



Branding the Cure

A consumer perspective on Corporate Social Responsibility, Drug Promotion and the Pharmaceutical Industry in Europe



About Consumers International (CI)

Consumers International (CI) is a federation of consumer organisations dedicated to the protection and promotion of consumers' interests worldwide through institution-building, education, research and lobbying of international decision-making bodies. It was founded in 1960 as a non-profit organisation, and currently has over 230 members in 113 countries.

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Branding the Cure: A consumer perspective on Corporate Social Responsibility, Drug Promotion and the Pharmaceutical Industry in Europe.

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Glossary and acronyms

ABPI	Association of the British Pharmaceutical Industry (ABPI)
ACCME	Accreditation Council for Continuing Medical Education
CSR	Corporate social responsibility
DACs	Disease awareness campaigns
DTCA	Direct-to-consumer advertising
EFPIA	European Federation of Pharmaceutical Industries Associations
Evergreening	The practice of obtaining patent protection for improved formulations for a 'known' drug or for using a 'known' drug to treat 'new' ailments.
Generic	Generic drugs come from pharmaceutical companies that have not developed these drugs themselves and are marketing them independently from the originator companies. Normally these drugs are no longer protected by patents.
ICRT	International Consumer Research and Testing organisation
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
MHRA	Medicines and Healthcare Regulatory Agency (UK)
OTC	Over-the-counter medication
Patent	A patent is a set of exclusive rights granted for a fixed period of time in exchange for the regulated, public disclosure of certain details of an invention industrially applicable.
PhRMA	Pharmaceutical Research and Manufacturers of America
PMPCA	Prescription Medicine Code of Practice Authority (UK)
R&D	[Pharmaceutical] Research and Development
WHO	World Health Organization

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Executive summary

The project

Why do consumers care about the corporate ethics behind the medicines they consume? Are the grand claims of responsible behaviour asserted by the pharmaceutical giants genuine, or another disappointing show of corporate savvy in masking ethically questionable behaviour?

These are some of the questions Consumers International (CI) and its consortium of partners sought to address via the Media Network for Corporate Social Responsibility (CSR) and Sustainable Consumption (SC). Through this project, initiated in 2005, CI and several of its member organisations teamed up with the International Consumer Research and Testing organisation (ICRT) to investigate the validity of industry claims about CSR in the context of drug promotion. CI members examined drug promotion practices in the Czech Republic, Denmark, Finland, Greece, Hungary, Portugal and Slovenia.

What does CSR mean for consumers?

CSR includes business activities beyond profit making, to protecting the environment and workers, being ethical in business operations and being involved in the local communities in which companies work. It should be stressed that from the consumer viewpoint, CSR refers to respect for consumer rights through responsible company behaviour, and not to philanthropy alone. Cross-

cutting operational aspects like transparency form an important part of CSR policies as well.

CI believes that media reporting of CSR issues is vital to consumer confidence in a company claims of socially responsible business practices. A large part of public opinion on CSR is shaped by the media, whether through positive or negative portrayals of company behaviour. In addition, phenomena such as 'brand loyalty' indicate consumers are susceptible to having their attitudes and behaviours shaped by the media. This project harnesses the influential potential of consumer media to sustain public dialogue on CSR. In doing so, the project is an innovative step in improving consumer engagement on the issue of CSR.

The problem

Pharmaceutical companies are major stakeholders in the global health agenda. In 2005 total global pharmaceutical sales grew 7% at constant exchange rates, to \$602 billion.¹ Virtually all drugs used by patients reach markets through promotion by a small number of corporations who have a tremendous impact on global health. Consumers have therefore identified drug promotion as a priority CSR issue.

However, existing CSR reporting mechanisms are extremely varied among companies, codes of conduct are not thoroughly implemented and enforced, and the information for consumers is incomplete or inaccessible.

The case of drug promotion highlights an emerging crisis of legitimacy for the concept of CSR. If barriers to transparent and verifiable information persist, the consumer movement – like other stakeholders – will begin to lose faith in the CSR dialogue. This potential outcome will be a major roadblock to understanding the role of CSR in addressing key global problems, especially in the health sector.

