacturing companies seeking new technologies and suppliers.

INTERPHEX Japan

June 2015 • Tokyo, Japan • ***interphex.jp/en***

Asia's largest pharmaceutical industry event, with 63,000 visitors and 1,400 exhibitors.

International Modern Hospital Show (IMHS)

July 2015 • Tokyo, Japan • ***www.noma.or.jp/english***

Major Japanese trade show for healthcare products. 78,000 visitors, 380 companies.

HOSPEX Japan (International Hospital Engineering Exhibition)

November 2015 • Tokyo, Japan • ***www.jma.or.jp/hospex/en***

Major trade show for hospital facility products, health and medical treatment information systems, and more. 35,000 visitors, 200 companies.

Additionally, there are a number of technical exhibitions held in conjunction with annual meetings of specialized Japanese medical societies. A list of Japanese medical societies is available at ***www.umin.ac.jp/ac/english.htm***. The organizations' home pages are in Japanese and some require membership for access.

Available Market Research

- Dental Industry (2010)
- Pharmaceutical Industry (2010)
- Medical Capital Equipment (2011)
- Generics Market (2011)

Jordan

Summary

- Jordan is a regional leader in Medical Tourism: The World Bank ranked Jordan the leader in the Arab region and the fifth in the world as a medical tourism hub.
- Medical tourism generates over USD 1billion in revenues annually. Jordan expects to reach 300,000 medical tourists in 2015, bringing revenues of USD 1.5 billion.
- Jordan's rate of healthcare expenditure is the third highest in the region and is growing at an annual expenditure rate of about 7 percent. 104 hospitals serve Jordan's population and 250,000 patients from neighboring countries annually.
- The number of Arab and foreign patients who received treatment in Jordan increased by 10 percent in 2014.
- Imports of medical equipment and pharmaceuticals exceeded USD 450 million in the year 2013 and are expected to grow to USD 615 million by the end of 2016.
- 10 percent of Jordan's GDP goes toward healthcare
- The Ministry of Health has prohibited the import of used and refurbished medical devices into the Kingdom.
- Jordan requires USFDA, CE mark or Japanese certification.
- The government plans to expand the "e-health initiative system" piloted in 2011 to public hospitals and beyond, including the storage, retrieval and updating of electronic health records of patients cared for by participating healthcare facilities.

Jordan's healthcare system is regarded as one of the best in the Middle East region, boasting the latest technologies and highly-educated, well-trained doctors. Many

Statistics

Capital:	Amman
Population:	6,.5 million
GDP (USD):	31.025 billion (est. 2013)
Currency:	Jordanian dinar (JOD)
Language:	Arabic (official)

Contact

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Jordanian physicians have received some form of medical training in the United States, giving U.S. products good exposure.

Market Entry

Successful market entry strategies for Jordan have three common elements: understanding the market, selecting the optimal partner, and providing ongoing support to that partner. It is important to gain an understanding of the Jordanian context for a product or service, its competitors, standards, regulations, sales channels, and applications. Success in the market will require appointing a Jordanian distributor or establishing a local subsidiary, and setting-up a local sales presence. Typically, distributors for medical products will cover the entire country and/or region and some may also have an office in Dubai, or Iraq.

U.S. companies are encouraged to appoint technically strong agents and distributors to sell their products and technologies in Jordan, and to participate in leading trade exhibitions, such as the "Arab Health" in Dubai, for market and product exposure. CS offers programs to introduce U.S. products and technologies in Jordan. Performing due diligence on potential local partners is just as important as in the United States.

Parastatal companies purchase commodities through calls for international tenders. These are announced in the daily press. CS reports most of these tenders to the U.S. Department of Commerce. U.S. firms must use a Jordanian agent to purchase tender documents from the issuing public sector entity.

In many cases, a U.S. firm may not be able to provide the wide variety of products required in large tenders. However, a company can offer a bid by forming a consortium. Jordanian buyers prefer a single bid or an entire tender rather than having to piece together bids for each component. Public sector hospitals may request credit in their procurement tenders. While suppliers offering credit will certainly have a better chance of winning bids, sales without credit are sometimes made since other factors such as price, quality, and a delivery schedule may be of greater importance.

Ministry of Health tenders are issued by the General Supplies Department, while the University of Jordan, Royal Medical Services and the Ministry of Defense all release their own tenders. Tenders are published in the Jordan Times and the Middle East Economic Digest.

Laws

For improving standards, the focus of health care policy in Jordan in 2011 was greater equity and accountability. The government has taken steps in areas such as medical responsibility and e-health care and creating a more account health care system through the implementation of medical responsibility, accreditation and e-health care regulations. One of those action was the draft of the medical responsibility law. Expected to pass in 2014, its current working protects patients' rights, ensures compliance with clinical guidelines and offers reasonable

compensation in cases of malpractice. The move should help with garnering international accreditation. 15 Hospitals in Jordan have received national accreditation based on reducing medical errors and preventable harm in the hospital and six hospitals have received Joint Commission International (JCI).

Current Market Trends

The USD 1 billion market is price sensitive and competitive. Jordan spends approximately 10 percent of its GDP on healthcare. Jordanians increasingly suffer from asthma; cancer; diabetes; obesity; heart stroke, vascular disease; osteoarthritis, rheumatoid arthritis; and osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

- As part of the government initiative to reform the healthcare sector, reforms underway include:
- Renovating and adding medical diagnostic devices and therapeutic equipment;
- Improving the quality of health care and hospital services;
- Establishing a number of new hospitals;
- Expanding and upgrading hospital infrastructure including the extension and modernization of pediatric facilities;
- Developing and implementing health information systems and medical research;
- Supporting the government hospitals' accreditation projects; and
- Improving emergency services.

Medical equipment

Demand for medical equipment and services should increase during the next few years with the increase in the number of government and privately owned hospitals; new equipment for hospitals under construction; renovated equipment to replace existing equipment in functioning facilities; upgrading clinics and health care structures; expanding health insurance coverage; and shifting from older conventional methods to modern treatment methods. It should be mentioned that since 1998, the Ministry of Health has prohibited the import of used and refurbished medical devices into the Kingdom.

In the meantime, Jordan continues to make efforts, such as marketing campaigns and web promotions, to attract medical tourists from new destinations, including the former Soviet Union and Africa. In May 2014Jordan held an international medical tourism congress aiming to develop new strategies to improve and expand the capacity of the private health sector while also seeking opportunities for growth from other markets. Regulatory policies are also being implemented to gain international quality accreditation to provide standardized protocols for global patients.

E-Health

The E-health care initiative is another key government program aiming to ensure the accountability of the health care system. The e-health system will operate the storage, retrieval

and updating of the electronic health records of patients cared for by all the participating healthcare facilities in Jordan. The government began a pilot project of the system in 2011 and will expand it to the entire health care system, starting with public hospitals.

Main Competitors

Imports supply approximately 80 percent of Jordan's demand for medical equipment. Key suppliers include the United States, the European Union, Germany, Switzerland, and Japan. Many suppliers in the Jordanian industry are distributors. The major U.S. medical companies represented in Jordan (either through local representatives or subsidiary offices) include GE Ultrasound, Philips, Johnson & Johnson Medical, and Medtronic.. U.S. companies may experience strong competition from other U.S. firms or multinationals already in the market.

Current Demand

Importers seek to source cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs. Opportunities exist for products that provide a significant improvement in clinical outcomes, and product with clearly differentiated capabilities.

Government healthcare policies and public health influence the volume and pricing of healthcare products and services. Both the public and private sectors provide healthcare in Jordan. Healthcare expenditure in 2014 is expected to reach USD 3.21 billion.

Hospitals, both private and public, will continue to expand and the demand for new hospitals, medical equipment and pharmaceuticals will continue to grow.

There is a need in the next five years for for new hospitals in Jordan, (focusing on the cities of Amman, Zarqa, and Irbid). This new hospital construction will trigger demand for both professional services and medical products:

Best prospects include:

- Consulting in hospital administration
- Quality control and certification standards
- Laboratory and hospital administration software
- Diagnostic imaging equipment like CT, MRI, and pet scanner
- Laboratory reagents and diagnostics;
- Testing equipment;
- Cardiology and kidney dialysis equipment
- Hospital furniture
- Consumables for clinical laboratories, i.E. Tubes/ glasses
- Equipment and supplies for plastic surgery
- Medical surgical sterilizers
- Medical x-ray, alpha, beta, gamma ray equipment
- Orthopedic and prosthetic appliances
- Clinical lab diagnostic equipment; and clinical laboratory equipment
- Organ transplant equipment

E-health best prospects include:

- Healthcare management systems
- Software modules for specific fields and applications (radiology, imaging, etc.)
- Integrated medical insurance solutions
- Medical devices and equipment
- Customer relations management
- Mobile healthcare applications
- Online medical content providers

Registration Process

The Ministry of Health sets technical rules and specifications applicable to all medical equipment to ensure that all products being sold to Jordanian end users meet the requirements of safety and quality. In Jordan, public sector tenders do not require regulatory review if the product has been authorized for marketing in the US, Europe or Japan. Other specifications are stipulated in the tender terms on a case-by-case basis.

Medical equipment procured by the public sector is tested either by the beneficiary itself (i.e. Ministry of Health, Royal Medical Services, etc.) or the Royal Scientific Society. This testing is not applicable to medical equipment procured by the private sector, which is not subject to any testing procedures.

Trade Events

Arab Health

January 26–29, 2015 • Dubai, UAE

International Dental Conference and Arab Dental Exhibition

February 17–19, 2015 • Dubai, UAE

Medical Tourism Conference

May 2015 • Amman, Jordan

Kenya

Summary

Kenya is the most developed economy in Eastern Africa and also the economic, commercial, financial and logistical hub of the entire region. Kenya's population is comprised of a large number of young (almost 70 percent of the population is under the age of 35) well-educated English-speaking, and multi-lingual professionals, and a strong entrepreneurial tradition. Kenya's healthcare markets are one of the fastest growing on the African continent and are expected to register strong double-digit growth with medical devices at 10 percent annually through 2014–18, clinical chemistry and diagnostic products at 15–25 percent annually and pharmaceuticals at 14–16 percent annually over the same period.

Market Entry

The Kenyan healthcare market relies almost entirely on imports of medical devices, pharmaceuticals (at least 70–80 percent), dental products, laboratory equipment, healthcare IT, clinical chemistry and diagnostics. Kenya is the key logistical conduit into East Africa and many foreign suppliers operating here do business under their own name to manage penetration into the larger, regional market. Success on the Kenyan market requires that local presence and after-sales support be considered via a local representative, for example an agent or distributor, or a joint venture partner or franchisee.

Current Market Trends

U.S. healthcare suppliers are in an excellent position to increase their market share in Kenya due to U.S. technical competitiveness in assuring quality and reliability of U.S. healthcare products although price is occasionally an issue. Leading private sector hospitals are very active in modernizing their medical equipment inventories, while public sector hospitals are constantly re-equipping with improved budgetary allocations. Additionally, the passage of a new constitution

Statistics

Capital:	Nairobi
Population:	45 million
GDP (USD):	80 billion
Currency:	Shilling (KES)
Language:	English, Swahili

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in August 2010 established 47 county governments, each of which is responsible for providing health facilities and services. These county governments, managed by a county governor, receive at least 15 per cent of their annual funding from the central government and a large portion of this funding is being used to re-equip county health facilities through a managed equipment services contract/leasing program that the Ministry of Health is launching in 2014.

Main Competitors

Major suppliers of healthcare products include India, China, United States, Germany, Belgium, Switzerland, Belgium, South Africa, Italy and Japan. Leading medical companies that sell product in Kenya include: GlaxoSmithKline, Roche, Sanofi Aventis, Pfizer, AstraZeneca, Philips, Siemens, Novartis, Abbot, GE Medical, Becton Dickinson, Drager, and Welch Allyn.

Current Demand

Past government tenders for medical equipment indicate requirements for basic equipment such as anesthetic machines, anesthetic trolleys, hydraulic operating tables, delivery beds, infant incubators, mortuary trolleys, hydraulic operating tables, mercurial sphygmomanometers, and oxygen flow meters among others. Best prospects for electro-medical devices include: CT scanners, ultrasound units, X-ray equipment, mammography units, MRI equipment, angiography, endoscopy, biochemistry, hematology, and immunology systems. Best prospects for clinical chemistry and diagnostics are in serology/hematology, immunochemistry, urinalysis, electrolytes analysis, diabetes testing and cardiac markers while those for pharmaceuticals are in affordable patented and generic drugs used to manage HIV/AIDS and associated opportunistic infections, malaria, cancer, diabetes and hypertension. Used and refurbished medical devices have an open market in Kenya so long as they conform to national standards.

Registration Process

The Pharmacy and Poisons Board (PPB) regulates the practice of pharmacy and the manufacture and trade in pharmaceuticals and medical devices in Kenya.

To register a pharmaceutical product, please visit ***pharmacyboardkenya.org/index.php?id=10***.

To register a medical device, please visit ***pharmacyboardkenya.org/index.php?id=13***.

Diagnostic kits and reagents that specifically test for sexually transmitted infections (including HIV/AIDS and hepatitis) are required to be evaluated by the National Public Health Laboratories to ascertain the quality and reliability of these products. Product evaluations typically involve 400 tests at a cost of about USD 1,000.

Barriers

In September 2005, the Kenya Bureau of Standards (KEBS) implemented the Pre-export Verification of Conformity (PVoC) program, a conformity assessment and verification procedure applied to specific "Import Regulated Products" from exporting countries to ensure their compliance with the applicable Kenyan technical regulations and mandatory standards or approved equivalents (international standards and national standards). KEBS requires that all consignments of regulated products entering Kenya must obtain a Certificate of Conformity issued by an appointed PVoC country agent, a mandatory customs clearance document in Kenya; consignments of regulated products arriving at Kenyan Customs Points of Entry without this document will be subject to delays and possibly denial of admission into Kenya.

Trade Events

MedExpo Africa

TBD 2015 • Nairobi, Kenya • ***expogr.com/kenyamed***

Korea, Republic of

Summary

Medical Equipment and Devices, 2012–15				
(USD Billions)	2012	2013 (est.)	2014 (est.)	2015 (proj.)
Total Market Size	4.078	4.404	4.757	5.137
Total Local Production	3.444	3.838	4.261	4.697
Total Exports	1.967	2.321	2.738	3.149
Total Imports	2.601	2.887	3.234	3.589
Imports from the U.S.	1.172	1.254	1.342	1.436

Source: Korea Medical Devices Industry Association (KMDIA)

The Korean medical device market is estimated to reach USD 4.8 billion in 2014. One factor that may slow import growth will be pricing and reimbursement measures the Korean government grapples with under its national healthcare system.

The importation of medical devices requires the assignment of an importer or representative based in Korea to manage medical device approvals and to ensure regulatory compliance. As part of pre-market approval requirements, the government of Korea requires testing reports of imported devices for safety and efficacy. In addition to medical device approvals, companies also need to negotiate pricing terms with the Korean Health Insurance Review and Assessment Service (HIRA) and the National Health Insurance Corporation (NHIC).

Market Entry

Medical devices are distributed mainly through local distributors. A local distributor may directly cover the whole country on an exclusive basis or a master distributor may contract with other regional sub-dealers for sales nationwide.

Statistics

Capital: Seoul
Population: 50 million (2014)
GDP (USD): 1.16 trillion
Currency: S. Korean won (KRW)
Language: Korean

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Sales leads for medical devices in Korea are normally created through steady communication with local subsidiaries or between distributors/commission agents and physicians on an individual basis. Local representatives call on physicians frequently and provide information on products to maintain good relationships.

One reliable distributor to cover the country on an exclusive basis is highly recommended for the Korean market since Korea is a geographically small country, and major users for high end medical devices are limited to general hospitals and university hospitals. More than one distributor often confuses clients in terms of representation and prices and diminishes the reliability of the foreign supplier.

Current Market Trends

In 2013, the top 10 medical devices imported into Korea included:

- Stents
- CT systems
- MRI systems
- Knee implants
- Soft contact lenses
- Kidney dialysis devices
- Lenses for eye glasses
- Medical probe
- Catheters
- Ultrasound imaging systems

Main Competitors

Korea depends on high-end medical devices from the U.S., EU, and Japan, to supply about 60 percent of total market demand. Currently, the United States has largest import market share in Korea, followed by the EU and Japan. Korean companies make comparatively lower-end (mid-technology) medical devices.

Current Demand

In 2014, total imports of medical devices were estimated at USD 3.2 billion, with U.S. imports totaling over USD 1.3 billion. The U.S. market share represents approximately 40 percent of the import market. Market demand for foreign advanced and innovative medical devices is estimated to have experienced slow growth in 2014. The Korean economy has not fully recovered to its pre-global financial crisis levels.

Registration Process

All medical devices are required to obtain marketing clearance from the Ministry of Food and Drug Safety (MFDS) before they are manufactured in or imported into Korea. Currently, medical devices are classified into four categories in Korea depending upon technical attributes and product use. MFDS requires pre-market notification for class I devices and pre-market approval for class II, III, and IV devices. Class III and IV devices must pass the most stringent technical review by MFDS with authorized labs to prove their safety and effectiveness. Since MFDS

issues product licenses only to locally based firms, all foreign suppliers must submit required documentation and receive necessary approvals through their Korean importers, or U.S. supplier's corporation located in Korea.

The lead-time for approval is typically six to 12 months, including company-working time for preparing applications. Although MFDS indicates its requirements for the approval in relevant regulations, specific detailed requirements could be different according to each product item. Thus, U.S. firms should closely work with their Korean importers to determine MFDS's requirements on a case-by-case basis to obtain approvals.

Barriers

National Health Insurance Program and Reimbursement Pricing

Korea has compulsory National Health Insurance (NHI) system for 50 million citizens. The NHI system was introduced in 1977 and covered entire population by 1989. The Korean government administers funds, coverage, coding, payment and pricing.

Tariffs

Due to the Korea-U.S. Free Trade Agreement (KORUS FTA) implemented on March 15, 2012, approximately 85–90 percent of imported medical devices in Korea will receive duty-free treatment within one year, and tariffs on the rest will be eliminated over the next five years.

Trade Events

Korea International Medical, Clinical, Laboratories, & Hospital Equipment Show 2015

March 5–8, 2015 • Seoul, South Korea • ***kimes.co.kr***

Korea's largest showcase for medical devices and technologies. Exhibits include consultation, diagnosis central supply, clinical examination, hospital accommodation, emergency equipment, radiology, medical information system, surgical apparatus, oriental medicine, cure apparatus, pharmaceutical, physiotherapy apparatus, obesity cure, healthcare, ophthalmic apparatus, medical device component, medical service, dental apparatus, disposable apparatus, and more.

Kuwait

Summary

n February 2010, the Kuwaiti Parliament approved a USD 110 billion (KWD 31 billion) National Development Plan (NDI), stretching to 2035, based on a series of five 5-year plans, which aim to convert Kuwait into a trade and financial hub of the region. The plan introduces ideas and laws to fund the development projects and to provide support to various sectors, including building a stronger healthcare system through the promotion of healthy lifestyles and behavior and enhancing the healthcare infrastructure.

Kuwait's public healthcare sector accounts for more than 80 percent of the healthcare spending in the country. Currently, Kuwait's Ministry of Health is the owner, operator, regulator, and financer of the vast majority of healthcare services rendered, pharmaceuticals purchased, and medical equipment acquired in the country. The government of Kuwait is currently operating 15 general and specialized hospitals with the private sector expected to grow moderately in the coming years. Private companies are estimated to take a share of 15–20 percent of healthcare spending.

In 2012, the Ministry of Health and the Ministry of Public Works announced a USD 4.42 billion (KD 1.250 billion) project to replace and/or expand nine operating hospitals (five general hospitals and four specialized hospitals), which will add an additional 5,400 beds, 150 operating rooms, and 500 outpatient clinics. In addition, the USD 1.1 billion (KD 304 million) Sheikh Jaber Al-Ahmed Al-Sabah Hospital, which is expected to be completed by end of 2014, will add another 1,200 beds. Currently the Ministry of Health hospital bed capacity stands at nearly 6,000 hospital beds.

Between 1995 and 2013, Kuwait's Ministry of Health operating budget has increased from USD 895 million (KD 253 million) to USD 4.5 billion (KD 1,294 million). In addition, during the same period, the Ministry of Health per capita expenditure has increased from USD 456 (KD 129) to USD 1,175 (KD 332).

Statistics

Capital:	Kuwait City
Population:	3.9 million (2014)
GDP (USD):	165.8 billion (est. 2012)
Currency:	Kuwaiti Dinar (KWD)
Language:	Arabic (official), English

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Approximately 50 percent of Kuwait's Ministry of Health operating budget is geared towards salaries and benefits. If the Compounded Annual Growth Rate (CAGR) stabilized at 7 percent, Kuwait's Ministry of Health operating budget would reach about USD 18 billion (KWD 5 billion), by 2030.

Although the population is young on average, the World Health Organization (WHO) indicated that Kuwait is ranked 13th in the world for obesity and 7th for diabetes. In addition, WHO's metabolic risk factor for both male and female Kuwaiti nationals indicates that 78.8 percent suffer from overweight, 42 percent suffer from obesity, and 54 percent suffer from raised cholesterol.

Market Entry

The GCC has a 5 percent flat rate tax on imports. Kuwait corporate income taxes for foreign corporations ranged from 15–55 percent, but have been changed to a flat 15 percent as of 2008. To be successful in the Kuwaiti market, U.S. companies often identify, develop and support a local agent, representative, or account executive to manage their marketing strategy. Some companies find having a Kuwaiti partner rather than an agent a preferable approach, in part due to the local tax law. Prior success in other GCC countries is helpful but companies rely on local experience and knowledge to conduct their business in these markets. Knowing regulations and the general business framework is a difficult task without the support of a competent local agent or business partner. U.S. companies should seek this type of business relationship and understand that the best representatives are those who are already active in their particular sector with cultivated contacts.

In summary, selecting the appropriate agent who will work for you is the single most important step a U.S. exporter can take in Kuwait. Getting competent local legal counsel to craft an agreement that protects your company from future liability is also a key. The best local partners are those who share both the risk and profit with their U.S. partners.

Main Competitors

The Kuwait market is totally dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate. European suppliers are aggressively gaining market share with their close proximity to the market and perceived high level of customer support.

Current Market Trends

The healthcare sector is moving toward becoming a regulated market sector through reform initiatives that are being implemented. The privatization initiative involves broadening public-private partnerships and giving the private sector a growing role in the provision of healthcare services. Recently, public healthcare centers began referring patients to private medical care providers for services like IVF treatment and physiotherapy. Such soaring healthcare spending

reflects the government's priority to improve the quality of life for both citizens and expatriates and to treat more Kuwaiti patient's in-country.

Registration Process

Kuwait Ministry of Health requires the following for product registration:

- Free Sale Certificate from the concern health authority of origin to be legalized by Kuwait Embassy. This certificate should mention the trade name of the product, its volumes or weight, and it should state the product is allowed to be sold freely in the country of origin.
- Certificate of composition (exact percentages) signed and sealed by the manufacturer.
- Certificate of analysis signed and stamped by manufacturer.
- Samples of each product to be tested.
- Additionally, having a Kuwaiti importer is recommended.

Current Demand

Currently, Kuwait has two hospital beds per 1,000 people, an undersupply of serious concern given the population growth and the growing disease burden.

Barriers

The need for a Kuwaiti agent, distributor, or partner tends to add to the cost of selling goods in Kuwait.

Imports to Kuwait require three certified and legal copies of the commercial invoice, three copies of the transport documents and two copies of the certificate of origin. The certificate of origin must describe the place of origin of the goods, the full name of the manufacturing plant or producer and the full name of the freight forwarder. It must also show gross and net weight, the trademark shown in the manifest, value, type of packaging and means of transport. The certificate must be certified by the Chamber of Commerce in the exporter country and most of the time by Kuwait Embassy or any one of the GCC states mission in the absence of a Kuwaiti mission.

Kuwait Customs is strict and most of the Kuwaiti importers/companies know the best ways to get the imported items faster to the country.

Trade Events

No medical or healthcare events are scheduled in 2013 or 2014. Most Kuwaiti companies attend Arab Health in Dubai, UAE, as well as shows held in Germany and the U.S.

Macedonia

Summary

Macedonia continues to undertake a series of major health sector reforms.

The purpose of these reforms is to enable access to high quality primary care that is financially sustained through more appropriate roles for public and private healthcare institutions and more efficient allocation of resources.

In order to achieve these goals of health sector reform, the Ministry of Health of the government of the Republic of Macedonia has set five core policy areas to improve: health expenditures; health revenues; provider payment mechanisms; information systems; and advocacy and public awareness strategies.

The main contributors to health system reform in Macedonia, other than World Health Organization (WHO), are the World Bank, UN agencies, and the government. Their broad based efforts focus on several components: health finance reform and management; basic health services; fostering public-private partnership in health sector; and pharmaceutical policy.

In parallel to health sector restructuring efforts, the health sector management project has continued to be a particular focus. The objectives of this project are to upgrade the Ministry of Health (MOH), the Health Insurance Fund (HIF) and the local health facilities capacity to formulate and effectively implement health policies, health insurance, financial management and contracting of providers, as well as to develop and implement efficient schemes for the restructuring of hospital services, with an emphasis on developing day care services and shifting to quality primary care.

The disease prevalence pattern is similar to other European countries, with cardiovascular and circulatory disease, neoplasms, metabolic and nutritional diseases, and respiratory diseases as the most prominent causes of morbidity and mortality. Diseases like HIV and TB are less prevalent.

Statistics

Capital:	Skopje
Population:	2 million
GDP (USD):	10.22 billion (2013)
Currency:	Macedonian Denar (MKD)
Language:	Macedonian, Albanian

Contact

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For the long term, Macedonia has continued to spend between 5.5 to 7.5 percent of its GDP on the healthcare sector.

Market Entry

There are no legal barriers to foreign businesses entering Macedonia. However, challenges to doing business in Macedonia remain, including the country's weak judicial system and significant levels of corruption. According to import regulations, all medical equipment entering Macedonia is free of import duties, but still subject to 18 percent value added tax (VAT). Exceptions are applied to the accessories and spare parts which are subject to 8, 10, and 15 percent customs import duty. CE mark of quality is mandatory, as are ISO standards.

Current Market Trends

Macedonia's healthcare sector remains in need of medical materials, including pharmaceutical drugs, disposable products, and medical equipment. Invasive and non-invasive surgery equipment, cardiology equipment, EKG and ultrasound, defibrillators, vascular stents, pacemakers, oncology equipment, urology, laboratory and testing equipment, remain in high demand as do computer tomography imaging systems, magnetic resonance imaging, and sophisticated digitalized x-ray equipment.

Main Competitors

European companies remain the main competitors to U.S.-produced medical equipment and pharmacies. Costumers in Macedonia are highly receptive to U.S. products but they are also very sensitive to prices. Siemens, Philips, Hitachi, and Toshiba are present in the market.

Registration Process

In order to harmonize country's legislation with European Commission recommendations, the Assembly of the Republic of Macedonia has adopted extensive amendments to the Law on Medicinal Products and Medical Devices that came into force on February 1, 2012.

According to this law, all medical devices marketed in Macedonia must be labeled according with the provisions of this law on the outer and inner packing in Macedonian and English language, and must enclose instructions for use.

A packing of medical devices must contain, at least, the following: information on the manufacturer, supplier, information necessary for the identification of the medical device and contents of the packing, different labels like sterile, custom-made, single use, for clinical trials, identification code, expiry period, storage conditions, a special method of use, warnings or precautions, purpose and other information related to proper use of the device and public health protection.

The medical devices and pharmaceutical products require registration at The Bureau for Medicine and Medical Devices, who is the administrative body regulating the Law of Medicinal Products and Medical Devices.

Barriers

No significant trade barriers or limitations related to U.S. produced medical devices.

Trade Events

No specialized medical and healthcare trade show scheduled in 2013.

Resources

- Ministry of Health of Macedonia, ***moh.gov.mk***
- Health Insurance Fund of Macedonia, ***www.fzo.org.mk***

Malaysia

Summary

Malaysia has a universal healthcare system. With minimal co-pay, Malaysian citizens have access to the entire public healthcare system. Most of the public healthcare MOH hospitals and public universities teaching hospitals also have a coexisting private-wing where in-patients can opt in for upgraded room and board. Fees charged at private-wings of public healthcare facilities are discounted in comparison to private healthcare. As of December 2012, there are 132 MOH hospitals and 209 private hospitals in Malaysia.

Private healthcare in Malaysia are predominantly used by the upper middle to the affluent segment of the population. Additionally, private healthcare providers are focusing on the healthcare tourism development front. The Malaysian government is optimistic over healthcare travel industry, and is forecasting 10 percent annual revenue growth for 2011–15.

On the dental side, Malaysia is adopting a one-stop dental trauma center as most of the dental clinics provide basic dental care, with subspecialty clinics scattered in various locations across the country. As of December 2012, there are 50 MOH dental clinics and 1623 private dental clinics in Malaysia.

The government has set aside MOH development budget allocation of MYR 1.924 billion/approximately USD 601 million for 2013. As a percentage, the total Ministry of Health allocation is about 7.7 percent of national annual budget allocation.

Market Entry

Many exporters designate a Malaysian-based trading company as their local sales agent responsible for handling customs clearance of imported goods, for dealing with established wholesalers and/or retailers, for marketing the product directly

Statistics

Capital:	Kuala Lumpur
Population:	29.9 million
GDP (USD):	312.44 billion (2013)
Currency:	Ringgit Malaysia (MYR)
Language:	Bahasa Malaysia

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to major corporations or the government, and for handling after-sales service. In some cases, especially when selling to the government, a Malaysian distributor is required.

In the field of medical devices, the passing of Act 737 and Medical Device Regulations 2012 has changed the regulatory framework for Malaysia. Industry players intending to export to Malaysia now need to register their medical devices with the Malaysian Medical Device Authority. There is a two year transition period from the passing of the law to mandatory medical device registration.

Current Market Trends

Overall, there is potential for Malaysia's private healthcare market due to its speedy service delivery and quality healthcare. Increasingly, more Malaysians are taking the approach of wellness and disease prevention rather than treatment.

Food and vitamin supplements are seen as preventive measures towards maintaining optimal health. As for dental market trends, we are seeing subspecialties in the area of orthodontics, implant and esthetic procedures increasingly being offered in private dental clinics. The United State is one of the leading suppliers of orthodontics products in Malaysia.

Main Competitors

Main competitors for the United States in the Malaysian market are predominantly the first world nations, i.e. the EU, and the Japanese. South Korea is also entering the market.

Current Demand

In addition to medical products and equipment, there is demand on skills-sets improvement. Interests in cross training for medical and dental specialists and post graduate education are high. Opportunities in cross training TDYs with U.S. hospitals in specialty medical and dentistry would be welcomed. Many of the older dental schools are in the midst of new facilities expansion, upgrades and refurbishment. Demand for orthodontics and endodontic appliances and services, implants and prosthetics solutions, lab equipment is expected increase in the near future.

Basic vitamin and pro-vitamins; natural and organic supplements are gaining popularity. The U.S. is the largest supplier of healthcare supplements to Malaysia commanding about 28 percent of the market share. U.S. brands are both trusted and well received by the Malaysian consumers.

Barriers

Malaysia continues to express a commitment to protection and enforcing IPR, and has made important progress with respect to the protection and enforcement of IPR in the past few

years. However, concerns remain about reports of the widespread availability of pirated and counterfeit products in street markets and over the internet.

Trade Events

SE-Asian Healthcare Show

April 6–8, 2015 • Kuala Lumpur, Malaysia • ***abcex.com/usa***
One of the region's most established trade shows, covering the entire healthcare industry. Regional visitors include Singapore, Indonesia, and other neighboring countries.

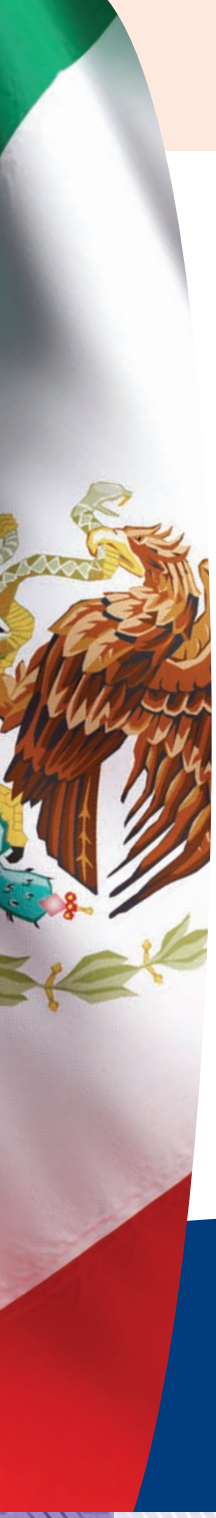
APHM International Healthcare Conference

June 15–17, 2015 • Kuala Lumpur, Malaysia • ***aphmconferences.org***
The Association of Private Hospitals of Malaysia (APHM) annual conference and exhibition. A significant annual medical event.

Available Market Research

- Country Commercial Guide (2014)

Mexico



Summary

Mexico is a big market for all types of medical devices. Imports of medical equipment, instruments, disposable and dental products reached USD 4.3 billion in 2013.

Imports of U.S. products are duty free if they comply with the NAFTA certificate of origin. U.S. products are appreciated because of their high quality, after sales service and good prices compared to competing products of similar quality. U.S. companies should take advantage of geographical proximity to start or increase their presence in Mexico.

Market Entry

All medical equipment and devices can be imported duty free with a NAFTA certificate of origin. Imports are subject to a 16 percent VAT tax over the invoice value.

All medical and health care products that touch or affect the human body need to be registered with the Mexican Secretariat of Health (SSA) prior to sale or use in Mexico. Foreign manufactures of medical devices need to have a legally appointed distributor/representative in Mexico who will be in charge of obtaining the sanitary registration/market approval and will be the responsible for the product(s) in Mexico. U.S. Commercial Service Mexico can provide a detailed list of requirements and advice for processing market approval in Mexico for U.S. medical devices.

Current Market Trends

Most large public and private hospitals try to have modern and very specialized medical devices. Some medium and small private hospitals with limited budgets buy used or refurbished equipment. Public hospitals by law, cannot buy used or

Statistics

Capital:	Mexico, D.F.
Population:	120 million (est. 2013)
GDP (USD):	1.2 trillion (2012)
Currency:	Mexican peso (MXN)
Language:	Spanish

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refurbished products. In order to save resources, recently many public and private hospitals are hiring companies that offer "integral surgery services" and provide service "per event," offering all the necessary products required to perform a surgery. This concept is been expanded to other areas where hospitals can use integral suppliers for different processes like sterilization or others. In this way, hospitals avoid making large investments in materials, pharmaceuticals, and instruments, and also reduce the costs involved in keeping and controlling inventories, and maintaining instruments for specialized surgeries.

All public institutions ask suppliers to register with their organization. These institutions may award purchases under USD 3,100 directly to a selected provider. Purchases over that amount must be done through public tenders.

All private health care facilities select suppliers by requesting price quotations. Their decisions are based on the best equipment at the best price.

Main Competitors

Most large international corporations offering medical devices have a presence in Mexico. Medium and small foreign suppliers usually sell through legally appointed distributors.

Current Demand

Public health care institutions account for 70–80 percent of total medical services provided nationwide while private health care institutions cover approximately 25–30 percent of the Mexican population, including 32 million people with private medical and accident insurance.

In the public sector there are 1,169 hospitals of which, 194 are highly specialized medical units. In the private sector, of the 3,560 hospitals, only about 100 have over 50 beds and offer highly specialized medicine. Most of the hospitals offering specialty health care services are located in medium and large Mexican cities. There are also some medium sized private hospitals that offer specialty services and focus on high income, insured patients.

Imports supply about 90 percent of medical equipment and instruments and about 40 percent of medical disposable and dental products. In 2013, total imports in these four groups of products reached USD 4.3 billion. Of these imports 50 percent, or 2.2 billion dollars, were of U.S. origin. Main competitors are from Belgium, Brazil, Canada, China, France, Germany, Israel, Italy, Japan, Netherlands, South Korea and UK.

Barriers

Obtaining the sanitary registration/market approval is a very technical and time consuming process. However, products already approved by the FDA to be sold in the U.S. should not have any problem in being approved in Mexico. However, in the last two years, there have been some delays in receiving registration/marketing approvals from COFEPRIS (***www.cofepris.***

gob.mx), the Mexican Agency in charge or registering and approving medical devices. The USCS Mexico and other USGOV institutions are working closely with COFEPRIS to help in resolving these delays.

Also, COFEPRIS has deregulated over 1600 products that are no longer considered medical devices and can be freely imported. They are working to expand the list of deregulated products by the end of 2014.

To be imported into Mexico, some medical products need to comply with technical standards or NOMs (Norma Oficial Mexicana). All standards are classified based on the Harmonized System Code (HS).

There are few Mexican standards for medical devices, but various agencies are preparing more standards to be issued in the near future. COFEPRIS maintains updated information on NOMs and other sanitary processes.

Trade Events

AMIC Dental

May 12–15, 2015 • Mexico City, Mexico • ***amicdental.com.mx***

Expomed

June 10–12, 2015 • Mexico City, Mexico • ***expomed.com.mx***

Expo DICLAB

September 8–9, 2016 • Mexico City, Mexico • ***expodiclab.com***
Clinical and scientific laboratory products.

Additionally, important events organized by medical academies and associations—focused on specialized, niche subsectors—may be excellent opportunities for companies offering high-technology medical devices.

Available Market Research

- Labeling for Medical Devices (2010)
- Sanitary Registration for Medical Devices (2011)
- Health IT Market Overview (2012)

Morocco, Kingdom of

Summary

The Health Market in Morocco is a growing sector that is full of opportunities for future investment. The government remains the main Health care provider since 70 percent of the population goes to public hospitals. There are five University Hospital Centers and six military hospitals that are located in the large cities such as Casablanca, Rabat, Fes, and Marrakech. In addition, there are 137 hospitals in the public sector. The private sector healthcare market is growing rapidly as there are 320 private clinics, and 9,661 specialist doctors in Morocco.

The Healthcare System is comprised of AMO (Mandatory Health Insurance), which is divided into "La CNSS" (private) that reimburses up to 70 percent and "La CNOPS" (public), that reimburses up to 80 percent. Additionally, we can find RAMED which is a health care system based on the principle of social assistance and national solidarity in favor of low income individuals. There is also a separate health care system that is solely dedicated to the military.

Market Entry

Moroccans base business on trust and mutual respect. However, U.S. exporters should be patient; procedures take more time in Morocco, as compared to the United States. Also, U.S. firms should work closely working with a locally-based agent or distributor, so that they can provide U.S. firms with essential knowledge of key contacts, customs regulations, and specific opportunities. U.S. firms should also fully understand the regulatory environment and procedures before jumping into the market to avoid problems. Also, Morocco's American Chamber of Commerce (Amcham) can organize collegial and informal meetings in Casablanca with other Amcham members to gain insight into the evolving market and learn how to best position product sales for the market. In addition, the U.S. Commercial Service in Morocco provides counseling to determine the best market

Statistics

Capital:	Rabat
Population:	32.6 million
GDP (USD):	104.4 billion
Currency:	Dirham (NOK)
Language:	Arabic, Berber (official); French, Spanish

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entry strategy for any given U.S. company/product/service such as for joint venture partners, resellers, agents and distributors.

Current Market Trends

The medical device market is estimated at USD 230 million with USD 181 million constituting imports. Medical equipment prospects are increasing for public and private sector opportunities for U.S. firms. The Moroccan government is planning to build four CHU by 2018, as well as develop emergency and mobile hospital units. The Ministry of Health requires all second-hand medical equipment to be registered within 12 months of purchase. Used equipment is also a good opportunity for U.S. Firms, mainly for private clinics and laboratories. The public sector only procures new medical equipment.

Main Competitors

Currently Moroccan does not manufacture medical equipment. The local production is limited to medical disposables. United States, Germany and France are the main suppliers. However, there is an increasing demand on Chinese and Korean products.

Current Demand

Public hospitals represent 85 percent of the demand and the private clinics 15 percent. By 2018, the Moroccan government is planning to achieve their goal of building four Hospital University Centers which will be a huge opportunity for U.S. companies to create partnership with Moroccan companies and export U.S. medical equipment. Also, Morocco is planning to develop emergency and mobile hospital units which could be a good opportunity for U.S. firms. Disposables and specialty medical devices are good prospects for U.S. firms. Sub-sector best prospects include magnetic resonance imaging and ultra-sonic scanning equipment, x-ray equipment, emergency aid equipment, monitoring and electro-diagnostic equipment, computerized tomography equipment, and ICT (E-medicine, equipment and related software).

Registration Process

To proceed with the registration of medical equipment with the DMP (Department of medicine and pharmacy), provide the following elements:

Documents needed for registration:

- CE certificate or similar
- Certificate of free sales or FDA
- Declaration of conformity
- ISO13485
- Technical files and quality test details
- Original catalog

The average time to obtain a certificate of registration is six months.

Barriers

The main languages spoken in Morocco are French and Moroccan Arabic, which provides a challenge for English-speaking companies. Another potential problem for U.S. firms is that Morocco is seen as a relatively small market for medical equipment, and there are many regulations that have the ability to hinder trade. Also, some customs procedures are not uniformly applied. Bribery, corruption and requests for payoffs are another issue that U.S. investors can be confronted to (When foreign bribery prevents you from competing fairly on the basis of price, quality or service). In addition to these barriers, Morocco had tariffs placed on some medical equipment imports:

- Free of custom duties if the product is 100 percent made in the country of importation
- 10 percent of custom duties are applied if the products are manufactured in Morocco in order to protect the Moroccan industry.
- 2.5 percent tariff rate if less than 100 percent of the product is made in the country of importation

Trade Events

Medical Expo

March 2015 • Casablanca, Morocco

New Zealand

Summary

All New Zealanders have access to a sophisticated healthcare system. New Zealand's health system is comprised of public, private, and voluntary sectors that coordinate to provide and fund healthcare. More than 80 percent of healthcare is government-funded. Due to an aging population, New Zealand's total health expenditure by 2050 is due to rise to 12.5 percent of GDP. The government's health budget for 2014 is approximately USD 10 billion. (Source: New Zealand Treasury). Both the public and private sectors aim to source the best and most affordable technologies.

The U.S. provides approximately 40 percent of New Zealand's total market demand. U.S. companies specializing in healthcare products have a strong reputation in New Zealand based on performance, cost, and reliability. Opportunities exist for U.S. companies specializing in new innovative technologies that reduce overall patient costs leading to faster patient recovery and reduced rehabilitation costs.

Market Entry

U.S. companies should establish a local sales presence to improve their market position and chances of success in New Zealand. While some businesses will open a subsidiary in New Zealand, for most U.S. exporters this means appointing an agent or distributor. We encourage U.S. firms to research three key determinants: the purchasing practices of their target customers, the competitive climate in the New Zealand market, and the importance of after-sales service.

New Zealand government tenders are advertised on the Government Electronic Tenders System (GETS, ***gets.govt.nz***). Subscription to GETS is free.

Current Market Trends

Health targets are currently the basis of New Zealand's key health strategies. This country's health targets focus on chronic diseases (diabetes, heart disease, cancers and obesity), child and youth services, primary healthcare, elderly care, elective services and infrastructure. Health targets are linked with extra government

Statistics

Capital:	Wellington
Population:	4.4 million
GDP (USD):	159 billion
Currency:	New Zealand Dollar (NZD)
Language:	English (official), others

Contact

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funding. For example, government investment in building new elective surgery theaters is beginning to help reduce the rising patient numbers for non-emergency surgical treatments.

New Zealand's aging population increases the demand for facilities such as retirement villages with on-site hospitals.

Main Competitors

U.S. companies can expect to face competition in this market from major global suppliers including other U.S. healthcare suppliers. New Zealanders recognize U.S. brands as reliable, robust but not always price competitive. Australia is New Zealand's nearest neighbor and across all sectors its most important trading partner.

Current Demand

The country's aging population influences public healthcare expenditure plans whilst at the same time the government is committed to delivering essential healthcare services. Higher living standards are contributing to an increase demand for medical equipment. New Zealanders expect accessibility to advanced equipment to manage chronic diseases (chronic diseases account for around 80 percent of healthcare use). Value for money is a key procurement-making decision. New, innovative technologies are important to meet this objective.

A third of New Zealand's population is concentrated in the Greater Auckland region. Approximately 80 percent of the population is urbanized. Specialist services are readily available in the main centers of Auckland, Wellington and Christchurch. Auckland is the leading center for advanced medical care in New Zealand.

Registration Process

New Zealand Medsafe (***medsafe.govt.nz***)—the New Zealand Medicines and Medical Devices Safety Authority—is a business unit of the Ministry of Health. Medsafe regulates by applying a framework that weighs up risks and benefits of medicines and medical devices, ensures there are therapeutic benefits, and manages the potential risks associated with use of these products. MedSafe manages a Web Assisted Notification of Devices (WAND). If not exempted, firms must notify their medical devices to MedSafe via the WAND system. For imported products, the New Zealand resident sponsor undertakes this process. There is no fee for notifying WAND or maintaining a notification.

Barriers

There are no trade barriers against U.S. products and services.

Available Market Research

- Country Commercial Guide (2014)

Nigeria

Summary

There is a growing interest by Nigerians living overseas to invest in the Nigerian healthcare sector and this trend will likely continue according to market intelligence. Many of the diaspora groups are exploring opportunities to sell medical equipment and some are researching the cost-benefit of building world-class hospitals, diagnostic centers; and organizing need-based interventions including air ambulance services and capacity building for healthcare professionals. Industry experts estimate that over 25,000 Nigerian travelers are medical tourists. While this presents an opportunity to U.S. medical institutions, it also presents prospects to suppliers of mid- to high-end medical equipment looking to expand into Nigeria. Market intelligence from industry associations, major importers and distributors estimates that Nigeria's market for medical equipment will grow by about 15 percent over the next two years.

Nigeria's health sector to GDP is estimated to be 5 percent. The country remains a net importer of medical equipment and prescription medicines. Local equipment production is limited to peripheral items such as hospital beds and gurneys. For medicines, limited local capacity exists in the private sector for over-the-counter drugs especially those for treating common cold, malaria and headaches. Across the country, there is a dearth of well-trained, well-equipped and adequately motivated medical professionals. For Nigeria's estimated 170 million people, there are about 13,703 primary care, 845 secondary care and 59 tertiary care facilities. The private sector is expected to be the primary driver of growth as healthcare demand in Africa is projected to grow to USD 35 billion in 2016.

There is zero tariff on imported medical equipment, pharmaceutical manufacturing machinery and packaging materials. However, pharmaceuticals attract a 10 percent duty.

Nigeria enjoys strong healthcare professional associations, including the Nigerian Medical Association (NMA, ***nigeriannma.org***), Association of General and Private Medical Practitioners of Nigeria (AGPMPN, ***agpmpn.org***), Association of Medical

Statistics

Capital:	Abuja
Population:	170,123,740 (est. 2012)
GDP (USD):	509 billion (est. 2014)
Currency:	Naira (NGN)
Language:	English (official), Igbo, Yoruba, Hausa

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Laboratory Scientists of Nigeria (AMLSN, ***amlsn.org***), Pharmaceutical Society of Nigeria (PSN, ***psnnational.org***), and Healthcare Federation of Nigeria (HFN).

Market Entry

The best way for U.S. manufacturers and suppliers to penetrate the Nigerian market is to combine the benefits of the network services and programs of U.S. Commercial Service, especially the extensive knowledge, industry contacts, and services of CS trade specialists located at the U.S. Consulate General in Lagos, Nigeria. We encourage seeking CS assistance before exploring an opportunity in this market.

To establish a presence in Nigeria, we recommend U.S. firms use a locally-registered agent/distributor. Terms and conditions must be fully defined up front.

Current Market Trends

In Nigeria, consumer health has been growing in the past 5 years due to the growing population becoming more aware of the need for preventative measures and also due to rising family incomes. Moreover, because medical treatment in Nigeria is quite expensive, most Nigerians prefer self-medication or advice from pharmacists, rather than seeking to go to hospitals or clinics. A report published by Euromonitor International in May 2014 indicated that independent chemists/pharmacies remain the major channel for the distribution of consumer health products. Modern channels, such as hypermarkets and supermarkets, are stocking analgesics, cough, cold and allergy (hay fever) remedies, as well as vitamins and dietary supplements; although their shares are still negligible, they will be increasingly important channels in coming months and years. Direct selling continues to be a relatively important channel, which is partly responsible for driving overall growth of consumer health. Internet retailing, however, remains insignificant, although enjoying growth.

Main Competitors

According to industry analysts, European exporters dominate this market but Asian firms, led by China and India, are making significant inroads into Nigeria's healthcare market. Every year, hundreds of Asian manufacturers and suppliers visit local markets, hospitals and talk to potential distributors. Until recently, imports from Europe accounted for over 60 percent of Nigeria's market for medical equipment, but that has now been eroded by Asian imports. According to industry watchers, the U.S. accounts for less than 20 percent of this market both for equipment and medicines.