The research

Specific issues covered in the project were:

- company transparency in reporting on marketing budgets
- medical sales representatives visits to health professionals and their distribution of free drug samples
- gifts, payments and hospitality to health professionals
- appropriate use of promotional materials
- direct-to-consumer advertising (DTCA)
- disease awareness campaigns
- sponsoring of patients' groups
- competition
- post-marketing research.

The companies studied included: Abbott, AstraZeneca, Amgen, Prodesfarma, Bayer, Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson (J&J), Lilly (Eli), Lundbeck, Menarini, Merck Sharp Dohme, Novartis, Novo Nordisk, Nycomed, Orion Pharma, Pfizer, Roche, Sanofi-Aventi, Schering AG, Schering-Plough and Wyeth.²

Main findings

Limited transparency in reporting CSR information

Evidence from the project shows limited transparency among the companies studied. For instance, Orion Pharma was the only company that provided information on the

specific composition of its marketing budget. Similarly, data on staff composition was only available for a handful of companies. Only two companies, GlaxoSmithKline and Novartis, report the number of confirmed marketing code breaches and resulting sanctions.

New marketing tactics may not be to consumers' benefit

In Europe, EU legislation does not permit the marketing of prescription drugs to consumers directly. For prescription medication, pharmaceutical companies are now using alternate pressure points to doctors, such as patient groups, medical students and pharmacists, coupled with new tactics, particularly using internet chat groups and drug or disease information websites, to market their products. There is generally little guidance to staff on the ethical considerations that need to be respected when using such forums for marketing.

Other techniques involve providing health and illness information via pamphlets, magazine articles etc, without the company actually promoting a specific product directly to the consumer or health practitioner. This type of 'nice-and friendly' marketing is often disguised as corporate social responsibility, and has been shown to create a subtle need among consumers to demand drugs for the diseases on which information is provided.

Breaches of regulations and CSR codes occur with regular frequency showing weak industry self-regulation

Large numbers of serious, recent and repeated breaches of marketing codes were found, especially regarding prescription drug advertising. The current regulatory framework is clearly insufficient to prevent systemic violations of marketing regulations, and to ensure the highest possible level of consumer protection.

Furthermore, the overall lack of documented approval procedures for drug promotion is

conspicuous. Nineteen of the twenty companies are obligated under the European Federation of Pharmaceutical Industries (EFPIA) Code of Practice on the Promotion of Medicines to clear all promotional materials before they are released. Despite these obligations however, only four companies (Astra Zanecca, Bristol-Myers Squibb, Novartis and Roche) describe clear corporate procedures for the approval of all promotional materials. Such examples show that industry self-regulation of drug promotion is weak and is generally inadequate to protect consumers from potentially misleading claims.

Recommendations

CI asserts that all relevant stakeholders, but particularly governments and the pharmaceutical industry, must act immediately to address the persistent roadblocks to consumer sensitive and socially responsible drug promotion. Specifically, collective action by consumer organisations, government authorities, the EU and the pharmaceutical industry is required to:

- 1) Develop uniform guidance and indicators for CSR reporting on drug promotion.
- 2) Ensure industry compliance with existing CSR codes, norms and regulations.
- 3) Bolster existing codes with stronger guidance on drug promotion tactics involving the Internet, patient groups and disease awareness campaigns.
- 4) Implement alternatives to a pure self-regulation framework for drug promotion.
- 5) Dissolve veiled relationships between pharmaceutical companies and health researchers.

The concluding chapter of the report recommends further follow-up actions for key stakeholders.

Footnotes

- ¹ Source: IMS Health: http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_77491316,00.html
- ² In some cases, reliable comparative data for specific companies was not publicly available. Where possible, such information gaps have been noted in the accompanying reports.

Chapter 1

Introduction

Project rationale

This report was produced as a key output of the CI-led project entitled *'The Media Network for Sustainable Consumption and Corporate Social Responsibility'*.