Current Demand

Market intelligence from industry associations, major importers, and distributors estimates that Nigeria's market for medical equipment will grow by about 15 percent over the next two years. For both new and used equipment, price is the most competitive factor followed by

service support and product origin. It is important to recognize the benefits of cultivating long-term personal relationships in a market as culturally diverse and relationship-driven as Nigeria. Demand exists for diagnostic equipment such as Magnetic Resonance Imaging (MRI), Computed Tomography scan (CT), Digital X-Ray, Ultrasound, Mammography, ultrasound scans, as well as anesthesia equipment and mortuary tools. Top priorities for Nigeria's healthcare agenda include: polio eradication, maternal and infant care, malaria control, pandemic influenza prevention and control, and non-communicable disease prevention, among others. Market analysts say malaria is one of the principal causes of illness and death in Nigeria. Current statistics indicate that nine out of 10 deaths related to malaria that occur in Sub-Saharan Africa, including Nigeria, are among young children and pregnant women. Tuberculosis is another pandemic in Nigeria, with the country ranking 10th among the 22 high-burden TB countries in the world.

Registration Process

The National Agency for Food and Drug Administration and Control (NAFDAC, ***nafdac.gov.ng***) regulates food and drug products in Nigeria.

The Federal Ministry of Health (***health.gov.ng***) is the supervising ministry for national provision of healthcare services.

The Standard Organization of Nigeria (SON, ***son.gov.ng***) is responsible for compliance with equipment specification and import standards. SON's Conformity Assessment Program (SONCAP) is designed to educate exporters to Nigeria, especially on matters related to product standards and regulations and to check indiscriminate importation of substandard goods into Nigeria.

Currently, Nigerian imports are inspected in Nigeria at the port of entry under a Destination Inspection program. CS Nigeria usually recommends that U.S. exporters persuade their Nigerian associates/product importers to facilitate appropriate import documentations (and issuance of certificates where necessary) with relevant government agencies.

Barriers

There are no barriers to trade and investments in the healthcare sector. Zero tariff is charged on imported medical equipment, pharmaceutical manufacturing machinery and packaging materials. A 10 percent duty is however charged on imported medicines.

Trade Events

Medic West Africa Exhibition and Congress

October 15–17, 2014 • Lagos, Nigeria • ***medicwestafrica.com***

Available Market Research

- Country Commercial Guide (2013)

Norway

Summary

Norway is one of the wealthiest countries in the world and this is reflected in its expenditure on medical care for its citizens. With the exception of the U.S. and Switzerland, Norway spends more of its GDP (8 percent/USD 35 billion) on healthcare than any other country in the world. The state-dominated medical system, covering 84 percent of total healthcare costs, is striving for technological advances and organizational improvements in a climate of budget constraints, a rise in chronic disease and an aging population. By 2025, there will be 40 percent more senior citizens in Norway than today.

U.S. companies are estimated to supply around 25–30 percent of Norwegian purchases of medical equipment. High end, quality products and a tailored marketing approach are key factors for U.S. companies in penetrating the Norwegian market. The perceived reliability and quality of a product, together with information received from health care providers/relevant certifying bodies/professional associations in Norway constitute the most significant factors in a purchasing decision for Norwegian buyers and end-users of medical equipment.

U.S. medical equipment suppliers have attractive opportunities in Norway.

Market Entry

Finding a local representative with established contacts with the public authorities is the key to success for a new-to-market U.S. company. The availability of technical service also plays an important role. Most communication is Norwegian so it is an advantage to have a local representative knowledgeable about of the current market conditions.

Statistics

Capital:	Oslo
Population:	5 million
GDP (USD):	488 billion
Currency:	Norwegian kroner (NOK)
Language:	Norwegian

Contact

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Current Market Trends

There is a major health reform underway, named the "Coordination reform" attempting to address some of the challenges the Norwegian healthcare services face. Issues include the inadequate coordination of services covering patient needs, too few initiatives aimed at limiting and preventing disease, changing demographics with an increase in chronic and complex illnesses. The aging population and increase in chronic diseases represents an extra burden for the healthcare system and the government has signaled that nursing and care for the aged must be given higher priority, as well as an increasing use of outpatient-based care at hospitals in an effort to rationalize. In addition technological advances and organizational improvements are prioritized to get healthcare costs under control and meet future challenges, so there is an increasing focus on healthIT solutions such as EPJ, tele and cloud based medicine and systems for integrating local/regional/national health information networks.

Main Competitors

Norway relies heavily on imported medical equipment. The major third-country suppliers of medical equipment are Germany, Denmark, Switzerland, Sweden, the United Kingdom, and Japan. The Nordic countries have traditionally had close contact and cooperation in several healthcare related areas over the last decades. Norwegian companies have also had a preference for participating in and seeking trading partners through European, and in particular German, trade events.

Current Demand

Estimates from the public health authorities and trade associations indicate that the total Norwegian market for medical equipment and supplies reached over USD 1.6 billion by 2012. The various public health care authorities are estimated to account for about 90 percent of the purchases of medical equipment, whereas private (non-publicly funded) purchases account for the remaining 10 percent. About half of all medical equipment is sold to hospitals.

Promising sub-sectors for U.S. suppliers of medical equipment include; surgical instruments and equipment, diagnostic apparatus, ultrasound, orthopedic equipment, monitoring instruments, laboratory/pathology instruments and equipment, digital x-ray systems and customized ICT equipment.

With a rapidly aging population, an increase in chronic disease and increasing healthcare costs, the Norwegian government has stated that telemedicine, e-health and welfare technology are a national priority as they are very important tools in the successful implementation of the key Integrated Health Care Reform of 2012. For example, telemedicine as an important part of future acute medical care, radiology (work-sharing among hospitals) with specialist consultations within the ear-nose-throat field (video conferencing) and specialist consultations in dermatology (e.g. video conferencing and still picture technology); and cardiography (e.g. heart rhythm/sound comparisons). Also, clinical information systems, home care and

personalized health systems/services for remote patient monitoring, systems for integrating local/regional/national health information networks represent significant potential for U.S. companies. However, there are barriers to entry such as requirement for local language, privacy and data protection concerns, standardization and interoperability issues, and reimbursement issues.

Barriers

Through the EEA Agreement (European Economic Area), Norway participates fully in the EU internal market and its efforts to establish common product requirements and methods of conformity assessment. Norway has the same rights and obligations as EU member states in regulation of medical devices. All medical devices must have pre-marketing approval and bear the CE mark confirming conformity with the essential requirements of EU/EEA directives, Medical Device Directive (93/42/EEC), Active Implantable Medical Devices (90/385/EEC) to be sold in the EU internal market.

There are no other significant barriers to trade.

Trade Events

Nordental

October 16–18, 2014 • Oslo, Norway • ***messe.no***
Dental equipment.

Lab '14

October 28–30, 2014 • Oslo, Norway • ***messe.no***
Laboratory equipment.

Most Norwegian distributors attend established international trade shows such as Medica.

Available Market Research

- Clinical Lab Market
- Medical Equipment Market
- Rehab and Home Care Market
- Dental Market.

Oman

Summary

Over the last 35 years, Oman has invested heavily in the health sector and succeeded in creating a relatively modern health care system. Health indicators attest to its comprehensive and well-developed standards: life expectancy at birth is a remarkable 75.5 years, placing Oman on a par with many advanced Western nations. The United Nations 2010 Human Development Report listed Oman at the top of the world's 10 countries that have made the greatest public health progress in recent decades.

Market Entry

With the U.S.-Oman Free Trade Agreement entering into force in January 2009, bilateral trade in industrial and consumer products, with the exception of certain textile and apparel products, is now duty free. Oman provided duty free access on virtually all products in its tariff schedule and will phase out tariffs on the remaining handful of products within a few years. More information on the FTA can be accessed at ***oman.usembassy.gov/us-oman-fta.html***. Under the "national treatment" provisions of the U.S.-Oman Free Trade Agreement, U.S. companies with 100 percent U.S. ownership may register under conditions no less favorable than Omani firms.

U.S. companies can still distribute their products in Oman using a local agent if they prefer not to register in Oman. Agents are particularly useful for sales to the Omani government due to their local contacts, language ability, and cultural knowledge. Constrained budgets encourage government procurement officials to buy direct; however, in practical terms, it is still difficult for foreign firms to sell to the government without an Omani agent scouting for and bidding on tender opportunities. As in other Gulf countries, regular, personal contact is the key to success in trade relationships.

Statistics

Capital:	Muscat
Population:	4.0 million
GDP (USD):	80 billion
Currency:	Omani Rial (OMR)
Language:	Arabic

Contact

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The manufacturer or supplier may not unilaterally terminate the agency agreement except where there is an unjustifiable breach of agreement by the agent. The Commercial Agencies Law governing agency agreements generally awards two to three years of profit as compensation for "unjustified" failure to renew even fixed-term agencies, so consultation with a lawyer in drafting an agreement is highly recommended. Agents are encouraged to register agreements at the Oman Chamber of Commerce and Industry (OCCI). Agents must register in writing and in Arabic with the Registrar of Agents and Commercial Agencies at the Ministry of Commerce and Industry (MOCI), renewable every three years. Agencies may be non-exclusive and more than one agent may be engaged to promote the same product or services. The agent is entitled to commission even if the principal has resorted to direct selling in contravention of the Commercial Agencies Law, which is widely considered to favor the agent.

Current Market Trends

The government's determination to provide all its citizens with free basic health care, along with treating persistent diabetes and cardiovascular disease, means that health-related expenditures are growing. The country's healthcare infrastructure now boasts around 65 modern hospitals with almost 6,000 beds, a ratio of 2.1 beds for every 1,000 citizens, in addition to more than 242 health centers and close to 1,000 private clinics throughout the Sultanate. The Ministry of Health (MOH) is the main healthcare provider,, now operating 116 health centers of which 53 have maternity beds and eight are extended health centers. Other providers include Armed Forces Medical Services, Royal Oman Police Medical Services, Sultan Qaboos University Hospital, Diwan Medical Services, Petroleum Development Oman Medical Services, and the private sector. In 2012, the two leading private hospitals, Starcare and Muscat Private, both received Joint Commission International certification.

After the MOH brought together stakeholders, investors, and international experts at a Vision 2050 Planning Conference in early May 2012, the Omani cabinet approved OMR 1 billion (USD 2.6 billion) to upgrade Oman's healthcare infrastructure over the next three years. A new medical city, to be located in Muscat, is approved by the cabinet to begin construction in 2013 with a budget of OMR 700 million (USD 1.8billion). The MOH also has plans to build 30 hospitals and health centers around the country in projects worth USD 1 billion including new hospitals in Salalah, Khassab/Mussandam, Duqm, and Ghala. The MOH will require support from specialized companies and international expertise as its Planning Division has only 11 employees and lacks the capacity to design and manage large-scale projects.

Projects that should be implemented during the new five-year plan include a new referral hospital in Muscat, at the cost of USD 358 million; a hospital in Salalah, at the cost of USD 122 million; and new hospitals worth USD 142 million in Suwaiq, Mahout, Sinaw, Dhalkut, and Al Muziunah. The MOH is planning to set up and renovate seven hospitals as part of its 36 projects planned for the Eighth Five-Year Health Plan 2011–15. Highlights include: 19 new health centers, a tumor ward at the Royal Hospital, a National Center for Cardiology, a National Center for Diabetes, a Cardiology Centre and an MRI unit in Salalah, a Diabetes Centre

in Sur, rehabilitation of Sultan Qaboos Hospital in Salalah (for outpatients), rehabilitation of Khoula Hospital (for accidents and emergencies), power transmission stations for the Royal Hospital, Al Maziouna Hospital, Dalkout Hospital, health centers at Sarfit and Al Hashman, and upgrading Khasab hospital to a referral hospital for the Governorate of Musandam. Finally, the Royal Oman Police will construct a new 400–600-bed hospital over the next three years, requiring equipment, management services, and drug imports.

The MOH has outlined other requirements including a full-fledged EMS/ambulance system, innovative health insurance solutions for the 1.3 million expat population (and eventually for citizens, currently covered by the government), customized patient catering plans, and help with recruitment to address Oman's severe shortage of doctors. Oman's Minister of Health, Dr. Ahmed bin Mohammed bin Obaid al-Saidi, announced early this year that the Sultanate will face a shortage of around 8,900 doctors and nurses by 2015, with 3,288 positions currently vacant. The MOH needs to send at least 50 high school graduates to an English-speaking country every year to study medicine in order to keep up with patient growth. Ministry officials are anxious to partner with U.S. universities to train and certify Omani healthcare practitioners. The MOH has also expressed specific interest in U.S. healthcare information management technologies as part of its efforts to standardize operations and establish interconnectivity among Oman's hospitals and clinics.

In addition, a private Saudi investor (Apex) is partnering with Methodist International, a U.S. healthcare management firm to establish a USD 1 billion International Medical City in Salalah. (Oman was chosen for its ample available land, Salalah's pleasant coastal weather, and the Sultanate's societal tolerance for international visitors staying for extended periods.) The company's goal is to offer a world-class local option for the GCC population currently seeking quality healthcare overseas, and to serve as a regional center of excellence for genetic diagnostics, organ transplants, and rehabilitation. The master plan for the seaside, resort-style hospital includes educational facilities as well as long-term villas and apartments for family members of patients from around the world. As of summer 2014, however, the project is rumored to have stalled over permitting, financing, and transplant adminstration issues

Main Competitors

The Omani market offers solid prospects for U.S. health care products. The Ministry of Health is the main provider of healthcare, but there is ample room for public-private partnerships as the Ministry seeks to transition to regulator status over the long term. Oman is focused on upgrading its facilities and diagnostic capabilities. The current five-year plan includes spending slated for preliminary and secondary healthcare in addition to women's health issues, infectious and non-infectious diseases, radiology, ophthalmology, mental health, and occupational health. The Ministry of Health has expressed interest in U.S. healthcare information management technologies as part of its efforts to standardize operations and establish interconnectivity among Oman's hospitals and regional clinics.

Current Demand

The healthcare market in Oman is expected to be worth USD 2 billion by 2015 as a result of population growth, rising levels of lifestyle-related diseases, and increased health insurance, according to a report by corporate advisory company Alpen Capital. The report states that the market in the Sultanate is "in the developing stage," and adds that the market is expected to grow at a compound annual growth rate of 9.3 percent between 2010 and 2015 from the 2009 market value of USD 1.2 billion. In addition, the number of hospital beds required to meet this demand is anticipated to rise from an estimated 5,722 to 6,300 by 2015, with a sizeable proportion expected to be absorbed by the USD 1 billion Oman Medical City, a 530-bed facility to be developed in Salalah. At USD 150, Oman had the lowest sales per capita of medicines in the GCC in 2012, according to Alpen Capital. The size of the Omani pharmaceutical market was valued at USD 476 million in 2012 as compared to USD 431 million in 2011. (QNB Capital reported USD 152 million in spending on drugs in Oman in 2012.)

The 2012 budget allocated USD 993 million to healthcare, an increase over the 2011 budget, which was USD 871 million. Oman increased its state budget for health by 9.4 percent in 2013, growing to OMR 547 million (USD 1.4 billion). The health budget accounts for 5 percent of the total state budget, which stands at OMR 12.9 billion (USD 33.5 billion).

Registration Process

Normally, medicines, equipment, and drugs require approval of Ministry of Health before being released. In January 2013, GCC health ministers signed an agreement to lower drug prices, though the move has not yet been implemented. The announcement was welcomed by local drug manufacturers while established pharmacy chains feared the impact on profit margins.

Barriers

A number of constraints affect trade and investment in Oman. The country has a relatively small population and there is no high-value consumer market beyond the capital area. This situation is exacerbated by intense competition from nearby global trading hub Dubai and industries in Saudi Arabia. In addition, other countries in the GCC typically offer higher industrial subsidies and lower quotas for hiring nationals.

While Oman is an attractive market for a number of products and services, at times it can present challenges for U.S. firms to do business. Bureaucratic obstacles exist, including clearances for visas and permits for foreign workers, lengthy business registration requirements for consultancies, and a prohibition on real property rights for foreigners outside of Integrated Tourism Complexes. (Land ownership is not covered by the FTA.) The divide between the government and the private sector is not well-defined in Oman, leading to potential conflicts of interest. Of note are the oligarchic, closely-held businesses with familial ties to government officials. Government decision-making is often opaque. Firms that have

been successful in Oman usually have previous experience in the Middle East or a full-time in-country representative or office.

Of particular concern for many international firms in Oman is the "Omanization" process, wherein the government sets quotas for Omani employment on a sectoral basis. Although the FTA provides for limited exceptions for specialized upper management, U.S. companies are responsible for complying with most Omanization requirements. Many companies, both Omani and international, have noted that some of the quotas are difficult to satisfy. Further, obtaining labor clearances for new foreign workers can be a challenge, and even more so for female expatriates. Despite considerable government efforts to replace expatriate workers with Omanis, Oman still heavily depends on South Asian and other foreign labor. The total number of expatriates in Oman with valid labor cards as of April 2013 was 1,363,265; approximately one-third of the population. Around 80 percent of expatriate workers have only secondary education or lower, and the majority work in low-skill construction and manufacturing jobs. The Omanization drive intensified in 2011 as a result of "Arab Spring" demonstrations demanding more opportunities for Omanis. The government estimates up to 50,000 new jobs per year are needed to absorb new labor force entrants. Companies are encouraged to meet and exceed their Omanization quotas, turn over management jobs to Omanis, and create training programs for new hires, which can be costly.

Several outstanding issues are of most concern to U.S. companies:

- Duties continuing to be charged on U.S. goods transshipped by road via Dubai despite the agreement in the FTA.
- Authenticated certificates of origin/shipping documents are at times still requested by Omani authorities despite not being required under the FTA.
- Company registration can be slow, especially for consulting firms.

Trade Events

Oman Health Exhibition and Conference 2014

September 9–11, 2014 • ***omanhealthexpo.com***

Available Market Research

- Country Commercial Guide (2014)

The Philippines

Summary

The medical equipment sector continues to present good opportunities for U.S. firms. The Philippine medical industry is almost completely dependent on imports. Additional requirements for medical services, new technology, and equipment replacement spur market growth. Philippine medical tourism continues to grow and offer good opportunities for U.S. sellers of medical equipment and instruments.

Several Philippine investment companies have taken an interest in healthcare and have acquired stakes in the healthcare sector, providing much-needed capital for facilities to upgrade and modernize equipment.

Real estate developers have partnered with known healthcare providers to construct health and wellness centers in and around the communities that they are building, adding more appeal to the community and more value to the real estate.

In addition to private investments, the government's Public-Private Partnership (PPP) program has allotted PhP5.69 Billion (Approximately U.S. USD 129 Million) for modernization of public hospitals. According to a Philippine Department of Health official, their medical equipment requirement would include capital-intensive linear accelerators for the cancer centers, dialysis machines, and radiotherapy equipment.

Statistical information for Medical Equipment does not reveal the opportunities that continue to present for U.S. firms. Hospitals still prefer U.S. technology over other foreign brands, although U.S. manufacturers are facing growing competition from Germany, the Netherlands, and Japan.

Statistics

Capital:	Manila
Population:	98.39 million (2013)
GDP (USD):	272 billion (2013)
Currency:	Philippine Peso (PHP)
Language:	Filipino, English, others

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The U.S. is strong in high-value, low-volume capital equipment although importation of smaller diagnostic devices and supplies from the U.S. has shown progress.

The market is price-sensitive, which explains the growing presence of inexpensive equipment from China and South Korea. Hospitals with limited budget source medical equipment from these countries, and distributors that supply equipment and replacement parts now also carry medical disposables and consumables.

Market Entry

U.S. suppliers interested in selling in the Philippines should appoint a local distributor, who will handle all aspects of importation including registration, obtaining a license, and getting customs clearance for the products. The local distributor not only helps facilitate the product's entry into the market, but also assumes responsibility for advertising and promotion through sales and dealer networks. He/she registers with the Food and Drug Authority (FDA, formerly the Bureau of Food and Drugs) before operating and receives a License to Import and a License to Operate (LTO) from the FDA.

The average tariff rate for Medical equipment is 3 percent plus a 12 percent value-added tax (VAT). The VAT is based on the valuation determined by the Bureau of Customs for the application of customs duties, plus those duties themselves, excise taxes, and other charges (i.e., charges on imports prior to release from customs custody, demurrage fees, including insurance and commissions).

The Bureau of Customs (BOC) is responsible for customs valuation, classification, and clearance functions.

Current Market Trends

Public hospitals tend to place a greater emphasis on preventive healthcare, while private hospitals concentrate on curative services. Private hospitals have traditionally been equipped with more sophisticated medical equipment due to their larger budgets.

Incidence rates for hypertension and heart diseases, lung and kidney diseases, and other respiratory diseases have remained high. To address the problem, most hospital improvements concentrate on specialized services for radiology, cardiac, lung and kidney examinations, and pathology; thus, demand for ECGs, CT Scans, X-ray and Dialysis machines, and other laboratory instruments should grow.

Main Competitors

The U.S. performs well with high value, low volume medical equipment such as ultrasound equipment, magnetic resonance imaging (MRI) equipment, breathing equipment, and other

radiology and electronic medical equipment. U.S. manufacturers, however, face increasing competition from third country suppliers such as China, Singapore, Japan, and Germany.

Current Demand

Besides linear accelerators, electro-cardiographs, ultrasonic scanning machines (ultrasound), magnetic resonance imaging (MRI) equipment, x-ray and radiation equipment, breathing appliances, and computed tomography apparatus (CT scan) continue to be the most promising subsectors for U.S. manufacturers. There is also a demand for clinical laboratory devices, supplies, and biological rapid test kits.

About 25 public hospitals expect to receive a boost out of the government's Public-Private Partnership (PPP) program. The first beneficiary is the Philippine Orthopedic Hospital, which PPP intends to transform into the country's primary center for bone and joint diseases at par with global standards.

Requirements for efficient healthcare services, new technology, and equipment replacement should drive market growth. All hospitals must continue upgrading facilities to remain competitive.

Some requirements of the hospitals under the PPP program are linear accelerators for eight cancer centers being proposed, dialysis units, various imaging equipment, and devices for treating kidney, heart, respiratory, and diabetes diseases.

Medical device distributors expect an average 10 percent growth through 2016, which is also when the current administration ends.

Registration Process

Foreign suppliers usually appoint a licensed distributor to represent their interests in the Philippines. Usually, the distributors handle all aspects of importation from registration of the products, to obtaining a license and a clearance. Distributors become responsible for the equipment (capability, safety, market performance, and after-sales service) and, thus, prefer exclusive contracts with foreign suppliers.

The Center for Device Regulation, Radiation Health and Research (CDRRHR) was created to oversee the regulation of medical equipment and devices. While waiting for the new guidelines to be developed and approved, the CDRRHR issues a Certificate of Exemption for all medical devices that are not yet required for mandatory registration. The requirements for the Certificate of Exemption include:

- Letter of intent
- Brochure of the product with product profile (intended use, etc.)
- Sample (only when necessary)

A Certificate of Exemption costs 500 pesos (approximately USD 12.00) per product.

The foreign company must provide complete documentation for its equipment to the distributor who will register them. Complete and correct documentation determines the outcome of registration and the length of registration process.

Barriers

There are no barriers to the sale or purchase of medical equipment of acceptable international standards.

Trade Events

No local trade shows dedicated to the medical industry.

Trade Associations

- Country Commercial Guide (2014)

Poland

Summary

Poland, the sixth largest country in the European Union with a population of 38 million people, represents one of the biggest health care markets in Central/ Eastern Europe. That stated, the healthcare sector in Poland has been in a somewhat challenging financial condition of late, and the short-term outlook in the public healthcare sector (the largest sector of health care in Poland) remains tentative.

Since 1999, the Polish health care sector has gone through several unsuccessful attempts at reform. It was expected that the current government will prepare and Parliament will pass major amendments to the existing Health Care Law and Regulations. To date only the new Reimbursement Act has been announced. It has been in force since January 1, 2012. Although it is considered to be revolutionary for the Polish healthcare system, it is still quite controversial. Once the major new healthcare laws become the legal basis as established legislative reform, U.S. Commercial Service Warsaw foresees major opportunities for U.S. companies in the healthcare-medical market. However, it is difficult to make any tangible predictions.

The most common causes of death in Poland are cardiovascular disease (45 percent), cancer (26 percent), injuries and accidents (7 percent). Also, contagious diseases, especially hepatitis and sepsis, are an important concern. In addition, there is a growing concern with health problems associated with the aging Polish population.

Polish manufacturers are not very competitive because they lack the latest technology, efficient production methods, investment capital, and appropriate marketing resources. Therefore, medical equipment represents a good prospect for foreign suppliers. However, U.S. medical equipment manufacturers face strong competition from European companies in particular. EU suppliers increased market share due to their competitive prices as well as availability of EU assistance

Statistics

Capital:	Warsaw
Population:	38 million
GDP (USD):	517.54 billion (2013)
Currency:	Zloty (PLN)
Language:	Polish

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packages for Poland. Poland imports medical equipment primarily from Western Europe (Germany, Netherlands, Austria, France, Switzerland, and United Kingdom), the United States, and Asia (Japan and China).

In general, U.S. suppliers of medical products have a good reputation for high quality products. However, technological advantage is not the only factor determining success in the Polish market. Therefore, U.S. companies should focus on educating end-users and other players in the health care sector. A successful exporter should strongly support its agent/representative with marketing strategies.

Market Entry

The medical market in Poland is a relatively difficult market to enter in most cases. Generally, niche and inexpensive products have a greater chance for success. Price is a more important factor than quality in Poland's health care market. The second factor is local availability of service and spare parts. Quality is usually the third element considered by most potential buyers of imported medical devices. Another sale-making factor is quick delivery.

Introducing new products successfully requires a considerable investment in time and expense. Extensive marketing and educational campaigns are recommended for widespread adoption into the marketplace. Polish agents/distributors expect foreign manufacturers to help extensively with marketing expenditures to promote awareness of new products at medical trade shows, seminars and conferences. Operational capital is limited in Poland, even among some larger, more successful Polish suppliers of medical products.

In Poland, medical recommendations are the major source of information on healthcare/medical products and medicines, so a good marketing strategy is to keep doctors well informed about new products. In addition, doctors obtain information from medical conferences and seminars, and expect educated agents/representatives to answer customer questions in order to help them buy the product that meets their needs.

Medical equipment and supplies for the public hospitals are purchased through a competitive bidding process. All tenders are announced in a public procurement bulletin. Private clinics can purchase medical equipment and supplies from any sources they wish or through any trading organization they choose. In spite of the poor financial condition in the health care sector, medical equipment purchases are made but no specific buying pattern has been identified.

Current Market Trends

The latest restructuring of public health care in Poland resulted in establishment of short-term and outpatient facilities. This change required implementation of advanced diagnostic techniques and new surgical procedures that, in turn, created a demand for new equipment. Also, the development of private health care sector in Poland created a need for equipment

not only for general and specialty practice consulting offices, but also for one-day-clinics and private hospitals.

The best prospects for U.S. suppliers are in sophisticated diagnostic equipment, patient-monitoring systems, surgery equipment (high-tech surgical devices and mini invasive surgery equipment), oncology and nuclear medicine, and cardiovascular surgical devices. Advanced diagnostic and operating rooms medical equipment also has market potential, especially equipment that increases efficiency and reduces occupancy rates in hospitals and medical clinics. The need for medical home-care for the increasing elderly population in Poland also brings prospects for the U.S. medical equipment market. The increasing elderly population reinforces the demand for all kinds of equipment and aid-supplies used by nurses and families for home-care. Also, the hygiene sub-sector represents good prospects. Patient and medical personnel safety is of growing concern to both members of the medical profession and the Polish public. Best sales prospects will certainly focus around assuring stringent personnel safety requirements. This is especially due to the concern regarding hepatitis, sepsis and other contagious diseases. In the near future, prevention should receive similar emphasis considering the present focus on protection.

Main Competitors

The Polish medical equipment market is growing rapidly and in many directions. This is both due to a growing internal market and the companies themselves, which become increasingly competitive and expand to overseas markets. The major export products manufactured by the Polish medical equipment industry include bio-electronic apparatus, operating theatre equipment, rehabilitation equipment, furniture for medical facilities, surgical instruments and devices using medical imaging technologies. One of the most thriving branches of the industry comprises producers of bio-electronic equipment, which is used for vital functions monitoring (patient monitors, defibrillators with the function of monitoring and data transmission, ECG equipment, Holter recorders, spirometers, etc.). Monitoring devices are also offered as network solutions which integrate separate devices into a central monitoring system.

However, imports remain a fundamental component of the local medical equipment market. About two third of all medical equipment used in Poland is imported. Therefore, medical equipment represents a good prospect for foreign suppliers. Though, U.S. medical equipment manufacturers face strong competition from European companies in particular. EU suppliers increased market share due to their competitive prices as well as availability of EU assistance packages for Poland. Poland imports medical equipment primarily from Western Europe (Germany, Netherlands, Austria, France, Switzerland, and United Kingdom), the United States, and Asia (Japan and China).

Current Demand

According to the latest accounts from PMR Research (***research-pmr.com***), the value of medical device market exceeded 6.5 billion PLN in 2013. By large, it was driven by imports and the European Union requirement defined in the EU Regulation of February 2011 on sanitary standards and equipment standards required in hospitals and other health care facilities, and availability of EU funds. In the first quarter of 2014 however, the Polish medical market registered much slower growth. Therefore, PRM estimates that this year the market growth will not exceed 3 percent and 4.13 billion PLN in value.

The predictions published in May 2014 by the Polish Chamber of Medical Industry (POLMED, ***polmed.org.pl***), the largest organization representing manufacturers and distributors of medical products in Poland, are less optimistic than in previous years.

This considerable correction to previous estimates calling for a high annual growth rate in years 2013–16 is linked directly to certain budgetary restrictions and managerial problems within the Polish public health system including the medical equipment reimbursement regulations, lower number of public tenders, and increase in hospitals' debts.

In Poland, the end-users of medical equipment are the service providers themselves. Service providers include public hospitals (the largest sector of health care in Poland), private clinics, and private doctor's offices. One should take into account the difference between the average patient in a private clinic and the average patient of public hospitals and medical facilities. The public sector receives annual funding for equipment purchases and medical supplies including drugs. Private institutions try to maintain a stock of products based on supply and demand, and generally respond better to a new technology or innovation if it is well marketed.

Barriers

As Poland is a member of the European Union, import regulations for medical equipment are harmonized with the European Union's Medical Device Directives, which cover essential safety, health and environmental requirements. Products manufactured to standards adopted by European standards organizations, and published in the Official Journal as harmonized standards, are presumed to conform to the requirements of EU Directives. The manufacturer then applies the CE Mark and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the European Union.

There are no restrictions in Poland on sales or the importation of used medical equipment by either state-owned or private medical facilities but market opportunities for used medical equipment is relatively small. Medical equipment for the public hospitals is purchased through a competitive bidding process.

All tenders are announced in a public procurement bulletin "Biuletyn Zamowien Publicznych" issued by the Public Procurement Office (***bit.ly/1o7h6dz***). Private clinics can purchase medical

equipment from any sources they wish or through any trading organizations they choose but no specific buying pattern has been identified. Leasing of medical equipment has become more and more popular in Poland, especially among an increasing number of private clinics and private medical facilities.

Trade Events

CEDE

September 11–13, 2014 • Poznan, Poland • ***cede.pl/?lang=en***
Conference and exhibition for the dental industry sector, held annually.

EXPODENT

October 17–18, 2014 • Torun, Poland • ***expo-andre.pl***
The National Dental Conference and Trade Fair.

REHMED-PLUS EXPO

TBD 2015 • Kielce, Poland • ***targikielce.pl/index.html?k=rehmed_en***
The Trade Fair of Rehabilitation, Therapy, and SPA/Wellness Medical Equipment.

SALMED

TBD 2016 • Poznan, Poland • ***salmed.pl/en***
Poland's largest event for the healthcare/medical industry sector. Held biannually.

Portugal

Summary

Over 80 percent of medical equipment expenditures are made by the public sector, while 20 percent of sales are made to the private sector in Portugal. The market for medical equipment has improved in recent years and is expected to present increased business opportunities for U.S. exporters in the future. Prices are considered to be of primary importance in all purchasing decisions, both by the public and private sectors.

Market Entry

In order to enter the medical equipment market in Portugal, U.S. suppliers should be familiar with the EU directives concerning the registration, marketing, and health/safety standards required throughout Europe as well as regulations specific to Portugal. It is therefore advisable to work with a local partner/distributor.

Current Market Trends

The Portuguese market for medical equipment is mature and presents a high level of sophistication. Portuguese are educated consumers and expect state-of-the-art medical treatment, which ensures continuous demand for innovative medical equipment and products. One of the prime characteristics of this market is its high level of imports. Total annual expenditures for new equipment are determined in the annual budgets of hospitals. These budgets are prepared according to estimates based on the previous year. The market is very receptive to U.S. products. A considerable portion of the market is penetrated by foreign products and imports from the United States are considered to be very competitive.

Statistics

Capital:	Lisbon
Population:	10.8 million
GDP (USD):	238 billion
Currency:	Euro (EUR/€)
Language:	Portuguese

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Main Competitors

Some of the major U.S. companies with offices and distribution of their products in the Portugal include GE Medical Systems, 3M, and Johnson & Johnson medical. Siemens and Philips also have a strong presence in the country.

Portugal has approximately 290 companies distributing medical products largely comprised of small or medium-sized companies employing on average 15 to 60 people.

Current Demand

High-quality and technically sophisticated medical equipment has the best market potential in Portugal, especially equipment that increases efficiency and reduces occupancy rates in hospitals. In Portugal, imports are a fundamental component of the Portuguese medical equipment market. Major suppliers are the United States, Germany, France and Japan.

Best prospects include:

- Surgery equipment
- Patient monitoring systems
- Mini invasive surgery (MIS) equipment
- Video endoscopes
- X-Ray equipment
- Digital image processing
- Magnetic resonance imaging (MRI) equipment
- Picture archiving systems

Barriers

There are no significant barriers on U.S. medical devices or products.

Trade Events

No major local trade events. Portuguese buyers frequently attend Germany's annual Medica trade show.

Romania

Summary

Healthcare in Romania is dominated by the public sector, which owns most of the hospitals and provides national health insurance to almost all Romanian citizens. The public healthcare system includes national health insurance, covering almost all Romanian citizens, as well as a growing and parallel network of private healthcare. The top 10 private clinics account for 35 percent of the private market, with the remainder made up of smaller clinics and laboratories, and individual medical practices.

According to the Government Program 2013–16, the Ministry of Health is committed to achieving structural reforms in health care to enhance the efficiency, quality and accessibility of the system, especially for the disadvantaged and remote and isolated communities and in the same time to reduce excessive reliance on hospitalization of patients, including improving outpatient services. There are additional opportunities in newly approved projects by the government of Romania in line with the National Health Strategy 2014–20, referring to the two important projects: rural telemedicine and improving health system quality and efficiency.

The market for medical devices, dental products and high technology diagnostic imaging equipment in Romania has excellent prospects for growth. The medical equipment market will continue to grow in the coming years as a result of increased demand, the development of local production, and the need to meet European quality standards and growing imports.

Statistics

Capital:	Bucharest
Population:	20.3 million
GDP (USD):	179.92 billion (2013)
Currency:	Romanian leu (RON)
Language:	Romanian

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The Ministry of Health intends to continue the Government Program 2013–16 on the provision of equipment and medical instruments to health care units:

- Endowment of health care units within the health network of the Ministry of Health and local authorities with necessary equipment and medical instruments, to meet the requirements of Health Minister order no. 914/2006 (on the standards for authorization and accreditation of hospitals);
- Provision of specific emergency transportation response equipment (ambulances, non-emergency transportation vehicles and helicopters);
- Equipping regional radiotherapy centers;
- Creating and equipping mobile screening units for oncological diseases;
- Upgrading and extending the national telemedicine emergency system;
- Equipment of specialized centers for outpatient diagnosis and treatment (diagnostic imaging, day surgery, cancer diagnosis, mobile screening units)
- Rehabilitation and equipment of public health surveillance labs (infectious diseases, radiation, drinking and bath water, etc.)

Market Entry

The U.S. companies wishing to enter the Romanian market must refer to the European Union legislation concerning the registration, marketing and safety standards required throughout EU. In addition it is advisable to check as well the national specific legislation that might apply. It is recommended to have a local distribution partner.

The Romanian market will most likely remain heavily reliant on imports (around 90 percent) as the domestic industry mainly produces outdated equipment that can only compete with foreign products in terms of price. Import growth is expected to continue due to insufficient high-tech equipment and acute need for renovation within hospitals.

Current Market Trends

The Romanian healthcare industry has high growth potential and there are sufficient human resources providing opportunities for local or foreign investors. A major drawback, however, is that the public sector does not provide support for the development of the healthcare industry. The legal framework and regulations are poor and, although suggestions come from the private sector, implementation takes time and is not always efficient. The public sector is in a difficult financial position and lacks the necessary resources for investment in this industry. Late payments (up to 300 days) slow down the growth rate.

The medical device market, estimated at USD 478 mil, contracted by 2.5 percent over the 2008–13 period, but it is expected to grow by 4 percent over the 2013–18 in line with economic growth and rising health expenditure, reaching USD 591 mil by 2018.

Romania's market for imaging parts and accessories was estimated at USD 39 mil in 2013, representing 31 percent of the overall diagnostic imaging market. This sector is expected continue its growth and 10 percent increase is foreseen for the period of 2013–18. The market is expected to reach USD 166 mil in 2018. The market for electro-diagnostic products including ECGs, ultrasound, patient monitoring, MRI and other electro-diagnostic equipment was estimated at USD 63 mil in 2013. Ultrasound equipment is the largest category within the electro-diagnostic products sector, with sales of USD 34 mil in 2013.

Main Competitors

Currently, over 100 medical equipment companies are active in the Romanian market, with the most important distributors coming from the US, Germany, Italy, France, Japan, China, Turkey and Switzerland. Among them are big names such as GE Healthcare, Roche, Johnson & Johnson, Olympus, Nihon Kohden, Greiner, Becton Dickinson, Beckman Coulter, Bioomerieux, Trinity Biotech and Oxoid. Annual exports of Romanian medical equipment are valued at approximately USD 30 million, with orthopedic equipment taking up the lion's share. The countries that import this equipment are Italy, Germany, France, Denmark, and Bulgaria.

Current Demand

The newly approved health project will support the 2014–2020 National Health Strategy focusing on three areas: hospital network rationalization, ambulatory care strengthening, and health sector governance and stewardship improvement.

For 2014, the Ministry of Health will continue to invest in improving the medical sector, however at a lower rate. Considering the top priorities, investments will focus in acquiring high-tech equipment such as RMN's, Angiographs and Radiotherapy equipment.

Hospital Network Rationalization (USD 249.3 million)

Will support the rationalization of the health care service delivery network by strengthening key hospitals that will become the backbone of the hospital networks. The Project will support selected medical services in seven regional emergency hospitals, 44 county hospitals and approximately 15 zonal hospitals. The component would finance civil works (within the facilities' current sites/rehabilitation), medical and other equipment, technical assistance, and training

Ambulatory Care Strengthening (USD 66.4 million)

Will support secondary ambulatory and primary care through two subcomponents. It will finance civil works, technical assistance, equipment, and training.

Health Sector Governance and Stewardship Improvement (USD 13.6 million)

Will support sector governance and stewardship improvements to bridge the gap between policy and practice and to increase the capacity for conducting and improving the quality of medical care services. This component would finance technical assistance, equipment, communications services, and training.

Barriers

For information on existing trade barriers, please see the National Trade Estimate Report on Foreign Trade Barriers, published by USTR and available at ***go.usa.gov/Df6T***.

Trade Events

ROMMEDICA

March 2015 • ***rommedica.ro/home***

International exhibition of medical equipment and Instruments.

ROMPHARMA

April 2015

International exhibition of medicine for human and veterinary applications.

ROMOPTIK

April 2015

International exhibition for optical equipment and apparatus.

DENTA

November 2015 • ***denta.ro/home***

International exhibition of equipment, instruments, accessories, materials, and chemical-pharmaceutical products for optical equipment and apparatus.

Russia

Summary

The Russian medical equipment and supply market is one of the fastest growing sectors of the economy. There is an unsatisfied deferred demand for medical equipment across the country. The Russian government is the largest provider of medical care through a national healthcare system, and hence decides which medical equipment to buy for the country. This fact shapes the demand for medical technology and products.

Market Entry

Companies attempting to enter the Russian market should be willing to:

- Commit time, personnel, and capital, as developing business in Russia can be resource-intensive.
- Conduct market research, such as the CS Gold Key or International Partner Search, to help identify opportunities and potential business partners.
- Conduct due diligence, with actions and programs such as the CS International Company Profile service, to find reliable business partners.
- Consult with U.S. companies already present in the market, as well as with the U.S. Commercial Service and business organizations such as the American Chamber of Commerce in Russia and the U.S.–Russia Business Council.
- Communicate regularly with Russian business partners to ensure common understanding of expectations.
- Frequently travel to Russia to establish and maintain relationships with partners, build rapport, and keep abreast of changing market conditions.
- Maintain a long-term thought process to implement solid-laid plans and achieve positive results.

Statistics

Capital:	Moscow
Population:	143 million
GDP (USD):	1.86 trillion
Currency:	Russian ruble (RUB)
Language:	Russian

Contact

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Current Market Trends

Russia instituted a comprehensive reform of its healthcare system, and healthcare is "Priority #1" among the government's national priority projects. Russia's healthcare system is rapidly evolving, which is creating many promising areas for U.S. medical equipment exports. It is currently estimated that only 20 percent of the Russian population of 142 million has access to quality healthcare. The majority of hospitals and polyclinics are public and belong to federal, regional, or local governments.

At the moment, the two major sources of public healthcare funding—mandatory insurance funds (30 percent) and spending supported by federal and regional budgets (70 percent)—do not cover all healthcare expenses. As a result, a significant portion of overall (public and private) healthcare spending (about 20 percent) is covered out of the patients' pockets. Voluntary healthcare insurance programs account for approximately one-third of total private healthcare expenditures. According to long-term reform plans, mandatory insurance funds will serve as the main source of healthcare funding and should provide transparency and control over cash flow within the system.

According to *Healthcare through 2020*, a document developed by the Ministry of Healthcare and Social Development, Russian citizens will begin to receive higher quality medical care which will be standardized throughout Russia. It states that there will be new and effective medical procedures introduced and that new medical equipment will be supplied to institutions. However, there are significant downward pressures on the Russian government budgets and it remains to be seen whether these goals will be reached. Russia has joined the WTO, which should lower tariffs for medical equipment from the present 15 percent to between 0–7 percent.

Russian Medical Equipment Market, 2012–14

(USD Billions)	2012	2013	2014 (est.)
Total Market Size	3,800,000	4,060,000	4,200,000
Total Local Production	620,000	700,000	800,000
Total Exports	140,000	170,000	220,000
Total Imports	3,320,000	3,530,000	3,620,000
Imports from the U.S.	200,000	300,000	400,000

Source: Korea Medical Devices Industry Association (KMDIA)

Currently, almost two-thirds of the medical equipment and devices being used in public clinics and hospitals are obsolete and need replacement. There are two major issues that the Russian healthcare system faces; Healthcare facilities are in very poor condition. According to data from the Russian Federal Statistic Service, 2 percent of medical facilities are in hazardous condition, 8.5 percent do not have cold and hot water, 32.5 percent do not have hot water,

more than 10 percent do not have central heating, 11.2 percent do not have a sewage system, and 6.7 percent do not have telephone connections. In order to solve these problems, the regional parts of the budgets allocated for modernization will be used. Secondly, new medical equipment terribly needed for those medical facilities to be brought up to par—a positive factor is that this will drive the demand for medical equipment.

The Russian government is aggressively seeking to increase the amount of medical equipment manufactured by Russian producers. Specifically, foreign manufacturers of medical equipment currently selling to the Russian government are strongly encouraged to "localize" production for medical devices and pharmaceuticals. If a company fails to demonstrate a sufficient percentage of local content, it may be disadvantaged in Russian government tenders or disqualified altogether. Previously, the Russian government had accepted packaging of products in Russia as meeting a minimal requirement for local content. However, that understanding will expire in 2015 after which the GoR will require more substantial investment in manufacturing or research and development. Foreign medical device and pharmaceutical companies have expressed that meeting these requirements will be highly disruptive, challenging, and perhaps not commercially viable.

Russian government organizations are the main users of medical equipment; approximately 80 percent of medical equipment is sold to them. Private hospitals and patients represent the other 20 percent. Because of that uneven distribution, government procurement programs ("tenders") play a crucial role in this market but are difficult to gain access to bid on them.

Main Competitors

According to several sources, imported medical devices constitute 60 percent of the Russian market. Statistical data show that 40–45 percent of imports come from Germany, 20–25 percent from the United States, 10 percent from Japan, and 5 percent each from Italy and France. For the last three years, a growing number of cheap analogs from China and Pakistan have entered the Russian market in large volumes.

Current Demand

Russia is still dependent on imports for a significant number of medical equipment industry sub-sectors, especially those requiring large investments in research and development (Research and development), innovative technologies, and automation. The most promising market segments include diagnostics and visualization, cardiovascular, ophthalmology, orthopedics, laboratory diagnostics, and urology equipment and technology

Registration Process

All medical equipment manufactured in Russia or abroad needs to be registered and certified in order to pass through customs, be sold, and used in Russia.

Required documents include a Registration Certificate, issued by the Federal Service of Health Care and Social Development Control and valid indefinitely. It act as permission for the product to be introduced to the market. Establishes the OKP code (Russian product classification system), in accordance with which the VAT rate is determined for customs clearance of the product—either 0 percent or 10 percent (the standard VAT rate is 18 percent);

Companies should treat seriously threats to Intellectual Property and take steps to protect their IPR. Existing Russian legislation, when adequate, is not enforced effectively or consistently.

Before starting the process of registration, a manufacturer of medical equipment should keep in mind that the process itself is costly and complicated since the regulatory procedures continuously change and are written only in Russian. It is highly recommended that U.S. companies work through a Russian representative, subsidiary, Russian distributor, or a specialized consulting company to navigate this difficult process.

Barriers

Despite positive changes in the last several years, the medical standards regime in Russia still lacks transparency. FDA approval is not accepted here and Russia continues to rely on product testing as a key element of the product approval process. Other types of product safety assurance, such as plant auditing, quality systems, and post market vigilance are still underdeveloped. Russia continues to follow redundant practices for the testing of internationally accepted certified products, which can delay the entry of products into the country. Problems with customs can also be a factor here.

Trade Events

Zdravookhranenie

December 8–12, 2014 • Moscow, Russia • ***zdravo-expo.ru/en***
International exhibition of medical equipment and drugs.

Saudi Arabia

Summary

The Saudi health care sector remains the largest in the Near East North Africa region. Total spending on health care is estimated at USD 20 billion per year, with the Ministry of Health accounting for about 60 percent, other government entities at 19 percent and the private sector representing the balance. Medical devices expenditures represented 15 percent and pharmaceuticals at 25 percent. The 2014 budget allocated to the health care sector increased 8 percent, from USD 15.18 billion in 2013 to USD 16.5 billion in 2014. The budget included the construction of new primary care centers, 11 new hospitals, two medical cities and about 20 medical centers and polyclinics. In 2013, the Ministry completed the construction of 16 new hospitals with a capacity of more than 3,700 beds.

Market Entry

Although 100 percent foreign ownership is allowed, it is advisable that U.S. companies designate a local agent/representative to conduct business in Saudi Arabia. It is also advised that companies work with local legal counsel when drawing up a contractual agreement. Shari'a courts are the courts of general jurisdiction in the Saudi judicial system, and these courts review all foreign court decisions to ensure consistency with Shari'a law.

Medical equipment is charged a 5 percent customs duty; in some instances, however, imported equipment is exempted, notably if the shipment is bound for a government entity and/or a government project.

Current Market Trends

The public sector dominates the supply oThe public sector dominates the supply of health care services in Saudi Arabia and account for the majority of health care expenditures. The public health care sector approximately represents 79 percent of bed capacity. Industry sources expect the government sector to outpace the

Statistics

Capital:	Riyadh
Population:	30.18 million (est. 2013)
GDP (USD):	745.3 billion (est. 2013)
Currency:	Saudi riyal (SAR)
Language:	Arabic (official)

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private sector in the level of investments and beds capacity. The latest figures suggest that the MoH bed capacity will almost double to 73,768 beds by 2020, the private sector will add 13,875 beds raising its capacity to 26,000 by 2020, while other government organizations will total 20,000 beds in 2020.

As of 2012, Saudi Arabia had 2.2 hospital beds per 1,000 residents, lower than the global average of 3.0, which mirrors the government drive to reform the sector, building hundreds of hospitals and providing interest-free loans to private entities. Additionally, a Royal Decree No. 6560 dated 23 January 2014 instructs the Saudi Arabian General Investment Authority (SAGIA) and the MoH to develop strategic plans to stimulate foreign investments in the Saudi health care sector. Part of this investment strategy will be to attract foreign investments in the construction, operation and management of hospitals, which expects to add more than 34,000 beds by 2020.

Notwithstanding, the Saudi government's ninth five-year development plan (2010–14) stipulates several objectives:

- Increase the number of hospital beds to reach 97,535 by 2014, about 58 percent for the MOH, 21 percent for the private sector, and the balance for other government entities
- Increase the number of Primary Health Care Center to 2,958 by 2014, and,
- Reduce infant mortality rate to under 12 per 1,000 live births

Morbidity and mortality statistics reflect that major diseases in Saudi Arabia include diabetes, respiratory infections, and cardiovascular disease. Recent trends also reflect an increasing rate of oncology patients—especially health services to combat breast cancer.