The project is an essential counterbalance to the business-dominated perspective on CSR currently prevalent in Europe. Spearheaded by organisations such as CSR Europe,³ the overwhelming approach is a business-centred one which assumes that to make CSR more widespread it is necessary to raise its profile and convince more companies of its benefits based on good business sense and value added. In general, consumers do not appear to be a priority in CSR mainstreaming efforts.

However, CI believes that simply focussing on the business sector is not good enough. Companies must make an equal effort to engage consumers and the general public in their CSR activities. It is consumers who are the users of products and services – and increasingly they demand that products be produced in more sustainable and ethical ways. Consumers have rights, as expressed in the UN Guidelines of Consumer Rights, and responsibilities. Strong and effective CSR must support both.

Consumer rights

The UN Guidelines for Consumer Protection were adopted in 1985 and cover eight essential rights

- the right to safety

- the right to be informed
- the right to choose
- the right to be heard
- the right to satisfaction of basic needs
- the right to redress
- the right to education
- the right to a healthy environment.

Media reporting of CSR issues is vital to consumer confidence in company claims of socially responsible business practices. A large part of public opinion on CSR is shaped by the media, whether through positive or negative portrayals of company behaviour. In addition, phenomena such as 'brand loyalty' indicate consumers are susceptible to having their attitudes and behaviours shaped by the media. This project harnesses the influential potential of consumer media to sustain public dialogue on CSR. In doing so, the project is an innovative step forward in improving consumer engagement on the issue of CSR.

Drug promotion is a consumer concern

Pharmaceutical companies are major stakeholders in the global health agenda. Virtually all drugs used by patients in Europe reach markets through the promotion tactics of a small number of corporations with a tremendous impact on global health. The sector is both fast growing and highly profitable. In 2005 total global pharmaceutical sales grew 7% at constant exchange rates, to \$602 billion.⁴

*'European pharmaceuticals stocks returned to robust health last year [2005]. The trend should continue this year. Double-digit sales increases, coupled with tighter cost control, are expected to produce earnings growth of about 18% for the Europeans. [...] This compares with an estimated 8% for European stocks in general.'*⁵

Effective marketing strategies are a crucial ingredient in making sure pharmaceutical products and profits flow in a 'virtuous cycle'. Despite its financial success, the pharmaceutical industry has come under sharp criticism for social responsibility failures in the last few decades. Even as recently as 2004, cases such as the withdrawal of Vioxx (see box), from the market had consumers seriously concerned about the conduct of pharmaceutical companies in relation to drug promotion and associated impacts on health.

The withdrawal of Vioxx

In September 2004, Merck announced a voluntary withdrawal of its blockbuster drug Vioxx (a cox2 inhibitor⁶ used to treat pain and inflammation) from the market due to concerns of an increased user risk of cardiovascular problems, including heart attack and stroke. As a result, over 6,000 lawsuits were filed in the US and elsewhere by people claiming that they or their family members had suffered heart attacks as a result of taking Vioxx. Subsequently, it was revealed that Merck had known about the risks associated with Vioxx as early as 2000. Furthermore, the company was accused of manipulating a study in *The New England Journal of Medicines*, whereby researchers who were sponsored by Merck deliberately erased a table with information about cardiovascular effects before sending it for publication. During the lawsuits two medical professionals testified that they were pressured by Merck not to publish test results that showed increased rates of cardiovascular disease. In early 2005 a study calculated that Vioxx caused between 88.000 and 140.000 cases of heart disease in the US.

In the first US lawsuit, which Merck lost, the jury demanded US\$ 229 million in punitive damages. The amount was based on an internal document of Merck that estimated that the company could make US\$ 229 million in profits if the publication of warnings on the product could be delayed for four months. Merck did spend about US\$ 160 million on marketing for Vioxx annually.⁷

As the Vioxx case demonstrates, unethical drug promotion is a consumer concern because:

- 1) It violates fundamental consumer rights to information about the products they use.
- 2) It may promote for irrational drug use by consumers. According to the World Health Organization, rational drug use is guided by scientific data on efficacy, safety and cost-effectiveness.⁸

Pharmaceutical industries have embraced the concept of corporate social responsibility (CSR) – that companies must pursue aims that benefit society as a whole rather than the narrow pursuit of corporate profit and growth – as an appropriate response to the mounting pressures to live up to their social and ethical responsibilities. Many companies proudly flaunt their CSR objectives in their annual reports, on their websites and their public relations activities.