- Over 30 percent of the population is classified as overweight
- Asthma affects 10–15 percent of children
- More than 22 percent of the population are regular smokers
- Growing prevalence of cancer patients, 52.7 per 100,000
- Heart disease increasing an average 5.3 percent annually
- An estimated 17 percent of the population is diabetic

The Saudi pharmaceutical market is highly dependent on imported drugs: 80 percent of the market is accounted for by imports. Pharmaceutical sales are expected to top USD 5 billion in 2014, growing an average of 10 percent annually. Over 70 percent of all prescription drugs sold in Saudi Arabia is patented drugs.

Main Competitors

The Saudi market is completely dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate. European

suppliers are aggressively gaining market share with their close proximity to the market and perceived better customer support.

On the other hand, the pharmaceuticals sector is characterized by a growing domestic manufacturing base, mainly for generic and OTC drugs, as well as licensing arrangements with branded research-based foreign innovative drug manufacturing firms.

The Saudi domestic pharmaceutical industry lacks Research and development capabilities, and it remains focused on producing basic formulations of off-patent preparations to feed into the generics market. The lack of Research and development is compounded by an unpredictable IPR regulatory system and, recently a vague pricing structure, which is affecting the introduction of many new research-based products into the market.

Nonetheless, government policies are biased in favor of domestic producers, providing them with exemptions, including interest-free funding, subsidized utility charges, and no import duties on raw materials and intermediate products. Industry sources expect domestic production to grow to USD 1 billion in 2014, accounting for about 20 percent of the total pharmaceutical market.

Current Demand

Total health care expenditures are estimated to be USD 20 billion in 2014, but growing an average of 11 percent annually. The demand for health care services has continuously outgrown supply and both the public and private sectors are struggling to accommodate growing demand. A growing population, compulsory health insurance coverage, and the prevalence of diseases that strike the affluent are serving to boost the demand for services and hospital bed occupancy. Today, the overwhelming majority of Saudi Arabia's 8.4 million health insurance holders are expatriates. The insurance reform could swell the pool with more than a million Saudi civil servants plus about five million dependents.

In addition to the Ministry of Health projects, other government organizations also have plans to build new hospitals and/or expand existing ones, including:

- The Ministry of Higher Education plans to build 20 teaching hospitals
- The Ministry of Interior plans to build two 1400-bed medical cities/complexes in Riyadh and Jeddah
- Supply of a Hospital Information System for the Medical Services Department at the Royal Commission for Jubail & Yanbu

Major players in the Saudi health care sector include (by expenditures):

- Ministry of Health
- Saudi Arabian National Guard
- Ministry of Defense and Aviation
- Ministry of Higher Education
- Ministry of Interior
- General Organization for Social Insurance
- Royal Clinics
- John Hopkins Aramco Helathcare
- Private Sector
- Executive Board of the Health of the Health Ministers Council for the GCC States

Registration Process

The Saudi Food and Drug Authority (SFDA) monitors and controls the import and distribution of medical devices, pharmaceuticals, and food products. For medical devices, the SFDA will usually accept, register, and authorize the marketing and sale of any device that complies with applicable provisions of the SFDA's Interim Regulations and relevant regulatory requirements applicable in one or more of the countries of the Global Harmonization Task Force (GHTF), which includes Australia, Canada, Japan, USA, and EU/EFTA. More information on the registration process can be found at ***sfda.gov.sa/en***.

Barriers

Commercial Dispute Settlement

The enforcement of foreign arbitration awards for private sector disputes has yet to be upheld in practice. Each arbitration award or legal decision must be reviewed—in effect, retried—in a local court, a process that can take years. Furthermore, government agencies are not allowed to agree to international arbitration without approval from the Council of Ministers, which is rarely granted.

In October 2007, King Abdullah issued a royal decree to overhaul the Kingdom's judicial system, including allocating SAR 7 billion (approximately USD 1.9 billion) to train judges and build new courts. The decree establishes two Supreme Courts, a general court and an administrative court, and specialized labor and commercial tribunals, although implementation has been slow. On February 4, 2009, the King reshuffled the government, appointing a new Minister of Justice, a new President of the Board of Grievances, and a new Chairman of the Supreme Judicial Council. Industry sources expect the reshuffle to expedite the overhaul of the Kingdom's judicial system.

Business Visas

All visitors to Saudi Arabia must have a Saudi sponsor in order to obtain a business visa to enter Saudi Arabia. On the positive side, in May 2008, the United States and Saudi Arabia

signed an agreement to grant reciprocal 5-year, multiple-entry visas for business travelers. This agreement represents a significant step forward in the visa process.

Intellectual Property Protection

Intellectual property protection has steadily increased in the Kingdom. Over the last seven years, Saudi Arabia has comprehensively revised its laws covering intellectual property rights to bring them in line with the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The Saudi government undertook the revisions as part of Saudi Arabia's accession to the WTO, and promulgated them in coordination with the World Intellectual Property Organization (WIPO). The Saudi government updated its Trademark Law (2002), Copyright Law (2003), and Patent Law (2004), with the dual goals of TRIPs-compliance and effective deterrence against violators. In 2008 the Violations Review Committee created a website and has populated it with information on current cases. The patent office continues to build its capacity through training, and has streamlined its procedures, hired more staff, and reduced its backlog.

In September 2009, the King approved a mechanism to protect Exclusive Marketing Rights (EMR) for certain pharmaceutical products which lost patent protection when Saudi Arabia transitioned to a new TRIPS-compliant patent law in 2004. The Saudi Ministerial Council in December 2009 approved the Kingdom's accession to both the Intellectual Property Owners Association Patent Cooperation Treaty (PCT) and its Implementing Regulations and the Patent Law Treaty (PLT) adopted by the Diplomatic Conference in Geneva on June 1, 2000. The Council of Ministers issued a resolution on 23/11/1428H (December 3, 2007) approving the Law of Trademarks for GCC countries.

Counterfeiting

Although anti-counterfeiting laws exist, manufacturers of consumer products and automobile spare parts are particularly concerned about the widespread availability of counterfeit products in Saudi Arabia. The Saudi government remains committed to stopping counterfeit products from entering into the country.

Arab League Boycott

The Gulf Cooperation Council (GCC: Saudi Arabia, Kuwait, Bahrain, Oman, Qatar, and the United Arab Emirates) announced in the fall of 1994 that its members would no longer enforce the secondary and tertiary aspects of the Arab League boycott. The primary boycott against Israeli companies and products still applies.

Government Procurement

Government contracts on project implementation and procurement strongly favor Saudi and GCC nationals. However, most Saudi defense contracts are negotiated outside these regulations on a case-by-case basis. Saudi Arabia published its revised government

procurement procedures in August 2006. Foreign suppliers participating in government procurement are required to establish a training program for Saudi nationals.

Shipping

Saudi Arabia gives preference to national carriers for up to 40 percent of government-related cargos. Two local companies take full advantage of this situation.

Standards and Labeling

As part of the GCC Customs Union, the six member states are working toward unifying their standards and conformity assessment systems. However, each member state continues to apply its own standard or a GCC standard. A new ICCP mandates that a Certificate of Conformity must accompany all consumer goods exported to Saudi Arabia. Labeling and marking requirements are compulsory for any products exported to Saudi Arabia.

Trade Events

Saudi Health Exhibition and Conference 2015

May 18–20, 2014 • Riyadh, Saudi Arabia

Showcasing the latest products, technology, and services. This is the only event with the full support of the Ministry of Health, and will cover the full spectrum of healthcare.

Available Market Research

- Country Commercial Guide (2014)

Singapore

Summary

According to the World Health Organization (WHO), Singapore's healthcare system ranks sixth globally and offers the 4th best healthcare infrastructure in the world. It also serves as the healthcare and medical hub of the region and is arguably Asia's best healthcare system. Demand for healthcare in Singapore is set to grow as the population increases and ages. The island state's population is likely to increase to 5.5 million by 2020. Demand for state of the art medical technologies is also expected to grow as Singapore strengthens its reputation as the region's healthcare hub and center for healthcare excellence offering first class healthcare delivery systems and facilities to both its resident population and the international patient market.

Singapore serves as a showcase for healthcare delivery and medical technology and is considered the gateway to the regional economies of South East Asia. The three key healthcare strategies Singapore is pursuing are clinical research, improving long-term care and moving towards more sophisticated care.

The national healthcare plan covers almost 100 percent of the population. This augurs well for the healthcare industry as Singaporeans all have access to medical care.

Market Entry

U.S. companies who are new to the market and interested in exporting to Singapore may consider appointing a local distributor to represent their company's product and services. Given the small market size of the island state, most potential distributors would request exclusive rights to sell the product. They will also likely ask for distribution rights for the regional South East Asia countries as Singapore serves as a gateway into the region. U.S. exporters of medical equipment should evaluate the suitability of the distributor based on the company's contacts in the market, their product range and whether their products

Statistics

Population:	5.31 million
GDP (USD):	296 billion
Currency:	Singapore Dollar (SGD)
Language:	English (business); Mandarin, Malay, Tamil

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complement that of the U.S. firm. As the sales in the local market increases, the U.S. firm can look into setting up an on-going presence in Singapore much like how some large MNCs have set up regional offices in Singapore. This brings the U.S. firm closer to their customers, demonstrates their commitment to the region and allows for prompt and enhanced customer service.

Current Market Trends

Singapore's public hospitals and specialty centers engage in clinical research with the many pharmaceutical, biotechnology and medical technology companies based in Singapore. Singapore's goal is to become Asia's premier healthcare hub via the attraction of foreign patients. There is also an emphasis towards a healthy lifestyle and a focus on preventive care.

Doctors here are also pushing ethical and professional standards, and it is expected that every major hospital in Singapore will have attained the widely recognized U.S. mark of quality health care. Already, the majority of private and public sector hospitals have been accredited by the Joint Commission International (JCI), the overseas arm of the United States' main hospital accreditation agency.

Main Competitors

Major competitors of the U.S. are medical devices from Germany, other European economies, Japan and Australia. Local production by multinational corporations and indigenous Singapore companies is primarily for export or contract manufacturing.

Current Demand

Singapore's healthcare services are comparable to those of other industrialized nations. The plan is to raise health spending to reach USD 1.37 billion/SGD 2 billion a year in the next five years. The Singapore government is focused on moving up the value chain by building up services that assist research and healthcare delivery in Singapore and the region. A total of 23 hospitals and six specialty centers, provide a complete spectrum of clinical services from basic health screening to complex quaternary care.

Registration Process

Medical devices are classified under four risk classes. All medical devices, except Class A devices, must be registered with the Singapore Health Sciences Authority (***www.hsa.gov.sg***) prior to placing them on the Singapore market. Only Class A devices supplied in a non-sterile state is exempted. Classification of medical devices will depend on a series of factors and these include how long the device is intended to be in use; whether the device is invasive, implantable, active or if it contains a drug or biologic component. The classification rules are adopted from guidance developed by the Global Harmonization Task Force.

Barriers

There are no barriers to entry as Singapore is an open economy and a firm believer in keeping trade open. There are no custom duties on medical devices. A 7.0 percent goods and services tax (GST) is imposed on all goods sold and services provided, locally. Imports are subject to GST, but payments are refundable on re-exports.

Trade Events

BioPharma Asia Convention 2015

March 23–26, 2015 • Singapore • ***terrapinn.com/exhibition/bio-asia***

Asia's leading biopharma industry event. Focus on human health and social work activities, drug discovery, and manufacturing.

IDEM 2016 (International Dental Exhibition and Meeting)

April 8–10, 2016 • Singapore • ***www.idem-singapore.com***

The leading dental trade fair in the Asia-Pacific region. More than 230 exhibitors and over 6500 visitors from approximately 56 countries are expected. Furnishings and equipment for dental practice/dental laboratory; instruments and tools for dentists and dental technicians; materials for dental practice use/dental laboratory use; pharmaceuticals, detergents, disinfectants, deodorants, sterilization products and other agents for protections against infection; teeth and veneering materials; and restorative, prosthetic, and orthodontic accessory parts.

Available Market Research

- Medical Device Registration Overview (2013)
- Dental Industry (2010)

Slovak Republic

Summary

Slovakia's market size is similar to Hungary or in per capita terms to Spain. Slovakia is seen as complying with international requirements for approvals as well as intellectual property protection. The country has a tradition of medical device manufacturing, but it is increasingly difficult for domestic production to compete with Western quality and innovative imports. As of December 31, 2013 the indebtedness of Slovakia's health-care system generated mainly by the State hospitals is USD 548 million.

Market Entry

Slovakia is one of the more developed health device and pharmaceutical markets in the Central and Eastern European region. For Slovakia, Euro zone membership has made trade with Slovakia easier by providing more transparent pricing and greater currency stability. A foreign producer that would like to export medical devices into Slovakia must first establish a contract with a local importer, who can help the company fulfill regulations such as the CE mark, Declaration of Conformity, translation of directions and manuals into Slovak, and a guarantee that the product has been approved by the Ministry of Health. Medical devices and pharmaceuticals are also subject to a customs duty and value added tax (VAT) of 20 percent. Some products carry a 10 percent VAT.

Current Market Trends

According to Market Research Reports, Inc. (***marketresearchreports.com***), the Slovak medical device market is expected to grow by 5.8 percent over the 2013–18 period, as the economy grows and health spending remains at a high level. In 2013, the Slovak medical device market was estimated at USD 583.7 million (USD 106 per capita) and should reach USD 774.7 million (USD 140 per capita) by 2018.

Statistics

Capital:	Bratislava
Population:	5.41 million
GDP (USD):	99 billion (2013)
Currency:	Euro (EUR/€)
Language:	Slovak

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According to 2013 OECD report medical goods in Slovakia represent the largest spending category at 38 percent and 37 percent of current health expenditure. Slovakia recorded the biggest rise (a 15 percent increase between 2000 and 2010) in the household share of health spending.

According to the Slovak National Information Center, in 2013 Slovaks consumed 84 million packs of drugs out of which 57.2 percent were prescription drugs reimbursed by health insurance companies in the amount of EUR 825 million (USD 1.12 billion) and co-paid by patients in the amount of EUR 149 million (USD 202.5 million). Compared to 2012 prescribed medical aids consumption rose by 6.62 percent whereas dietetic foods consumption fell by 16.64 percent. Analgetics, anti-rheumatics and antiflogistics are the TOP three over the counter drugs (over the counter drugs sales amounted EUR 147 million (almost USD 200 million) sold in Slovakia in 2013.

Launch of Diagnoses Related Groups (DRG) classification system and E-Health project (electronic services in health care) remain Slovakia's priority. The Ministry of Health of the Slovak Republic launched a competition over software components for the National Health Information System worth EUR 40.25 million (USD 55 million, to be financed from the EU Operational Program Digitalization of Society) last summer. Because of a complaint submitted by an unsuccessful bidder in the competition (currently under scrutiny by the Slovak Public Procurement Office) the ministry cannot sign an agreement with the winner and the implementation is delayed by two years until 2017.

Ministry of Health of the Slovak Republic continues plans to erect a new hospital as a part of the BioMedPark project. The cabinet approved a feasibility study on June 11, 2014 moving Slovakia's very first health care sector PPP project from the preparatory to the implementation phase. BioMedPark project includes the construction of university hospital (with capacity of 700 beds securing 40,000 in-patients annually), bio-medical scientific park of the Slovak Academy of Sciences, new premises of the Medical Faculty and the Pharmacy Faculty of Comenius University. The private investor could be chosen by the end of 2015 and construction might be completed with a full year delay in 2017. The current price tag is EUR 250 million (USD 340 million) contrary to the original construction cost estimated at twice as much.

Inspired by foreign countries Ministry of Health of the Slovak Republic plans to build integrated health care centers in 140 Slovak municipalities. Centers should provide social services aside from housing general practitioners, gynecologist and dentists. This initiative is calculated at EUR 250 million (USD 340 million) and should be financed by Brussels. First centers are expected to operate within two years.

Prime Minister Robert Fico is still looking for state budget funds to acquire private health insurance companies Dovera and Union. Both companies insure about 1/3 of the Slovak population and their estimated market price is EUR 650 million (USD 883 million). The plan

is to unify the country's private and public health insurance funds into a single state-owned insurer, but there is likely to be a lengthy negotiation and a legal battle before this is realized.

Due to domestic legislation which allows pharmacies to sell medicines back to distribution companies, Slovakia has been facing problems with drug trafficking. Experts estimate that drug sales in Slovakia amount to about EUR 1 billion (USD 1.359 billion) annually, with re-exports representing EUR 300 million (USD 1.359 million) and mainly targeting the German, Czech and Scandinavian markets. In order to decrease the parallel trade in drugs plaguing the country, Slovakia is the only country in the European Union started banning the re-export of medicines. In 2013 The Slovak State Institute for Drug Control banned 24 types of drugs (usually prescription ones covered by health insurance) in almost 86,000 packages to avoid shortages.

Kosice Self-governing region and the company Svet zdravia introduced the concept of new hospital in Michalovce, Northern Slovakia. Svet zdravia which belongs to the Penta financial group already operates twelve hospitals. The cost of the investment was estimated at EUR 34 million (USD 46.2 million) and the project is planned to be completed in early 2018.

Main Competitors

Slovakia's medical device manufacturing sector is skilled, yet it still remains small. Thus, most of the Slovak medical device market is dominated by imports mainly from the U.S. and European Union countries. Around 85 percent of the medical device market is supplied by imports out of which Germany and the U.S. account for almost 50 percent of all imports. Local producers focus a large part of their resources on export markets such as the Czech Republic, especially in dentistry. Domestic medical device production is estimated to be in excess of USD 300 million.

284 companies (out of 294) selling pharmaceuticals cover 43.7 percent of the local market. U.S. pharmaceutical companies, e.g. Abbott, Amgen, J&J, Merck and others, have a 30 percent market share. According to 2013 turnover, the TOP pharmaceuticals companies in Slovakia are Novartis, Glaxo Smith Kline and Roche.

In Slovakia, there are 127 licensed pharmaceutical distributors, the biggest one being Phoenix (38 percent market share) and Unipharma (30 percent market share). Medications are sold through 1,954 pharmacies. Dr. Max with 200 pharmacies and Domov Zdravia also with 200 pharmacies are the biggest pharmacy networks, followed by SunPharma with 48 pharmacies.

Current Demand

Slovakia has excellent market opportunities in the fields of sophisticated health technologies and equipment, dental care equipment and many other devices that increase efficiency and reduce occupancy rates in hospitals.

Leading exports from U.S. to Slovak Republic, 2012–13			
(USD, September through September)		2012	2013
9031	Machines, Nesoi In Chapter 90; Profile Project, Pt	14,702,775	9,849,654
9018	Medical, Surgical, Dental Or Vet Inst, No Elec, Pt	7,620,199	7,629,818
9026	Inst Etc Measure Or Check Flow, Level Etc, Pts Etc	2,259,585	6,869,277
9027	Inst Etc For Physical Etc Anal Etc; Microtome; Pts	3,192,693	4,382,113
9032	Automatic Regulating Or Control Instruments; Parts	3,770,615	2,198,815
9029	Revolution and Production Count, Taximeters Etc, Pts	523,155	941,662
9030	Oscilloscopes, Spectrum Analyzers Etc, Parts Etc	723,263	888,400
9022	X-Ray Etc Apparatus; Tubes, Panels, Screen Etc, Pt	1,100,094	804,677
9021	Orthopedic Appl; Artif Body Pts; Hear Aid; Pts Etc	1,060,162	517,602
9001	Opt Fibers and Bund Etc; Pol Sheets; Unmoun Opt Elem	703,826	508,232
9013	Liquid Crystal Devices Nesoi; Lasers; Opt Appl; Pt	164,890	494,543
9015	Survey, Hydrogr, Meteoro Etc Inst; Rangef Etc, Pts	210,017	471,955
9024	Machines Etc For Testing Mech Prop Of Material, Pt	784,662	401,035
9019	Mech-Ther, Massage, Psych Test, Ozone App Etc, Pts	226,910	220,969
9014	Direction Finding Compasses and Navig Inst Etc, Pts	68,145	197,328
9028	Gas, Liquid Or Electric Supply Etc Meters, Parts	180,834	195,595
9025	Hydrometers, Thermometers, Pyrometers Etc; Pts Etc	80,588	154,442
9005	Optical Telescopes and Mount; Astro Inst and Mount, Pt	108,067	132,038
9031	Machines, Nesoi In Chapter 90; Profile Project, Pt	14,702,775	9,849,654

The significance of therapeutic appliances (eye-glasses, hearing aids, etc.) in household's total medical spending is around 30 percent in Slovakia compared to 12 percent, the average across OECD countries.

Barriers

Health care debt remains a key concern in the Slovak health system.

Medical device or pharmaceuticals importers may sometimes have problems in obtaining approval to be placed on insurance reimbursement lists—something that is also a challenge in other Central and Eastern European countries. If a product is not included on the reimbursement scheme paid by insurance companies, the market for the product is limited. Catalogue of reimbursed operations, medical aids and pharmaceuticals is reevaluated every three months. Drug categorization takes place on monthly basis, on the first day, and impacts 200 drugs. Drug price referencing is executed twice yearly and influences almost ¼ out of 4,500 drugs.

Trade Events

Slovak Dental Days

September 25–27, 2014 • Bratislava, Slovak Republic • ***bit.ly/1o7lUPW***
Exhibition of dental instruments, tools, and materials, supported by the Slovak Chamber of Dentists and Association of Dental Producers and Sellers. The Slovak Republic's top event for dental suppliers.

SLOVMEDICA

October 15–17, 2014 • Bratislava, Slovak Republic • ***bit.ly/1APC0lH***
the latest medical techniques, technologies, and equipment for experts active in the field of medicine, and working in hospitals and nursing homes; as well as expert health education and science.

NON-HANDICAP

October 15–17, 2014 • Bratislava, Slovak Republic • ***bit.ly/1APC0lH***
Annual specialized exhibition for handicapped people. Will host exhibitors promoting equipment and medical aids for the disabled.

South Africa

Summary

Healthcare in South Africa is divided into two categories—namely the public and private sector. The public sector focuses mostly on basic primary healthcare, to highly specialized, high tech health services mostly found in the private sector.

Public healthcare spend is thinly stretched and many public medical facilities are under-resourced—in equipment, medicines and staff. The state contributes about 40 percent of all expenditure on health and delivers services to approximately 83 percent of the population. While the Department of Health ultimately holds overall responsibility for healthcare, some power has devolved to the provincial health departments (there are nine provinces), who provide and manage comprehensive health services via a district-based public healthcare model. Local hospital management delegates authority over operational issues, such as budget and human resources to facilitate a better response to local needs. Around 11 percent of the government's total budget is spent on public health, which is allocated and spent by the nine provinces. Quality and standards of these services varies from province to province.

South Africa burden of disease is considerable. National priority is given to programs for HIV/AIDS, tuberculosis and increasingly, non-communicable and lifestyle diseases such as diabetes and coronary disease. The Health Department has also singled out the improvement of maternal health. South Africa has a maternal mortality ratio of 310 deaths per 100 000 (WHO estimates), with infant (under age one) mortality rates of 41 deaths per 1000 live births, and under five mortality rate was 57 per 1000 live births (WHO).

The private sector, which spends roughly the same amount as the public sector—± USD 1.4 billion on about 17 percent of the population, is run largely on commercial lines and caters to middle and high income earners who are generally members of a medical insurance. Most health professionals in South

Statistics

Capital:	Pretoria
Population:	51.7 million (2011)
GDP (USD):	350.63 billion (2013)
Currency:	South African rand (ZAR)
Language:	English (business), others

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Africa are found in the private sector. This sector boasts high quality facilities and state-of-the-art equipment.

Market Entry

U.S. firms entering this market must contend with a typically mature and competitive market with well-established European and Asian competition. A trade agreement with the European Union enables many European products to enter South Africa duty-free or at lower rates than U.S. products.

Because the South African market is sophisticated, entry should be well-planned, taking into consideration:

- The skewed demographic income distribution pattern
- The price-sensitive nature of the majority of consumer demand;
- Increasing consumer protection enforcement albeit in a still largely non-litigious environment;
- South Africa's position as the pre-eminent stepping stone for developing most sectors in sub-Saharan Africa: the marketing mix should anticipate this medium-term option.

A judicious selection of one of three low-risk entry strategies (representation, agency, or distributorship) is required by new-to-market entities. If you are selling to the government or to government-funded organizations, any local partner should be B-BBEE compliant and be aware of local procurement regulations.

Current Market Trends

South Africa is defined as a middle-income country and there is demand for a full range of medical equipment. The USD 1.2 billion market is extremely price sensitive and competitive. Imports have risen approximately 10 percent per year since 2007 (in local currency terms). This is set to continue as the South African government is planning to spend around USD 48 billion on health over the next three years as part of the impending National Health Insurance Scheme. The majority of the spending will be on upgrading hospital infrastructure and medical equipment, as well as HR resource development programs. According to Business Monitor International, almost 2,000 health facilities and 50 nursing colleges were in different stages of planning, construction and upgrading in 2012. South Africa's Finance Minister's Budget Speech in February 2013 has set aside USD 15 billion for health spending in this year.

National priority is given to communicable diseases such as HIV/AIDS and tuberculosis. However, there is increasing focus on chronic and lifestyle diseases such as asthma; cancer; diabetes; obesity; coronary, and vascular diseaseand osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

Main Competitors

Around 90 percent of medical equipment is imported with the U.S. playing a dominant role (27 percent), followed by Germany at 13.7 percent. However, imports from China have doubled over the last five years to 8.4 percent. Other notable countries include Switzerland, Japan, UK, and France. Countries like Mexico and Singapore have also increased their supply to South Africa.

Many suppliers in South Africa are subsidiaries of overseas corporations. The major U.S. medical companies represented in South Africa (either through local representatives or subsidiary offices) include 3M, Advanced Orthopaedics, BSN Medical, BARD, Beckman Coulter, GE Health, Johnson &J ohnson, Abbott Labs, Alcon, Medtronic, and many more. U.S. companies new to this market may experience strong competition from U.S. firms or multinationals already established.

Current Demand

Medium-term prospects for the medical device industry look promising. The market is expected to grow at a compound annual growth rate of 8.7 percent from 2012 through 2017. The market is extremely price-sensitive. The sophisticated South African medical community is generally interested in new technology developments and products. The South African government is also revamping public hospitals and building new clinics as part of their campaign to introduce and develop national health insurance (NHI).

Registration Process

South Africa does not have a comprehensive system for medical device regulation. But there will be no opportunities for products that are not FDA approved or carry the CE mark.

The South African Health Department is in the process of drafting policy documents aimed at establishing the South African Health Products Regulatory Authority which will regulate all health products—devices and pharmaceuticals. The regulatory framework is likely to lean towards European Community guidelines. Products will need to carry the CE mark in addition to FDA approval. The exception is electro-medical devices (radiation emitting devices), which are regulated by the South African Health Ministry: Directorate—Radiation Control. FDA approved only devices will no longer be acceptable. All electro-medical devices need to carry the CE mark.

U.S. exporters must appoint a South African representative to obtain regulatory approval from the directorate and an import certificate.

Barriers

Electro-medical devices that are FDA approved only are no longer acceptable. The device must carry the CE mark.

There are national plans to reform the regulatory authority in South Africa by dismantling the Medicines Control Council and replace it with the South African Health Products Regulatory Authority (SAHPRA), which will report to the Ministry of Health. SAHPRA will regulate all health related products—including devices, which are currently not regulated (excepting electro-medical and combi-devices). Devices will need to carry the CE mark. FDA approved only devices will not be acceptable.

At present, combination devices—devices that have a pharmaceutical attached to them are regulated by the Medicines Control Council (MCC). This is a lengthy, complicated process with wait times of 48 months or more, before the product comes to market.

Trade Events

Africa Health

May 5–7, 2015 • Johannesburg, South Africa • ***africahealthexhibition.com***
More than 6092 trade visitors. Approximately 452 exhibitors, 53 companies represented, 17 country pavilions, 14 accredited conferences.

Trade Associations

- South African Medical Devices Association (SAMED, ***samed.org.za***)
- Pharmaceutical Industry Association of South Africa (PIASA, ***www.piasa.co.za***)

Spain

Summary

Spain has a comprehensive public health system that accounts for approximately 85–90 percent of the sector's activity. The market for healthcare technology equipment in Spain is estimated at USD 9.5 billion for 2014. The sector continues to rely heavily on imports. Despite difficult economic circumstances and budget cutbacks, imports in 2013 increased by 1 percent to USD 6.2 billion. Germany accounts for approximately 50 percent of the imports, while the United States has approximately 25–30 percent of the market share. Many U.S. companies centralize their products in other EU countries where the import requirements are less demanding, and then trans-ship their products to other EU markets.

Spanish exports, on the other hand, have been increasing continuously since the start of the crisis, as the challenging situation forced many companies to reach out beyond their traditional clients. Medical device exports from Spain have increased 13 percent since 2008. Exports for 2013 are estimated to be approximately USD 2.4 billion, an increase of 1 percent over the previous year. The European Union (EU) accounts for almost 70 percent of the exports.

Small and medium sized companies make up 90 percent of the market and account for more than 40 percent of the turnover. Large companies account for only 8 percent of the market but they generate approximately 60 percent of the turnover. Most of the large U.S. names are well established in Spain.

Spain is no exception to the tendency across the European Union to reduce health spending as governments grapple with budget deficits. Based on OECD statistics, Spanish healthcare spending is in the range of 9 percent of GDP, in comparison with 10.5 percent in Belgium, 11.1 percent in Denmark, 11.6 percent in France, 11.3 percent in Germany, 9.2 percent in Italy and 9.4 percent in the U.K.

As the result of government measures to reduce the budget deficit, the level of healthcare procurement experienced substantial cutbacks in 2012–13.

Statistics

Capital:	Madrid
Population:	47.7 million
GDP (USD):	1.4 trillion
Currency:	Euro (EUR/€)
Language:	Spanish

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Market Entry

All medical products/equipment imported into Spain need to have the CE Mark. Because of this requirement, many U.S. companies have been centralizing their import operations into one single country where they register the products and from which they distribute their products to the rest of the EU. Spanish importers of medical products also require an authorization issued by the Ministry of Health.

85–90 percent of purchases are made through public hospital tenders from companies that are pre-selected for public tender opening bids. That is the main reason why having a qualified importer/distributor with access to the procurement decision makers is so important for U.S. companies. All importers/distributors of medical equipment and products into Spain need to reside in the EU and be registered with the Spanish Ministry of Health.

The official approach to vitamins and health supplements in Spain is quite different to that of the U.S. Many vitamins and supplements commonly found in the U.S. health food stores are considered prescriptions by the Spanish MOH; U.S. companies interested in the Spanish market need to provide the MOH with technical data on the product's composition and need to meet the labeling requirements. The approval of products considered drugs can be lengthy.

Import of refurbished medical equipment into Spain is technically permitted, but both public and private medical providers in Spain have traditionally preferred new equipment. Refurbished equipment also requires a current CE mark.

U.S. products that are competitive in price or innovative in the U.S. market and that are already being sold in European markets have a better chance of success in Spain.

Current Market Trends

U.S. medical equipment is highly-regarded by Spanish doctors, domestic importers, and distributors. However, current budgetary concerns and the ongoing need to reduce public spending are severely limiting current procurement and growth. The last few years have seen a significant shift in sourcing. In an effort to restrain/reduce expenditures, more and more items are being imported from Asia. However, when it comes to more complex and sophisticated items, quality continues to be a decisive factor in the purchasing decision.

Prior to the current crisis, diagnostics, orthopedics, and disposable items accounted for 70 percent of the market. Once the market recovers, best prospects will include innovative and efficient cardiology, respiratory/anesthesia, neurology, orthopedic, MRA, ETP, CT, and dermatology/wound treatment products.

According to the Spanish Healthcare Technology Federation (FENIN), the overall healthcare budget decreased by 7.8 percent in 2013. Five of the 17 regional healthcare budgets experienced two-digit budget cuts. 4Sector sources indicate that the level of domestic activity dropped by approximately 5 percent for these reasons, taking it back to 2008 levels.

The drop in demand, exacerbated by reimbursement delays and a severe credit crunch, caused serious cash flow problems for numerous distributors/importers, particularly the smaller ones that make up the bulk of the distributors. These companies rely on the most part on their dealings with the Administration to cover most of their operating expenses and actively participate in public tenders. Many companies had to close over the last couple of years while many others have opted for an extremely conservative approach that does not lend itself to much innovative devices and/or equipment. Contrary to their traditional way of operating, numerous companies currently prefer to focus their efforts on essential basic products rather than on new products that require investment, without any guarantee of generating demand. While U.S. products are highly regarded in Spain, pricing is now a decisive factor, with greater emphasis on cost-effective products and equipment rather than on innovation and quality.

No official statistics are available for the sector as a whole. The above figures are not all-inclusive but reflect market trends. Furthermore, life expectancy continues to improve. A growing ageing population will generate greater demand for products directly connected with geriatric ailments and illnesses.

Main Competitors

The United States and Germany are the two main suppliers, with France, the U.K., Italy and Switzerland following. However, France, the U.K. and Holland are also used as storage and redistribution centers for U.S. companies. Imports from Asia are on the rise.

Many suppliers in the Spanish industry are subsidiaries of overseas corporations, including leading U.S. firms. These well-established firms often represent serious competition for companies trying to break into the market.

Current Demand

Both the public and private sectors provide healthcare in Spain. The public system accounts for 85–90 percent of total healthcare expenditure. The private sector covers the rest.

Because of the current economic situation, demand for products has decreased and cost-efficiency has become a determining factor in many cases. According to the FENIN annual report, the sectors that showed a slight increase in 2013 include ophthalmology, absorbents, medical probes, and osteotomy. In contrast, electro medical devices continue to decrease due to the reduction in acquisition and/or renewal of new equipment in the hospitals; other areas that experienced negative growth include: cardiology (-6 percent); trauma implants (-2 percent); in vitro diagnostics (-6 percent). Several other areas continued the downward trend of 2012, including nephrology (-5 percent), disposables (-6 percent) home care oxygen therapy and medicinal gases (-2 percent), as also dressings and wound treatments (-4 percent). While there is a good demand for disposables, Asian products are gaining in popularity because of greater cost control.

Official healthcare policies is influenced by the volume and pricing of healthcare/ pharmaceutical products.

Trade Events

There are no major trade shows specifically for medical devices. Congresses and conventions, however, often include an exhibition area. Several international events are scheduled to take place, such as:

XVI World Congress of Psychiatry

September 14–18, 2014 • Madrid, Spain • ***www.wpamadrid2014.com***

ESMO 2014 Congress (European Society for Oncology Medicine)

September 24–25, 2014 • Madrid, Spain • ***bit.ly/1mqpUWr***

13th Annual World Congress of the Human Proteome Organization

October 5–8, 2014 • Madrid, Spain • ***www.hupo2014.com***

5th Congress of the European Academy of Paediatric Societies

October 17, 2014 • Barcelona, Spain • ***kenes.com/eaps***

ORTO Medical Care

November 20–21, 2014 • Madrid, Spain • ***ortomedicalcare.com/index_en.html***

EUROGIN 2015 (Cervical Cancer and Human Papillomavirus)

February 4, 2015 • Sevilla, Spain • ***eurogin.com/2015***

COPD 2015 (Second International Workshop on Lung Health)

February 19, 2015 • Valencia, Spain • ***lung-health.org/?page_id=29***

EXPO ECOSALUD (Health and Quality of Life)

April 17–19, 2015 • Barcelona, Spain • ***www.expoecosalud.es/?locale=en***

6th IVI International Congress (Reproductive Medicine and Beyond)

April 23, 2015 • Alicante, Spain • ***comtecmed.com/ivi***

Forum Dental

May 7–9, 2015 • Barcelona, Spain • ***forum-dental.es/en***

European Association for Clinical Pharmacology and Therapeutics (EACPT)

June 27, 2015 • Madrid, Spain • ***bit.ly/1lEStPT***

Sweden

Summary

Sweden's health system is one of the best and most well developed in the world. The population of 9.7 million enjoys very good health. Sweden invests about 10 per cent of its GDP in health and medical services, which is on par with most other European countries. The infant mortality rate is less than 2.7 deaths per 1,000 in the first year of life and the average life expectancy is 80 years for men and 84 years for women. As Sweden has a population that is one of the oldest in the world, more than 18 percent are 65 years or older, there will be an increasing demand for medical equipment and supplies, and longer medical treatments, to meet the health needs of an ageing population.

Health and medical care responsibility is shared by the central government, county councils, and municipalities. Sweden is divided into 290 municipalities and 21 county councils. The county councils have the responsibility to provide health and medical services and to work for a good standard of health among the population. They also decide on the allocation of the resources to the health services and are responsible for the overall planning of the services offered. It is also the county councils that own and run the hospitals, health centers and other institutions. County Councils are also responsible for dental care for local residents up to the age of 20. The 290 municipalities are responsible for the nursing homes, care of the elderly in their homes and the disabled. They are also responsible for providing care for people with psychological disorders and providing support and services for people released from hospital care as well as for school health care. Private health care, accounting for some twelve percent of total health care costs, mainly offers primary care like running health care centers or homes for the elderly. A few hospitals that are managed by private entrepreneurs.

There are approximately 90 hospitals in Sweden; 60 provide specialist care and with emergency services. Eight of these are regional hospitals offering highly specialized care and where teaching and research is based. There are about 32,000

Statistics

Capital:	Stockholm
Population:	9.7 Million
GDP (USD):	557.9 billion
Currency:	Swedish krona (SEK)
Language:	Swedish

Contact

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physicians and 120,000 nurses in Sweden. Outpatient care is organized into primary care districts, each with 5,000 to 50,000 inhabitants.

According to trade sources, the Swedish market for medical equipment was estimated at USD 2.7 billion in 2013. For the next coming years, the market is expected to show a moderate growth, around 4 percent per year. Domestic production is strong and Swedish innovations such as the pacemaker, hemodialysis and the gamma knife have gained international recognition. As most of the domestic manufacture is for export (estimated value at USD 2.8 billion), the medical equipment market is dependent on imports. In 2013, imports were estimated at USD 2.5 billion.

Market Entry

U.S. firms are recommended to establish a local presence, either through local agents and distributors or sales subsidiaries. All products sold in Sweden must carry the CE mark, and all labeling and instruction manuals must be translated into Swedish.

Sweden's customs laws and regulations follow those of the EU. This means that Sweden applies external EU tariffs to imports from the U.S. and other non-EU countries. Goods imported to Sweden are also subject to a value-added-tax (VAT) of 25 percent. Sweden uses the metric system and products sold in Sweden should be adapted for use with the metric system whenever possible. Electric current in Sweden is 50 Hz, AC 230V single-phase and 230/240V three-phase.

Current Market Trends

Two main factors are expected to strongly affect Sweden's the future health care system:

- An aging population, which is likely to lead to increased demand for health care products as well as health care related services such as equipment and supplies for the home health care sector.
- Lifestyle related diseases (diabetes, obesity, etc.).

Of the predominant diseases, the main causes of death are cancer and cardiovascular conditions including strokes. Chronic diseases that require monitoring and treatment, and often life-long medication, place significant demands on the system.

The incidence of smoking, however, has been falling in Sweden since the mid-1980s. According to a study by the European Union, Sweden has the lowest proportion of smokers (18 per cent) among EU member states.

Main Competitors

Domestic production is strong and the medical device sector is one of the leading export sectors in Sweden. Some of the internationally known Swedish medtech companies include

Gambro (dialysis equipment, blood component products), Getinge (Medical Systems, Extended Care and Infection Control), Molnlycke Healthcare (single-use surgical and wound care), Nobel Biocare (dental implants), and Elekta (the Leksell Gamma Knife). Major global companies with a strong presence in Sweden include GE Healthcare, St. Jude Medical, Fresenius, Philips, Abbott, Thermo Fisher, Johnson & Johnson, Siemens, and Medtronic.

Current Demand

Although the Swedish health care market continues to operate under cost-containment regulations, there is an eagerness to be at the forefront of technological developments. The market looks to the U.S. for developments in research and application of the newest medical technology. U.S. firms will find that the market is quite receptive to high-quality equipment that offers both ease of use and cost efficiency. Future demand is expected in e-health, telemedicine, non-invasive surgical equipment, orthopedic and prosthetic equipment, and home health care equipment and supplies.

Registration Process

The Medical Products Agency (MPA, ***lakemedelsverket.se***) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and marketing of medical devices, drugs and other medicinal products.

Barriers

There are no significant trade barriers to U.S. medical devices.

Trade Events

Vitalis

April 2015 • Goteborg, Sweden • ***vitalis.nu/en***
Telemedicine and e-health.

Apoteksmassan

September 2014 • Stockholm, Sweden • ***apotekegenvard.se***
Pharmacy and over-the-counter products.

Health, Wellness & Fitness

November 2015 • Stockholm, Sweden • ***alltforhalsan.se***

Available Market Research

- E-Health
- Medical equipment
- Dentistry
- Vitamins

Thailand

Summary

In 2013, Thailand had a healthcare market of USD 16.1 billion. Per-capita spending on healthcare was almost USD 240. Thailand's elderly population is expected to increase to 17.2 percent of the population, or about 17 million people, within the next decade. Thailand's aging population is a major catalyst of the demand for medical devices and medicine. Thailand has a universal healthcare system that provides at least a basic level of care to all Thai citizens. This system is divided into three programs. The Civil Servant Medical Benefit Scheme gives approximately seven million government workers excellent healthcare benefits. The Social Security Scheme covers about 10 million private sector workers and is based on an employer contribution system. Finally, the Universal Coverage Scheme provides free basic healthcare coverage to the remaining 50 million Thais. As a percentage of total government expenditure, the Thai government spends 14 percent on healthcare.

Market Entry

Use of local agents or distributors is highly recommended for market entry into Thailand. Local agents provide immediate access to an established marketing network and in-depth knowledge of regulations. End users expect local representatives to handle after-sales service and stock spare parts. A local agent needs to develop close personal relationships with buyers and end-users because this is a critical factor for future procurement decisions. An agent's role includes not only marketing of the products but also handling product registration with Thailand Food and Drug Administration (FDA), Ministry of Public Health, a requirement prior to importation.

Statistics

Capital:	Bangkok
Population:	67 Million
GDP (USD):	387 billion
Currency:	Thai Baht (THB)
Language:	Thai

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Current Market Trends

The medical device industry is thriving in Thailand, with the country acclaimed as a major healthcare hub in Asia. Thailand has over 1,000 public hospitals and 400 private hospitals staffed with overseas-trained doctors operating at international standards and offering the best healthcare available at a fraction of the cost of similar procedures in developed countries. Nearly two million foreign patients visit Thailand each year for a range of healthcare services, including sophisticated procedures like stem cell treatment. Local firms primarily manufacture basic medical devices like gloves and syringes. Two-thirds of medical devices in the country are imported, with products from the United States accounting for 30 percent.

The medical device market was valued at USD 1 billion in 2013 and is expected to grow at least nine percent annually. Today, roughly two-thirds of the medical devices in Thailand are imported. Thailand relies on these imports for higher value and more sophisticated medical devices. Generally, local manufacturers tend to produce lower-end medical devices, which are more labor intensive, such as disposable syringes, disposable test kits, and surgical latex gloves. Public hospitals in Thailand account for roughly 55 percent of the total medical device purchases. Even so, market growth is fueled mostly by medical facility upgrades and replacement largely at specialized private hospitals.

The vitamin and dietary supplements market has good potential but there is a lot of competition. Thais are among the top consumers of vitamins and dietary supplements in the world. In 2013, the sales value of dietary supplements in Thailand was estimated at USD 833 million, with a projected annual growth rate of 10–15 percent over the next five years, reaching USD 1.7 billion in 2018.

Thailand's cosmetics and toiletries market also enjoys healthy growth fuelled by increasingly sophisticated consumers, including men who are proving to be a particularly lucrative market. The value of the beauty and personal care market in Thailand grew eight percent in 2012 and is forecasted to reach USD 5.5 billion by 2016.

Main Competitors

The U.S. is a market leader in medical device, clinical diagnostic laboratory equipment and biotechnology. On the other hand, the U.S. has a lot of competitors in the dental equipment market because there has not been much new technology advancement in this area. Major competitors of U.S. manufacturers are mainly from European countries and Japan.

Current Demand

Medical devices with the best growth opportunities tend to be surgical procedure equipment, diagnosis equipment and devices to treat lung and heart diseases. Examples include respiratory devices, orthopedic implant devices, heart valves and neurosurgical devices. The dermatological device market also has good potential, as standalone skin care and

dermatological clinics are becoming more popular. Best prospects for U.S. beauty products include anti-aging facial and eye treatment, brightening facial and body lotion, premium make-up products, organic cosmetic and skincare products.

Registration Process

Importing medical device, pharmaceuticals, food, food supplements, products for animal health, or other medical, narcotic and toxic substances into Thailand requires registration with the Food and Drug Administration of Thailand (FDA). The time required for filing a product registration application in Thailand and receiving registration certificates with the FDA can vary widely. Approximate times for registration are as follows: cosmetics one week, general medical devices and toxic substances between one month to four months, whereas pharmaceuticals can take several months.

In Thailand, medical devices are regulated by the Medical Device Control Division of the Thai FDA. To import medical devices into Thailand, an importer must apply for and receive an import authorization and registration permit from the Thai FDA prior to shipment. Thailand prohibits the import of used/refurbished medical equipment. In addition, devices that cannot be marketed or sold in the country-of-origin will not receive permission to be registered in or imported into Thailand.

The CS in Bangkok facilitates the certification and legalization of documents as required by the Thai FDA, in order to support the importation and sales of U.S. products in the Thai market. The standard timeframe for completing a certification service is three business days from the date of documents submission.

The Thai FDA accepts devices that meet the following jurisdictions' requirements, as demonstrated by a certificate of free sale: the United States (USFDA), European Union (CE mark), Japan (Pharmaceutical Affairs Bureau), Australia (Therapeutic Good Administration) and People's Republic of China (State Drug Administration). The authenticity of Certificates to Foreign Government must be further attested to by the Commercial Section of the U.S. Embassy in Bangkok. Foreign medical device companies wishing to sell their products in Thailand must first register them according to a risk-based classification system. Medical devices will require either licensing or registration. The Thai FDA groups medical devices into three sub-categories:

- Class I "licensed" devices: only seven medical devices include condoms, examination gloves, surgical gloves, sterile hypodermic disposable syringes, sterile insulin disposable syringes, HIV test kits for diagnostic use and contact lenses.
- Class II "notification" devices include rehabilitation devices, blood alcohol level measuring kits, silicone implants, and test kits other that for diagnostic purposes.
- Class III "general" devices, the lowest-risk devices category, covering 90 percent of all applications.

The Thai FDA is responsible for regulating health supplement products. The classification of these products depends on the types of ingredients used, daily dosages and claims. A health supplement is classified as a 'food supplement' if it contains common herbal ingredients and other bioactive ingredients at a daily dosage level recognized by the Thai FDA as safe for food. For common vitamin and mineral supplements, the levels of the nutrients must be kept between 15–100 percent of the Thai Recommended Daily Intake (RDI) in order to be classified as a food supplements. Health supplements containing ingredients not approved as food ingredients and/or containing vitamins and minerals that exceed the Thai RDI value, must be registered as traditional medicines, drugs or any other related sub-categories, such as modern herbal drugs, generic drugs or new drugs.

Products classified as traditional medicines and drugs must be evaluated and approved by the Thai FDA's product evaluation committee prior to marketing. Registration dossiers are required, which include information such as quality controls reports, manufacturing processes, safety evidence, and efficacy data. Products classified as food supplements, on the other hand, require a notification process.

Barriers

Thailand has rigorous regulatory requirements and lengthy product registration. U.S. companies have also faced increased competition from cheaper healthcare products from other countries.

Trade Events

ASEANbeauty

April 8–10, 2015 • ***aseanbeautyshow.com***

ThailandLab 2015

September 9–11, 2015 • Bangkok, Thailand • ***thailandlab.com***

Turkey

Summary

Turkey has a population of 81 million people and is a growing market for medical technologies and healthcare services. The Ministry of Health (MOH) is the largest provider of healthcare and the only public provider of preventive services in Turkey. At a national level, MOH is responsible for the country's health policy and health services. In fiscal year (FY) 2014, TL 18.6 Billion (approximately USD 9 billion) was allocated to the Ministry's budget, which is an increase of 10 percent in TL terms compared to FY 2013. Turkish medical equipment market is approximately USD 3 billion and has been growing at the rate of 5–10 percent every year since 2002. 90 percent of the products used are imported; however, there is strong push by Turkish government to strengthen and grow local manufacturing. In the coming years, percentage of imported products in the market may go down; however, Turkey and region will continue to be an attractive market for advanced and innovative U.S. products.

Market Entry

U.S. medical equipment manufacturers can either open their own offices in Turkey and equip it with their own sales and marketing force or appoint national and, most of the time, exclusive distributors in Turkey. The distributor/importer should have strong reseller base to market and service the products all around the country, follow the tenders and also be knowledgeable about shipping products into Turkey.