CSR includes business activities beyond profit making, to protecting the environment and workers, being ethical in business operations and being involved in the local communities in which companies work. It should be stressed that from the consumer viewpoint, CSR refers to respect for consumer rights through responsible behaviour of companies in their business operations, and not to philanthropy alone. Cross-cutting operational aspects like transparency form an important part of CSR policies as well.

However, in the context of drug promotion, the questions remain – how genuine are these CSR

activities and do they benefit those who consume the goods and services produced by these companies? Do these initiatives actually ensure ethical drug promotion by companies? And do they promote rational, sustainable drug use by consumers?

Marketing aims to increase drug consumption

In Greece, Mr Kyriako Soulioti, Professor of Economics and Health Politics at the School of Public Health, in an interview with consumer journalist Dimitrios Kappos observed: 'On average, each Greek person uses about 44 pharmaceutical products – an amount that is large and has doubled over the past few years in absolute numbers. This type of drug consumption has led to tenfold increase of spending on pharmaceutical products.'

Seeking some answers to these questions, CI teamed up with consumer member organisations across Europe and the International Consumer Research and Testing (ICRT) organisation to examine the CSR performance of 20 pharmaceutical companies in Europe with respect to drug promotion. Using established benchmarks, such as the WHO *Ethical Criteria for Medicinal Drug Promotion* and The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) *Code of Pharmaceutical Marketing Practices*, we sought to verify whether corporate claims of CSR match actual performance and the implications for consumers.

Report structure

In this report, we explain the research approach, scope and limitations in Chapter 2. This is followed, in Chapter 3, by a description of the project's findings on the new drug promotion tactics being used by major pharmaceutical companies, as well as breaches of existing regulations and CSR codes. It also highlights the limited levels of transparency in CSR reporting, which point to a considerable gap between the

actions and the CSR rhetoric of drug companies. The analysis of what such violations mean for consumer confidence in CSR, as well as options for improving compliance with CSR codes and policies with a view to enforcing higher standards of consumer protection, are elaborated on in the final chapter.

Footnotes

- ³ See: <http://www.csreurope.org/>
- ⁴ Source: IMS Health: http://www.imshealth.com/ims/portal/front/article/C/0,2777,6599_3665_77491316,00.html
- ⁵ Financial Times, 17/1/06.
- ⁶ COX II inhibitors, are a relatively new family of non-steroidal anti-inflammatory drugs (NSAIDs), introduced in 1998. Though not necessarily more effective at reducing inflammation and pain than older, traditional non-steroidal anti-inflammatory drugs such as aspirin and naproxen, they represented an advance over the older drugs because they were believed to cause less stomach irritation. They are called COX-2 inhibitors because they block an enzyme called 'Cyclooxygenase'. 'Cyclooxygenase' is believed to trigger pain and inflammation in the body. If you block the COX-2, you block the inflammation. http://www.coreynahman.com/arthritis_drugs_database_nsaids.html, Arthritis Drugs Database; Updated on 7/7/05, What is a COX II inhibitor? Why were 2 of them taken off the market?
- ⁷ M van der Broek, 'Problemen Vioxx al eerder bekend', Volkskrant, 2/10.04; 'Vioxx saga continues to weigh on Merck', Financial Times, 5/1/05, Website Geneeskunde voor het Volk, section weblog Dirk van Duppen, <http://www.gvhv.be/nl/>.
- ⁸ See: http://www.who.int/medicines/areas/rational_use/en/index.html

Chapter 2

Research approach

Methodology

The research was carried out as part of the Media Network for Sustainable Consumption (SC) and Corporate Social Responsibility. Through the project, consumer journalists in the Czech Republic, Denmark, Finland, Greece, Portugal, Hungary and Slovenia conducted qualitative research into the marketing practices of drug companies at the national level and analysed the implications of these practices for corporate responsibility and consumers. The choice of countries primarily reflects a regional balance.

Their work has been complemented by an in-depth technical study of CSR issues facing the pharmaceutical industry co-ordinated by the International Consumer Research and Testing (ICRT) organisation. Among other CSR issues, the technical study also included marketing practices of the selected companies. This technical study yielded a qualitative rating of companies' performance on CSR issues and will be published in consumer print and online magazines across Europe in 2006.

Primary research methods were survey questionnaires, qualitative interviews with key stakeholders (companies, consumers, and regulatory bodies), and desk research. The ICRT technical reports are internal working documents, and were used as the basis of the articles to be published in the consumer magazines. Detailed descriptions of the methodology used to generate the project findings are available on the CI

website at www.consumersinternational.org/pharma. In addition a technical report commissioned during the project on drug promotion issues faced by economically developing countries, along with a number of background documents covering topics such as the European regulatory regime for drug promotion and key CSR issues in pharmaceutical industry are also downloadable at this website.

The pharmaceutical industry

This report focuses mainly on the branded industry (however, many branded companies have divisions or subsidiaries that produce generics as well). Tables 1 and 2 show global pharmaceutical sales and growth estimates.

The largest national pharmaceutical markets are, in order of importance, the USA, Japan, and the five European countries: France, Germany, the UK, Italy and Spain. The considerable influence of these countries on the pharmaceutical industry provides an added weight to the European regional focus of this report.

Scope

Our discussion of the pharmaceutical industry focuses on those elements of the industry involved in the manufacture of pharmaceutical end products (NACE Class 24.42)¹¹ which can be subdivided in different ways:

Table 1: Top 20 companies by global pharmaceutical sales in 2004⁹

Rank	Company name	Country	Sales (\$bn)	Market share (%)
1	Pfizer	US	50.9	9.8
2	GlaxoSmithKline	UK	32.7	6.3
3	Sanofi-Aventis	France	27.1	5.2
4	Johnson & Johnson	US	24.6	4.7
5	Merck & Co / Merck Sharp & Dohme	US	23.9	4.6
6	Novartis	Switz.	22.7	4.4
7	AstraZeneca	UK	21.6	4.2
8	Hoffman-La Roche	Switz.	17.7	3.4
9	Bristol-Myers Squibb	US	15.5	3.0
10	Wyeth	US	14.2	2.7
11	Abbott Laboratories	US	14.2	2.7
12	Eli Lilly	US	12.6	2.4
13	Amgen	US	10.6	2.1
14	Takeda Pharmaceutical Co.	Japan	8.8	1.7
15	Boehringer Ingelheim	Germany	8.2	1.6
16	Schering-Plough	US	6.9	1.3
17	Bayer	Germany	6.3	1.2
18	Schering	Germany	6.9	0.9
19	Eisai Co.	Japan	4.8	0.9
20	Teva Pharmaceutical Industries	Israel	4.3	0.8
Total top 5			159	31
Total top 20			338	65
Total market			520	100

Table 2: Estimated regional and world pharmaceutical markets in 2005¹⁰

Region	Market Size (\$bn)	Share (%)	Growth 2004-2005 (% at constant \$)
North America	255.1	47.8	7.7
Europe	158.4	29.7	6.2
Japan	59.0	11.1	2.8
Asia/Africa/Australia	41.0	7.7	11.7
Latin America	20.3	3.8	11.5
World	533.7	100	7.1

- Into human and veterinary use. This study covers products for human use only.
- By **technical product characteristics and/or production process of the active ingredient**. Three classes are pharmaceuticals¹², vaccines and biologicals,¹³ and homeopathic or other products. This report covers pharmaceuticals, and vaccines and biologicals only.
- By **anatomical therapeutic chemical (ATC)** classification.¹⁴ This detailed classification

system categorises substances according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. An overview of the categories in the first level is provided below.

- By **prescription status**: Prescription (Rx) drugs have to be prescribed or administered by healthcare professionals. Over-the-counter (OTC) drugs, also called self-medication drugs, can be purchased without a prescription.

Our findings examined promotion activities for both types of drugs.