Current Market Trends

Turkey has a 2-level approach to the delivery of public healthcare services. First-level treatment is delivered by family practitioners who are appointed to population groups of 3,000 people living in the same area. For illnesses requiring further treatment, patients are referred by family practitioners to second-level

Statistics

Capital:	Ankara
Population:	81,619,392 (est. 2013)
GDP (USD):	1.167 trillion (est. 2013)
Currency:	Turkish Lira (TRY)
Language:	Turkish

Contact

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treatment facilities, which are "state" and "university" hospitals. There are 1,453 hospitals and 194,000 hospital beds operating in Turkey. 840 of these hospitals are built and operated by the MoH and are known as "state hospitals." These hospitals constitute 57 percent of the current hospital stock and 62 percent of current hospital bed capacity in Turkey. There are 503 "private hospitals" and 65 "university hospitals."

There is an emerging group of hospitals that will be built and managed by the Public-Private-Partnership (PPP) model. The MoH has recently been contracting out the construction and management of 29 healthcare campuses around Turkey. Each campus will house 2,000 to 4,000 beds divided among general and specialized hospitals, laboratories, and accompanying recreational areas. For more information on these projects, please visit ***bit.ly/186eXEt***.

All people living in Turkey can benefit from being treated in these hospitals. If they are "universal healthcare insurance" holders, all of their expenses are reimbursed by the Social Security Institute (SGK, ***www.sgk.gov.tr***). Today, 95 percent of the population is covered under this insurance plan. SGK reimburses expenses incurred by using the treatment type and medical device listed in the Healthcare Implementation Communique (SUT). The SUT is revised every few years to include new medical technologies, equipment, techniques, and an updated reimbursement price list. In order for medical equipment to be listed in SUT, it has to be registered in the National Databank managed by the MoH.

Registration in the National Databank can either be done by the distributor of the manufacturer or manufacturer itself. Objective is for the MoH to track devices that are present in the market and to call these devices back through its manufacturers should a post-sales problem occurs. MoH collects data on the manufacturer of the device, device's GMDN code and also documentation of its Declaration of Conformity. Every device needs to be registered in this database.

Turkey has been leading a rather aggressive approach since 2005 towards establishing an electronic system to manage patients' records, reimburse healthcare expenses, manage prescriptions flow, and use of telemedicine for offering healthcare services to remote parts of the country. The Ministry of Health's

E-Health Department cooperates with industry to develop various software to reach a position where all elements of Turkish healthcare system will be integrated in the central system. At this point, the area where there is good potential for health IT companies is in the area of business analytics through which patient data collected in hospitals can be analyzed by management to derive decisions.

Medical tourism is a new sector developing in Turkey, which is a triggering factor in the investments made by the private sector in healthcare. Increasingly, patients from Europe and the Middle East go to Turkey for medical treatment, as costs are more affordable. Size of the medical tourism market in Turkey is around USD 500 million. Increased emphasis on medical

tourism will also have a positive impact on U.S. manufacturers as it will bring create avenues for medical equipment exports.

Main Competitors

Imports of U.S. origin is about 15 percent of the total imports market in Turkey. The rest are mainly from the European Union, predominantly from Germany, Italy, United Kingdom, France and the Netherlands, and China and India. There is also an emerging group of medical device and equipment manufacturers in Turkey, which are active in the manufacturing of disposables, orthopedic devices and tools, surgical and cardiological tools; like stents. There are close to 100 health IT software development companies.

Current Demand

(USD Millions)	2012	2013	2014 (est.)	2015 (proj.)
Total Market Size	2,603	2,790	2,990	3,206
Total Local Production	390	418	508	609
Total Exports	156	139	179	224
Total Imports	2,369	2,511	2,661	2,821
Imports from the U.S.	355	377	400	560

Source: Industry feedback, Turkish Ministry of Industry reports

Best prospects include:

- Advanced pre-screening
- Imaging and diagnostic devices
- Advanced point-of-care devices
- Advanced surgical devices using laparoscopic and robotics technology
- Cancer treatment devices
- Clinical chemistry and laboratory devices
- Dental devices
- Health IT and M-health systems
- Remote patient monitoring devices
- Orthopedic and trauma implants
- Telemedicine systems

Barriers

As Turkey is an accession country to the European Union (EU) and has been part of Customs Union with the EU since early '90s, medical rules and regulations applicable in the EU are mostly applicable in Turkey, too. This cannot be considered a barrier but U.S. companies have to be abiding with the requirements set by EU when selling to Turkey. This implies that FDA certification is not, by itself enough, for exporting to Turkey but where CE Mark is requested,

devices and equipment have to have it. Due to Customs Union rules, products manufactured in the EU are exempt from customs tax; however, customs tax is levied on some medical equipment and devices imported from non-EU countries, which includes the U.S.

Trade Events

EXPOMED Eurasia

March 26–29, 2015 • Istanbul, Turkey • ***expomedistanbul.com/en***

Ukraine

Summary

The majority of healthcare funding in Ukraine is provided by the government and local tax revenues, which have fallen short over the last several years. Ambulatory and hospital healthcare services are provided predominately by the public sector. Ukraine does not have a developed healthcare insurance system, which significantly limits the level of healthcare financing. According to the Ukrainian Constitution, the government provides a comprehensive package of healthcare services at no cost to citizens, but due to a lack of funding, patients are usually forced to pay for quality care and treatment. Out of pocket costs account for an increasing portion of healthcare costs.

According to Espicom Business Intelligence, in 2013, the Ukrainian medical device market was estimated at USD 672 million, or about USD 15 per capita. This market size is comparable to Greece; in per capita terms, the market is similar to Argentina. In 2009–13, the Compound Annual Growth Rate (CAGR) of the medical device market is estimated to be -2.8 percent, but the market is expected to expand at a CAGR of 7.9 percent over the 2014–18 period, reaching USD 985 million, or USD 23 per capita by 2018. However, the outlook for 2014 is unclear due to current situation in Ukraine.

Around 80 percent of the medical device market is supplied by imports. Despite a decrease of total size of medical device market in 2009–13, imports showed annual growth. Introduction in 2014 of a 7 percent VAT on import and distribution of medical devices and decline of local currency will lead to the increase of prices, and the domestic industry will gradually account for a larger share.

Despite Ukraine's significant number of primary care units and hospitals (the number of hospital beds per 1000 people is twice as high in Ukraine that in the EU on average), the resources are not distributed evenly. There is an excess of healthcare facilities in the cities and a dearth of them in rural areas. There is also a

Statistics

Capital:	Kyiv
Population:	44.3 million
GDP (USD):	337.4 billion
Currency:	Ukrainian Hryvnya (UAH)
Language:	Ukrainian, Russian

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significant disproportion of resources in favor of hospital and specialized care at the expense of primary healthcare.

Medical equipment currently used in public hospitals is typically obsolete and worn-out. Given the available financial resources of most public health institutions, replacement will be slow until the State budget strengthens. As a consequence the lack of resources in public hospitals, the number of private clinics and practitioners is growing steadily.

Market Entry

U.S. companies entering the Ukrainian market should approach with a long-term perspective. Business in Ukraine is often based on relationships, so selecting a good local partner and/or establishing a local office are crucial to minimizing risk and long-term success. To find a potential partner, we recommend using the U.S. Commercial Service's International Partner Search and/or Gold Key programs to conduct initial screening for prospective partners. U.S. companies should use appropriate due diligence in selection of partners and should be mindful of the parameters of the Foreign Corrupt Practices Act.

Kyiv is not the only trade hub in Ukraine. Look for distributors that have nationwide capabilities, including those located in the cities of Dnipropetrovsk, Donetsk, Lviv, Odessa, Zaporizhzhya, and Kharkiv. These regions are considered important industrial centers in Ukraine and are densely populated. Covering the Ukrainian market from regional offices in Poland or Russia is not an effective approach. Ukrainian buyers are reluctant to go through regional offices, preferring to order direct for the manufacturer/wholesaler. On-the-ground presence is very important to successful business development in Ukraine.

Joining the American Chamber of Commerce and obtaining experienced legal and accounting support are other important considerations when considering doing business in Ukraine.

While many U.S. firms have experienced marked success here, Ukraine is not a market for the first-time exporter. Companies doing business here must develop a tolerance for unpredictability.

Current Market Trends

A key issue for Ukraine is to select a more efficient healthcare financing model. Today, the healthcare system is financed through general taxes and is based on contractual state purchases of healthcare services. There have been suggestions to introduce compulsory medical insurance which would attract funds to medicine from private insurance sector, though still there is no consensus in the government and the parliament as to the future model of healthcare insurance—private, state or mixed.

The Ukrainian market is receptive to high-quality, advanced diagnostic and therapeutic equipment, including surgical navigation systems, implantable cardiac devices, neurostimulation systems, diagnostic point-of-care tests. The cardiovascular segment is growing due to an increase in heart diseases.

Main Competitors

Looking at the dynamics of foreign medical manufacturer penetration in the Ukrainian market, European and Japanese firms are more aggressive than their U.S. competitors. They were the first to establish representative offices and focus on Ukraine as a potential market.

Domestic medical equipment production is not competitive on a global scale. Ukraine has some production capacity, but firms are generally under-capitalized and unable to compete with the high quality and relative low costs of imports.

Current Demand

- Diagnostic imaging equipment (ultrasound, computer tomography, magnetic-resonance tomography)
- Emergency medical equipment (ambulances, mobile hospitals)
- Operating rooms
- Telecommunication equipment for telemedicine
- Laser surgery devices
- Dental equipment and materials
- Laboratory equipment

The Ukrainian market is receptive to high-quality, advanced diagnostic and therapeutic equipment. Innovative technologies such as laser-optics in vascular surgery, urology, gastroenterology, dermatology and neurosurgery; and new diagnostic devices are becoming more popular. Modern equipment offering ease of use and cost savings is required in the fields of micro-surgery, radiology and bio-medicine.

Registration Process

Registration is a requirement for the importation of medical equipment into Ukraine. It is performed by the State Service for Medicinal Products and Medical Devices under the Ministry of Health (MoH), and is based on evaluation of the product by expert testing agencies. Applications for registration must be submitted (on a standard form) to the State Service.

Ukraine is moves towards harmonization with European standards. The Technical Regulation on medical devices was adopted in October 2, 2013. The new system will utilize national conformity assessments similar to those used by EU regulators, and also introduces the following requirements for Ukrainian medical device registrations:

- Foreign registrants must appoint Authorized Representatives based in Ukraine
- Expanded list of documentation and sample submissions required for registrations
- Manufacturing site inspections for Classes I, IIa, IIb and III
- Special symbols of national conformity will be required for medical devices imported into Ukraine on or after July 1, 2014
- National conformity certifications valid for five years

Ukrainian officials plan a transition period for manufacturers that have already obtained registration; registrations that are currently valid will remain so either for the next three years or until their expiration dates, whichever come sooner.

Barriers

Although the new Ukrainian registration system will bear many similarities to the CE Marking process for medical devices in Europe, no simplified or expedited market pathways are planned for devices already approved or cleared for sale in major markets such as Europe or the U.S. Manufacturers should also be aware that Ukrainian regulations will require inspection of facilities even if those sites are already ISO 13485-compliant.

According to current regulations, government tenders are to be non-discriminatory against foreign bidders, with some exceptions granted on a tender-by-tender basis. These exceptions give priority to domestic suppliers.

Trade Events

Public Health

September 30–October 2, 2014 • Kyiv, Ukraine • ***publichealth.com.ua/en***
The largest medical equipment and pharmaceuticals trade show in Ukraine, including dental, clinical laboratory, and optical. Held annually. Organized by Premier Expo, part of the UK's International Trade Exhibitions Group.

United Arab Emirates

Summary

The Healthcare sector remains among the priority sectors identified by the United Arab Emirates' (UAE) government and, as a result, the UAE healthcare industry has displayed extraordinary growth and significant progress in the past few years. The government's focus on healthcare is aimed not only to diversify the oil-reliant economy but also to develop unprecedented healthcare infrastructure to ensure that adequate services are provided in the Emirates.

The World Health Organization determined that a third of adults in the UAE are obese, and one out of five people live with diabetes. As the incidences of lifestyle diseases increase, these populations, supported by relatively high levels of income, will demand greater quality of healthcare. Demand growth in this segment could act as an incentive for private investors to establish multi-disciplinary hospitals and specialized centers for complex diseases.

Healthcare is regulated at both the Federal and Emirate level. Federal level legislation dates back to the 1970s and 1980s and there are pending legislative reform initiatives in order to facilitate the development of the healthcare industry.

Market Entry

UAE represents a major market for U.S. exports and serves as an important regional hub for U.S. companies conducting business throughout the Middle East, Africa, and South Asia. Due to recent years' rapid bilateral trade expansion, UAE has overtaken Saudi Arabia as the largest Middle East market for U.S. products

Reflecting the country's role as a major regional commercial center, a significant portion of the UAE's import volume is ultimately re-exported. Dubai in particular plays a central role as a regional trade facilitation, logistics and tourism hub.

In terms of foreign investment, the UAE is the second largest recipient of foreign direct investment in the Gulf region. According to investment experts, some of

Statistics

Capital:	Abu Dhabi
Population:	9,205,651
GDP (USD):	360.2 billion
Currency:	UAE dirham (AED)
Language:	Arabic

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the biggest opportunities are likely to be found in healthcare projects which have already attracted major global companies such as General Electric and Siemens, both of which have large infrastructure business as well as being major suppliers of healthcare IT and diagnostic imaging technologies.

Initiatives such as the creation of free zones, including the two free zones, Dubai Health Care City (DHCC) and DuBiotech are an expected increase of FDI in general and investment in healthcare research in particular.

As a general rule, a foreign company intending to conduct business in the UAE must do so either by (a) incorporating a local entity "onshore," (b) incorporating an entity in one of the UAE's many free zones, (c) establishing a branch of representative office (either "onshore" within the UAE, or in one of the free zones, or (d) via a local commercial agent.

- Restrictions on foreign ownership limit foreign companies' participation to a maximum of 49 percent of the equity in a UAE "onshore" company.
- While an entity within one of the UAE's free zones can be wholly owned by a foreign company, as a general rule, such free zone entities may only conduct their business within the boundaries of the free zone. Accordingly, in order to distribute products throughout "onshore" UAE, the services of a local distribution agent are required.

Current Market Trends

Reports estimated that the UAE spent 3.7 percent of GDP on healthcare in 2013, equal to USD 15.8 billion or USD 1,692 per capita, which is among the top 30 highest rates in the world. Public healthcare expenditure represents around three-quarters of the total. Private healthcare expenditure makes up two-thirds of the total. The government plans to improve its healthcare infrastructure to ensure that adequate medical services are provided in the Emirates. While many UAE residents have traditionally sought medical care overseas, the UAE government hopes to ultimately reverse this flow, turning the UAE into a medical tourism destination. Imports of medical devices reached USD 746.9 million in 2013. The UAE is a zero-tax country, with excellent transportation and logistics infrastructure and is geographically well positioned to be the commercial hub in the region. These factors make it an attractive location for establishing a regional distribution center for medical devices. Healthcare is regulated at both the federal and Emirate level. Registration of medical devices is regulated by the UAE Ministry of Health. The regulation of medical devices in the UAE is aimed at maintaining a balance between product safety, quality and effectiveness.

The medical devices market is projected to expand at a 2013–18 CAGR of 7.3 percent which should see it grow from an estimated USD 841.2 million in 2013 to around USD 1,198.1 million in 2018. The orthopedics and prosthetics product area is expected to record the highest 2013–18 CAGR, whilst the diagnostic imaging product area is expected to register the lowest CAGR.

Definition of Medical Devices

Products including accessories used in healthcare for diagnosis, prevention, monitoring or treatment of illness or handicap excluding drugs. Medical devices can be consumables, diagnostic imaging, dental products, orthopedic and prosthetic products, and patient aids.

Medical Device Regulations

All medical devices must be approved by the UAE Ministry of Health Drug Registration and Control Department. Imported medical devices will not be cleared by Customs unless a pre-approval for importation of the consignment is issued by MOH.

If the exporter company/manufacturer has no legal presence in the UAE, it will have to appoint a local representative to act on its behalf to register the devices. The local representative must be appointed by written contract stating the appointment of the local authorized representative by the company. The local representative should be licensed by the Ministry of Health.

Qualification of Registration of Medical Devices

An application to register a medical device in the UAE must be made by the device manufacturer or its local representative/distributor. The local representative/distributer must be formally authorized by the manufacturer to handle the application process and the manufacturer's legal obligations and responsibilities with regard to placing the medical device in the UAE market. The authorized representative/distributer must be available to interact between the medical device manufacturer and the Ministry of Health.

Supporting Documents to the Committee

The applicant must provide the committee with the following documents: Copies of all certificates related to ISO 9001:2000 standards; the ISO 13485:2003 standard attested and authenticated GMP (Good Manufacturing Practice) original certificate issued by the relevant health authorities at country of origin attested and authenticated; device description, intended use, directions for use, contraindications, warnings, precautions; specifications of material used in device manufacturing and packing; copies of certification and documents certifying conformity to product standards, safety, and quality systems in design and manufacturing; list of countries where it is marketed and details of regulatory status; a summary of "mandatory" reported problems with device since its introduction in the market; risk assessment comprising risk analysis, evaluation and reduction measures; detailed information on safety studies which includes pre-clinica and clinical studies, software studies, software validation studies where appropriate, and bibliography of published reports dealing with the device; stability studies; price information, such as ex-factory price; and post-market requirements, i.e.,: providing evidence of established procedures and systems for distribution records.

These documents may be submitted in English or Arabic. The applicant must declare that all submitted documents are true and that she will be fully responsible for the product and

post-market plan submitted for complaint handling and recall and, that she will fully comply with the requirements of the Drug Control Department after the placing of the product in the market.

Main Competitors

The UAE market is totally dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate, European suppliers are aggressively gaining market share with their close proximity to the market and perceived better customer support.

Registration Process

Current medical device regulations in the UAE are based upon EU, Australian TGA and U.S. FDA regulation. Products with EU, Australian, FDA, Canada's TPP approval are eligible for a shortened registration process in the UAE.

Foreign countries wishing to export their products into the UAE must do so through a local representative or distributor who has a licensed medical store/entity from the MOH.

For example for the medical devices registration: the appointed local distributor/ representative must submit a medical device registration application form to the MOH Drug Control Department. If the application is approved, a registration number will be given, which will be valid for five years. The application can be written in either English or Arabic.

According to the MOH, approval process takes between 8–12 weeks after the application is submitted.

Barriers

The UAE Commercial Companies Law requires that each company established in the UAE have one or more UAE national partner(s) who hold at least 51 percent of the company's capital. Foreign companies may engage in a commercial agency arrangement whereby a foreign company is represented by a UAE agent to distribute, sell, offer, or provide goods or services within the UAE. The agent must either be a person holding UAE nationality or a company that is 100 percent owned by UAE nationals.

Trade Events

Arab Health 2015

January 26–29, 2015 • Dubai, UAE • ***arabhealthonline.com***

Hospital Build 2015

June 1–3, 2014 • Dubai, UAE • ***hospitalbuild.com***

United Kingdom

Summary

The UK healthcare sector was worth USD 240 billion in 2013. It is split between the public healthcare system (National Health Service, NHS), the principal purchaser of medical products, which was valued at just over USD 188 billion in 2013, and private healthcare (USD 52 billion). The NHS, which is publicly funded through taxation, provides free treatment at the point of delivery for the majority of its services. Private healthcare is mainly funded through private medical insurance. Its strengths lie in the provision of secondary and tertiary care, fields not traditionally offered by the NHS (for instance cosmetic surgery), or where public health services are limited (dental care). The nature of the UK healthcare market means that private sector growth is closely linked to public sector performance, policy and funding for core services.

The country's medical equipment market was valued at USD 9 billion in 2013. It is the world's sixth and one of Europe's largest medical equipment markets. It is expected to increase in value by between 4–5 percent each year in 2014 and 2015. The U.S. is the most important overseas source of medical devices, with an estimated 21 percent of share of the market in 2013. It is a leading supplier of diagnostic, dental, orthopedic equipment and high quality wound care products to the UK.

The UK medical technology sector comprises of just over 3,100, mainly small to medium sized companies. They are evenly spread across the country with small clusters of firms situated in the Midlands and East of England. Radiotherapy equipment, neurology and cardiovascular devices were the top performing segments, in terms of increased turnover, in 2013. Other well performing segments included single use technology, in vitro diagnostic technology and orthopedic devices.

Market Entry

The NHS is traditionally regarded as one system, and receives funding from central government, but is essentially managed as four separate segments: NHS Wales, NHS Scotland, HSC Northern Ireland and NHS England. NHS England, the largest

Statistics

Capital:	London
Population:	64.1 million (est. 2013)
GDP (USD):	2.5 trillion (est. 2013)
Currency:	Pound Sterling (£/GBP)
Language:	English

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segment (82 percent of the UK population), is comprised of around 200 general practitioner-led (GP) clinical commissioning groups (CCG's), which plan and commission NHS services, such as hospital care or community health services, for their local patients; 166 acute trusts, which provide hospital services; 12 ambulance trusts; and 60 mental health trusts. Most medical device procurement is done by acute trusts that have the choice of purchasing through organizations such as NHS Supply Chain (***www.supplychain.nhs.uk***), which maintains a product catalog of "approved" medical products and services. Trusts may also buy individually or pool resources with each other for procurement decisions.

Companies developing or selling innovative products can approach organizations, such as the NHS Supply Chain or NHS Innovations, for guidance. As there is very little opportunity to sell directly to the NHS from overseas, U.S. exporters are advised to form distribution partnerships with well-established local companies. This enables new entrants to take advantage of their partner's market expertise as well as their access to buyers and other decision makers within the NHS. Potential suppliers can approach private sector firms directly about procurement opportunities.

Current Market Trends

- The UK's aging population is causing an increase in age-related health problems and demand for adequate social care. One way the NHS is seeking to address this is through the use of assistive technology which enables patients to self monitor their health. The growing use of home technology is part of a trend towards a shift in healthcare provision from hospitals to community services, and the wider use of e-health technologies.
- Demand exists within the rehabilitation and orthopedic area due to government efforts to promote disabled and elderly independence.
- There continues to be a focus on preventative care, in areas such as oral health, diet and fitness, to address the rise in 'lifestyle related' conditions such as diabetes and obesity.
- Within the dental market the private sector should continue to benefit from the shift of patients from the public sector to private providers. This is because the NHS limits the treatments it offers, while the private sector is able to offer more aesthetic and innovative treatments that patients are willing to pay for.
- Recent healthcare reform in England is creating opportunities for private sector health providers to supply more goods and services.

Main Competitors

Many of the leading U.S. medical device manufacturers have subsidiaries in the UK. They include companies such as Medtronic and GE Healthcare Ltd. The UK medical device industry is still fragmented with many small companies selling specialist equipment and devices. Approximately 98 percent of firms are classed as SMEs.

Current Demand

Substantial resources are currently committed to treating several diseases:

- Cancer
- Alzheimer's
- Parkinson's
- Diabetes
- Rheumatoid Arthritis
- Digestive Disorders
- Communicable Diseases
- Obesity

Registration Process

Medical devices and medicines require an appropriate CE mark or marketing license, respectively, to be sold and marketed in the UK. The Medicines and Healthcare Products Regulatory Agency (***mhra.gov.uk***), an agency of the Department of Health, governs the regulation of medicines and devices.

Barriers

U.S. companies should not encounter any political or trade barriers to market entry. The UK adheres to EU procurement rules and conducts most buying through commercial negotiation. That said, the NHS faces considerable financial pressure and so will often make purchasing decisions based on price alone, rather than factoring in quality or patient outcomes.

One hurdle that companies can face is the UK National Institute of Health and Clinical Excellence (NICE), which judges the clinical and cost-effectiveness of new and existing drugs, treatments, and medical devices. It provides the NHS with guidance on treatment strategy and influences procurement decisions by stating which products are reimbursable on the NHS.

Trade Events

Naidex and Naidex Scotland

Birmingham, England; Glasgow, Scotland • ***naidex.co.uk***
Home, disability, and rehabilitation exhibition.

Medical Device Technology Exhibition (MEDTEC)

London, England • ***medtecuk.com***
Exhibition for the medical devices manufacturing industry.

The Dentistry Show

Birmingham, England • ***thedentistryshow.co.uk***
Dental conference and exhibition.

Uruguay

Summary

Uruguay imports almost all its medical equipment. Major market opportunities are for new, technologically advanced supplies and equipment, particularly in the areas of non-invasive procedures, ultrasound, magnetic resonance imaging, and CT scans. All products must be registered with the Ministry of Public Health by a duly approved and registered local representative. CS can assist U.S. firms with finding their local business partner.

Market Entry

Approximately 35 percent of Uruguay's total medical equipment imports are for the public sector and 65 percent are for the private sector.

Customs duties and other taxes for medical equipment range from 0–20 percent. The only products that require special processing are those associated with orthodontics, on which a 5 percent Professional and University Orthodontics tax is applied.

Current Market Trends

With the exception of low-tech monitors, almost none of the medical equipment and surgical supplies sold in Uruguay is produced locally. Major market opportunities are for new, technologically advanced supplies and equipment, particularly in the areas of non-invasive procedures, ultrasound, magnetic resonance imaging, and CT scans. Buyers turn to U.S. suppliers for cardio instruments and imaging, as well as for blood transfusion, IV, and surgery equipment.

Statistics

Capital:	Montevideo
Population:	3.3 million
GDP (USD):	55.8 billion
Currency:	Uruguayan Peso (UYU)
Language:	Spanish

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Main Competitors

The majority of products for local distribution are imported from Argentina, Brazil, Mexico, the EU, and the United States. Asian countries and particularly China have increased their market share since 2008 at steady rates.

Current Demand

Cardiovascular problems are the most common cause of death amongst the population over 45 years old, with malignant tumors as the second leading source of mortality.

Imports of refurbished medical equipment are authorized and many times preferred by small private clinics (refurbished protocol must be presented with registration request).

Registration Process

All medical products have to be registered and approved by the Ministry of Public Health (MPH). The Ministry's Division of Control is responsible for all registrations. With prior authorization from the MPH, orthopaedic prosthesis as well as other items for handicapped patients or institutions may be exonerated from tariff duties. Only local and duly approved companies may register medical equipment and supplies.

Barriers

Local importers and distributors, as well as health institutions, face challenges due to the requirement that the purchase of any new or replacement of old equipment valued at more than USD 15,000 needs the MPH's prior approval.

Trade Events

Medical conventions may include exhibits, but the exhibits are primarily from the companies that are sponsoring the event. Most local importers/distributors/physicians attend shows in Brazil, Argentina, and the United States.

Available Market Research

- Medical Equipment Overview
- Registration Process Brief (Medical equipment and Pharmaceuticals)
- Clinical Lab Equipment and Supplies

Vietnam

Summary

Vietnam represents a potentially large healthcare, medical equipment and device market. Identified as one of the national development priorities, the Vietnamese public healthcare sector has received increasing government budget allocations as well as interest from the private sector. Healthcare experts estimated that the market size was USD 265 mil in 2014. The market growth was approximately 12 percent during 2009–11; but is currently only growing at 5–6 percent.

The Vietnamese healthcare system currently has an estimated 1,062 state hospitals, 100 local private hospitals and 15 foreign invested hospitals that total 145,000 beds. There are 273 new hospitals at some stage of the planning process with slightly over half of these projects located in Southern Vietnam.

Market Entry

The government encourages import of medical equipment because local production cannot meet Vietnam's demands. Imported medical equipment faces low import duties and no quota restrictions. However, medical devices are subject to regulation and licensing requirements set by the MOH. By regulation, only companies with a legal business entity registered in Vietnam and that have an import license are eligible to distribute medical equipment in Vietnam. To fulfill this requirement, foreign suppliers often sell their products through local distributors or agents. Good representatives provide immediate access to an established marketing network and in-depth knowledge of pertinent regulations.

Current Market Trends

The best opportunities for medical devices in Vietnam are ones which help fight liver cancer, diabetes, orthopedics and cardiovascular diseases. Devices which

Statistics

Capital:	Hanoi
Population:	92 million
GDP (USD):	171.39 Billion
Currency:	Vietnamese dong (VND)
Language:	Vietnamese

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will be strong areas of growth include operating theaters, emergency equipment, sterilizing equipment, patient monitoring equipment and imaging diagnostic equipment such as CT scanners, color ultrasound machines, MRIs and X-ray machines.

Main Competitors

Over 95 percent of the market is made up of foreign goods. The main sources are from the U.S., Germany and Japan. In addition, Taiwan, Italy, France and South Korea also account for significant shares. Local production is extremely limited in terms of value, but volume levels suggest the foundation for ascent up the value chain. There are presently 50 domestic firms making approximately 600 products officially licensed by MOH. They tend to produce products such as hospital beds, scalpels, cabinets, scissors, and disposable supplies. They also tend to offer limited or no warranty or after-sales services, especially in isolated areas.

Registration Process

MOH determines the guidelines for medical device purchase for all health systems in Vietnam. Within the MOH, the Department of Medical Equipment and Construction is in charge of medical devices. The Ministry of Science and Technology ("MOST") performs some regulatory functions for domestically made medical devices. There is a list of selected medical devices (Circular 24/2011/TT-BYT) that require import licenses in order to be imported and sold in Vietnam. Dossiers of application of an import license must be sent to the Department of Medical Equipment and Health Works (DMEHW) under the MOH for synthesis and submission to the MOH's Science and Technology Council for consideration and grant of permits within 15 working days after the full receipt of valid dossiers.

Most imports of used and refurbished medical equipment are strictly controlled by the MOH. Decision 2019/1997/QD-BKHCNMT dated December 1, 1997, stipulates that the Ministry of Science, Technology, and Environment (MOSTE) must inspect and certify all imports of used medical equipment. Because of the restriction, local companies are generally not willing to deal with foreign suppliers of used and refurbished equipment. In practical terms, MOH accepts used equipment for donation purposes only.

Trade Events

VIETNAM MEDI-PHARM EXPO 2014

TBD 2015 • ***medipharmvietnam.com***
international hospital, medical, and pharmaceutical exhibition.

Available Market Research

- Medical Device Market—Department of Medical Equipment and Health Works
- Pharmaceuticals and Healthcare Report—BMI.
- Vietnam Healthcare Sector Overview—Stoxplus

DM MÉXICO

DISPOMED®

DISPOMED, is a company with highly qualified professional and technical staff with over 20 years of experience in quality assurance and sanitary regulations for pharmaceutical products and medical devices under the schemes of Good Manufacturing Practices (GMP) in Mexico (COFEPRIS), USA (FDA), Brazil (ANVISA), Argentina (ANMAT), ISO 9001, ISO 13485, CE MARK and other European Medical regulations.

The company's staff has served in various positions in different companies in the pharmaceutical and medical device sectors and knows how to implement and apply such systems and regulations in benefit of the companies. It also has a representative in Europe and agreements with companies in other countries, in order to support its clients that require assistance there.

They focus in supporting companies in lowering their costs and having a more efficient operation. They offer high confidentiality treatment of all the information and cases they handle.

Offered services

File (dossier) review for sanitary registration process with COFEPRIS, FDA, and European, Canada and Brazil authorities.
Act as your Sanitary Registration Holder.
Quality systems review and/or implementation.
Quality system audits.
Training and coaching in Quality Systems and Health Regulatory processes.
Regulatory compliance for national and international shipments.
Business facilitation before other Agencies such as: Authorizations, Certifications, etc.
Risk Analysis report preparation.
Resolves and technical support of non-conformities as result of submit of sanitary registration process or review to the quality system.
Technovigilance and Pharmacovigilace units (notification of integration to the authority)
Preparation of documents for specialized translations (Legal and simple traslations)

Permanent follow up
Medical devices distribution in Mexico (hosting)
Administration of regulatory affairs for companies.

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Resources

export.gov
Locate your local CS office and find information about our international business services.

CS Global Healthcare Technologies Team (*export.gov/industry/health*)
Information on industry-specific trade events, trade leads, newsletters, and more.

Trade Finance Guide (*export.gov/tradefinanceguide*)
A quick reference for U.S. exporters. Offers the basics of numerous financing techniques, from open accounts, to forfeiting, to government assisted foreign-buyer financing.

A Basic Guide to Exporting (*export.gov/basicguide*)
First published in 1938, the recently-revised Basic Guide is designed to help U.S. businesses, especially small and medium-sized enterprises, face the challenges of today's global economy.

Free Trade Agreements (*export.gov/fta*)
Learn how Free Trade Agreements can help make exporting easier for you.

Ex-Im Bank Medical Equipment Initiative (*go.usa.gov/Dutj*)
Offers solutions to increase the export of medical equipment, including creative financing structures and enhanced coverage.

Subsector Reference Chart

Rating Definitions

1 Little to no probability of success for U.S. exporters

2 More challenges than opportunities

3 More oportunities than challenges

4 Very high probability of success for U.S. exporters

	Medical Devices—General	Medical Devices—Monitoring Equipment	Medical Devices—Orthopedic	Medical Devices—Surgical	Medical Capital Equipment	Biomedical	Clinical Chemistry Diagnostics	Dental	Dietary Supplements	Drugs & Pharmaceutical	Health IT	Laboratory Equipment	Used Equipment	Veterinary Medicine	Consulting Services
Europe															
Austria	4	4	2	4	3	4	4	3	2	4	3	4	1	3	2
Belgium	3	3	3	3	3	3	3	3	2	2	3	3	2	3	2
Bulgaria	3	2	3	2	2	4	3	3	3	3	3	2	2	3	2
Croatia	4	4	4	3	3	3	4	4	4	4	4	4	3	4	3
Cyprus	4	3	3	4	3	4	3	3	3	2	4	2	1	2	2
Czech Republic	3	3	3	3	2	3	3	3	2	3	3	3	2	3	2
Denmark	3	3	2	3	3	3	3	2	1	3	4	3	1	2	1
Finland	3	3	3	3	2	3	2	3	2	2	4	3	1	3	2
France	3	3	3	2	2	2	4	3	2	4	3	3	1	2	1
Germany	3	3	3	3	2	3	3	3	2	2	3	3	2	3	3
Greece	3	2	3	3	2	2	3	3	3	3	3	2	1	2	3
Hungary	3	3	2	2	2	3	4	3	3	3	4	3	2	2	2
Ireland	3	2	3	3	2	3	2	3	3	3	3	2	2	3	2
Italy	3	3	3	3	2	3	3	3	2	2	3	3	1	2	2
Macedonia	3	4	3	3	3	3	3	3	2	4	3	4	2	3	3
Netherlands	3	3	2	2	2	2	3	2	2	2	3	3	1	3	2
Norway	4	4	3	3	3	3	3	3	1	2	4	3	1	3	2
Poland	2	2	2	2	1	2	2	3	2	2	2	2	2	2	2
Portugal	3	3	3	3	3	3	3	3	3	3	4	3	2	3	3
Slovak Republic	3	3	2	3	2	3	3	3	2	3	4	3	2	2	2
Spain	2	2	2	2	2	2	2	2	2	2	2	2	1	2	1
Sweden	4	4	2	3	2	3	3	3	2	3	4	3	1	2	2
Turkey	4	4	3	4	4	4	4	4	2	3	4	3	1	3	2
United Kingdom	3	3	3	2	3	3	3	3	2	3	3	2	2	3	3
Ukraine	3	3	2	4	3	3	3	3	2	3	3	3	2	2	1
Western Hemisphere															
Argentina	3	3	2	2	3	3	3	2	1	2	2	3	1	1	1
Bolivia	4	4	3	3	2	2	2	4	3	3	3	4	4	3	2
Brazil	3	2	2	3	3	3	3	2	3	2	3	3	1	2	4
Chile	3	3	4	3	1	3	2	2	1	1	3	2	1	3	2
Colombia	4	3	3	4	3	3	2	3	3	2	3	3	1	3	1
Costa Rica	4	4	4	4	1	3	2	4	1	2	2	2	1	2	1
Dominican Republic	3	4	4	3	3	2	3	3	3	2	3	3	2	3	2
Guatemala	4	4	3	3	3	2	3	2	3	3	2	3	2	3	2
Mexico	3	3	3	3	3	3	2	2	2	2	4	3	3	3	3

Rating Definitions **1** Little to no probability of success for U.S. exporters **2** More challenges than opportunities **3** More oportunities than challenges **4** Very high probability of success for U.S. exporters	Medical Devices—General	Medical Devices—Monitoring Equipment	Medical Devices—Orthopedic	Medical Devices—Surgical	Medical Capital Equipment	Biomedical	Clinical Chemistry Diagnostics	Dental	Dietary Supplements	Drugs & Pharmaceutical	Health IT	Laboratory Equipment	Used Equipment	Veterinary Medicine	Consulting Services
Middle East/Africa															
Egypt	3	3	3	4	2	3	3	3	3	3	2	3	1	3	2
Ghana	2	3	3	3	3	2	3	3	3	3	2	3	4	2	3
Israel	4	4	4	4	4	4	3	3	3	4	3	3	1	4	2
Jordan	3	3	4	2	3	3	3	2	3	3	4	3	1	2	2
Kenya	4	4	4	4	4	3	3	3	2	3	3	3	4	2	2
Kuwait	4	4	4	4	4	4	4	4	4	4	3	4	1	3	2
Nigeria	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Oman	3	3	3	3	3	3	3	3	2	2	4	3	2	2	3
Saudi Arabia	4	4	4	4	4	2	4	4	2	2	4	4	1	2	2
United Arab Emirates	4	4	4	4	3	3	3	3	2	3	3	3	2	2	2
Asia/Southeast Asia															
Australia	4	4	4	4	4	4	4	4	2	3	3	4	1	4	3
China	3	2	3	3	2	3	3	3	2	2	3	3	1	4	2
Hong Kong	4	4	4	4	3	4	4	4	3	3	3	3	1	3	2
India	4	3	4	4	4	3	4	3	3	3	3	3	3	2	2
Indonesia	3	4	3	3	3	3	3	3	3	2	3	3	1	2	2
Malaysia	3	3	3	3	3	3	3	3	3	3	3	3	1	3	2
Japan	3	2	3	3	2	3	2	2	2	3	3	3	1	2	2
Korea, Republic of	3	2	3	3	2	2	2	3	3	2	2	2	1	2	1
New Zealand	3	3	3	3	3	2	2	2	3	3	2	3	1	3	1
Philippines	3	3	3	3	2	3	3	1	1	2	3	3	3	2	1
Singapore	3	3	4	3	3	3	3	3	3	3	3	3	1	3	2
Taiwan	3	3	3	3	2	3	3	3	3	3	3	3	1	2	2
Thailand	4	4	4	4	2	3	4	2	2	3	4	4	1	3	1

Certification Reference Chart

Rating Definitions **1** Little to no probability of success for U.S. exporters **2** More challenges than opportunities **3** More oportunities than challenges **4** Very high probability of success for U.S. exporters	Requires FDA Certification?	Accepts FDA Certification?	Requires CE Mark Certification?	Accepts CE Mark Certification?	Other Certification Required?	Other Certification Accepted?	Certifying Body	Preferred Certification
Europe								
Austria	No	No	Yes	Yes	No	No	*tuev.at*	CE
Belgium	No	No	Yes	Yes	Yes	Yes	*fagg-afmps.be*	CE
Bulgaria	No	No	Yes	Yes	GMP[1]	Yes[2]	*bda.bg*	CE
Croatia	No	No	Yes	Yes	No	No	*halmed.hr*	CE
Cyprus	No	No	Yes	Yes	No	No	EU Notified Bodies	CE
Czech republic	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Denmark	No	No	Yes	Yes	No	No	Dansk Standard	CE
Finland	No	No	Yes	Yes	Yes[3]	No	*valvira.fi/en*	CE
France	No	No	Yes	Yes	No	No	*www.gmed.fr*	CE
Germany	No	No	Yes	Yes	RoHS/WEEE	Yes	EU Notified Bodies	CE
Greece	No	No	Yes	Yes	Yes[3]	No	EOF, ELOT, EKEVYL	CE
Hungary	No	No	Yes	Yes	Yes	Yes	*mkeh.gov.hu*	CE
Ireland	No	Yes	Yes	Yes	Yes[4]	N/A	*www.imb.ie*	CE
Italy	No	Yes	Yes	No	Yes	N/A	Yes	CE
Macedonia	No	No[5]	Yes	Yes	No	Yes[6]	N/A	CE
The Netherlands	No	No	Yes	Yes	No	N/A	Yes	Yes
Norway	No	No	Yes	Yes	No	No	Nemko, Justervesenet, Nordic Dental, DnV	Yes
Poland	No	No	Yes	Yes	Yes	No	*urpl.gov.pl; pcbc.gov.pl*	CE
Portugal	No	Yes	Yes	Yes	No	No	N/A	CE
Romania	No	No	Yes	Yes	Maybe	No	EU Notified Bodies	N/A
Russia	No	No	No	No	Yes	No	Yes	N/A
Slovak Republic	No	Yes	Yes	Yes	Yes	Yes	*sukl.sk*	Yes
Spain	No	No	Yes	Yes	Yes	Yes	*agemed.es*	CE
Sweden	No	No	Yes	Yes	No	No	*lakemedelsverket.se*	CE
Turkey	No	No[7]	Yes	Yes	No	No	*global.tse.org.tr*	CE
United Kingdom	No	No	Yes	Yes	Maybe	No	*mhra.gov.uk*	
Ukraine	No	No	No	No	Yes[8]	N/A	Yes[8]	

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Western Hemisphere								
Argentina	Yes	Yes	-	-	Yes[8]	-	ANMAT	FDA
Bolivia	No	No	No	No	Yes[8]	No	Yes[8]	-
Brazil	Yes	Yes	No	Yes	Yes	Yes	Anvisa/Inmetro	Yes
Canada	No	No	No	No	Yes	No	Health Canada	-
Chile	No[9]	No[5]	No[9]	No[5]	Maybe[10]	No	Instutue of Public Health	FDA, CE
Colombia	Yes[11]	No[11]	-	-	-	-	*www.invima.gov.co*	-
Costa Rica	Yes	-	-	-	-	-	Yes[8]	FDA
Dominican Republic	No	Yes	No	Yes	No	Yes	N/A	N/A
Guatemala	No	Yes	No	Yes	No	-	Yes[8]	FDA, CE
Mexico	Yes	No	No	No	Yes	No	COFEPRIS	N/A
Uruguay	No	No	No	No	Yes	No	Yes[8]	N/A
Middle East/Africa								
Egypt	Yes	Yes	Yes	Yes	ISO	ISO	Yes[8]	Yes[8]
Ghana	Yes[12]	Yes[13]	No[14]	Yes	Yes[13]	Yes[13]	Yes[15]	FDA, CE
Israel	Yes	Yes	Yes	Yes	Yes[16]	Yes	Yes[8]	FDA
Jordan	Yes	Yes	Yes	Yes	ISO	ISO	Yes[15]	Yes[15]
Kenya	No	No[5]	No	No[5]	Yes[8,10]	-	Pharmacy and Poisons Board (PPB)	Yes[8]
Kuwait	Yes	Yes	Yes	Yes	ISO	ISO	Yes[8]	Yes[8]
Nigeria	Yes	Yes	Yes	Yes	Yes	-	SONCAP (equipment); NAFDAC (food/drugs)	-
Oman	Optional	Yes	No	Yes	No	No	Yes[8]	N/A
Saudi Arabia	Yes	Yes	Yes	Yes	ISO	Yes[17]	Yes[15]	FDA, CE, GHTF
South Africa	No	Maybe	Yes	Yes	Yes	No	Yes[8]	CE
United Arab Emirates	Yes	Yes	Yes	Yes	ISO	ISO	Yes[8]	Yes[8]

1 WEEE for electronic elements.
2 All European certifications accepted.
3 Notify national certifying body about high-risk devices.
4 EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC
5 Having this certification will assist with receiving preferred certification.
6 ISO 9001; ISO 13485; ISO 14001.
7 Certified devices preferred in marketplace.
8 National health ministry or similar organization.
9 Certification not required; however, limited or no opportunity without certification.
10 Depends on product.
11 Not as final certification.
12 Company must also be in good standing.
13 Local registration and representation also required.
14 Not unless company is based in EU.
15 National food and drug authority/administration.
16 Electric safety testing.
17 One of the GHTF founding member jurisdictions.
18 Additional documentation also required.
19 Australian, Canadian, and Japanese Health Ministries.

Rating Definitions **1** Little to no probability of success for U.S. exporters **2** More challenges than opportunities **3** More oportunities than challenges **4** Very high probability of success for U.S. exporters	Requires FDA Certification?	Accepts FDA Certification?	Requires CE Mark Certification?	Accepts CE Mark Certification?	Other Certification Required?	Other Certification Accepted?	Certifying Body	Preferred Certification
Asia/Southeast Asia								
Australia	No	No	No[5]	Yes	Yes[10,8]	-	Yes[8]	-
China	Yes	No	No	No	No	No	SFDA	FDA
Hong Kong	No	Yes	No	Yes	No	Yes	Yes[8]	Yes
India	Yes	Yes	Yes	Yes	No	N/A	*cdsco.nic.in*	N/A
Indonesia	Yes	Yes	No	Yes	Yes[18]	No	ISO, EU	FDA
Japan	No	No	No	No	N/A	N/A	Yes[8]	N/A
Korea, Republic of	No	No	No	No	-	-	Yes[8]	-
Malaysia	No	Yes	No	Yes	Maybe	Yes	Yes[8]	Yes
New Zealand	No	No	No	No	N/A	N/A	Yes[8]	-
The Philippines	No	No[5]	Yes	Yes	-	Legislation pending	Yes[8]	-
Singapore	No	Yes	No	Yes	No	Yes[19]	Health Sciences Authority, Singapore, Medical Device Branch, Health Products Regulations Group	Yes
Taiwan	No	Yes	No	Yes	Yes[18]	ISO 13485	Yes[8]	N/A
Thailand	Yes	Yes	Yes	Yes	Maybe[10]	ISO 9001; ISO 13485	Yes[8,15]	FDA
Vietnam	Yes	Yes	Yes	Yes	Yes	N/A	Yes[8]	FDA

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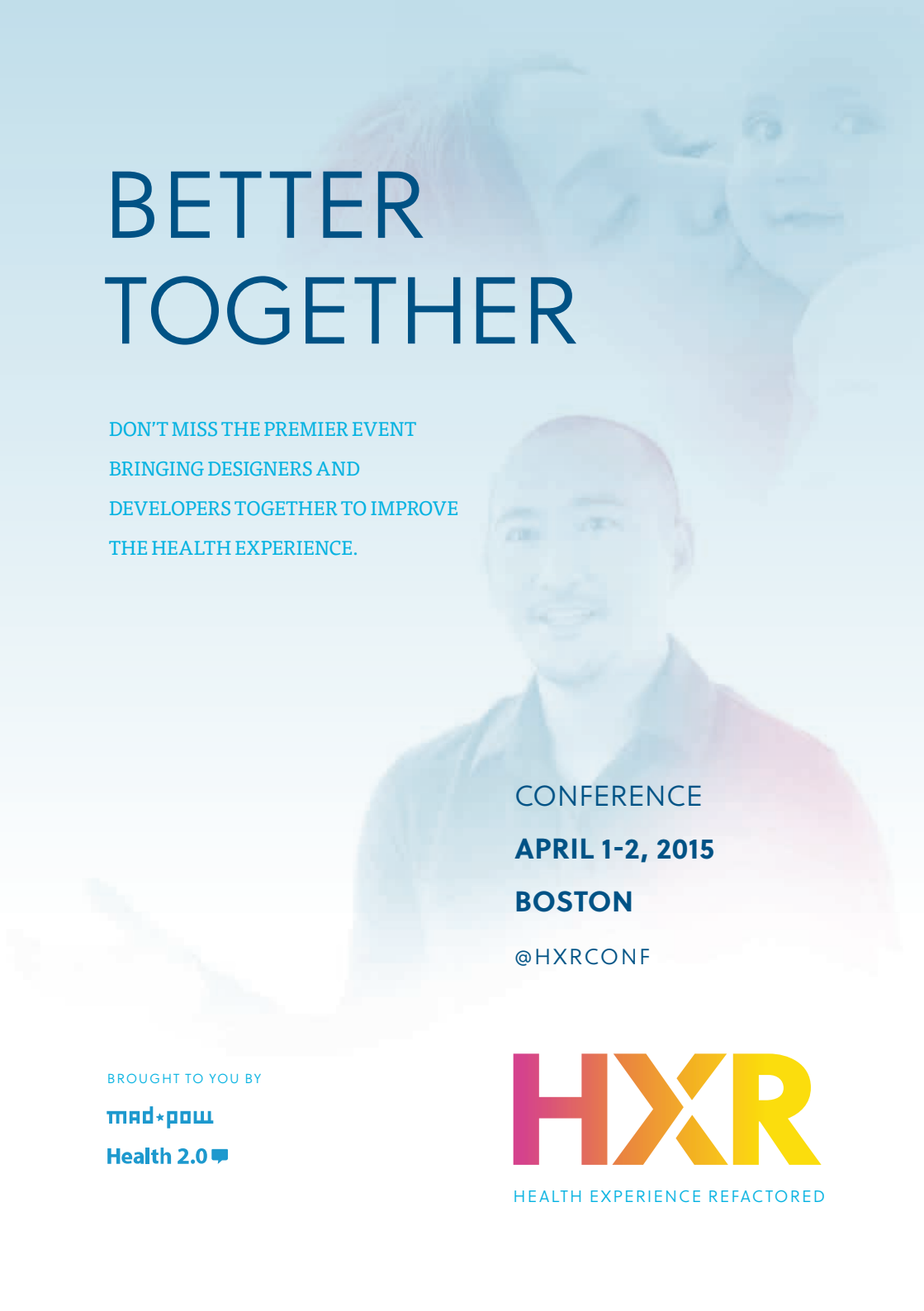

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