- By **type of manufacturer** such as:
 - **Branded products** come from research-based companies, carry out Research and Development (R&D) for new drugs themselves (or contract others to perform R&D for them) and launch new drugs. Initially, their products are protected by patents. Their clinical test data, required for the approval of the drugs, is usually also protected.
 - **Generic drugs** come from pharmaceutical companies that have not developed these drugs themselves and are marketing them independently from the originator companies. Normally these drugs are no longer protected by patents.
 - **Branded or authorised generics** are generic drugs launched by the originator itself or by another company with authorisation from the originator before market exclusivity on the patented product is expired.
 - **Biosimilars** are generics of biologicals or vaccines. Whereas generic pharmaceuticals contain chemical compounds identical to the branded product, biosimilars are approximate copies only, due to the variations inherent to new production lines for these products.

The technical research co-ordinated by ICRT focussed on marketing issues for prescription drugs only, whereas research conducted at the national level by the consumer journalists covered CSR issues stemming from both prescription and over-the-counter drug promotion. Pharmaceutical companies mainly target health professionals – mainly doctors – for the prescription-only products, while direct-to-consumer (DTC) strategies are used for over-the-counter (OTC) products.

The report concentrates on the following 20 companies, all of which have a global market and particular relevance for the European market.

- AstraZeneca (AZ)
- Abbott Laboratories

- Adirall Prodesfarma
- Boehringer Ingelheim (BI)
- Bristol-Myers Squibb (BMS)
- GlaxoSmithKline (GSK)
- Johnson & Johnson (J&J)
- Lilly (Eli)
- Lundbeck
- Menarini
- Merck Sharp Dohme (MSD)
- Novartis
- Novo Nordisk
- Nycomed
- Orion Pharma
- Pfizer
- Roche
- Sanofi-Aventis
- Schering
- Wyeth

Limitations

The research team noted a number of limitations of the report itself and within the research process. In summary, these were as follows:

- Some European market research on pharmaceutical companies was not accessible for consumer researchers. Such barriers have led to information gaps, but wherever possible, these have been noted.
- In some cases the report made use of North American data or benchmarks where comparable European information was not available, or where the North American benchmarks were of a higher standard.
- Overall, the technical research team found low co-operation or response rates from the companies, many of whom did not come on board until very late in the process. This has minimised opportunity for industry input in certain areas. Any information gaps have been noted, or filled by alternate publicly available information sources.
- A comparative review of the companies is not always possible when information gaps persist.

These have been identified where possible.

- The complexity of the issue means that we could not explore all the many issues connected with the drug promotion context. Instead, we focused on the issues prioritised by consumers' organisations in Europe, as being the most important and pressing.

Footnotes

⁹ Source: IMS Health 2004. Totals may not be accurate due to rounding. In M A Ismail, 'Drugs lobby second to none', 7/7/05, <<http://publicintegrity.org/rx/printer-friendly.aspx?aid=723>> (11/7/05). Note: the market share adopted in the parallel study entitled *Drug promotion – Social responsibility or complications? Rapid systematic review of data and opinion in developing countries* varies slightly due to different sources and geographical scope adopted within the research criteria.

¹⁰ Source: IMS Health, Challenges and opportunities for the pharmaceutical industry to 2009 (*IMS Health 2005*), p. 4.

¹¹ NACE: *Nomenclature Generale des Activites Economiques dans l'Union Europeenne* (General Name for Economic Activities in the European Union).

¹² Pharmaceuticals are those products where the active chemical compounds are often newly invented and produced using chemical synthesis.

¹³ Vaccines are based on live bacteria and viruses and biologicals are relatively large and complex molecules extracted from plants, animals and microorganisms.

¹⁴ WHO Website, The Anatomical Therapeutic Chemical Classification System with Defined Daily Doses, <www.who.int/entity/classifications/atcddd/en>_(16/11/05).

Chapter 3

Key findings on drug promotion in Europe

New tactics

At first glance, the relationship between doctors and drug companies, as well as advertising practices for over-the-counter medication, appears tightly regulated in the European countries studied. Is drug promotion and advertising in Europe reaching truly ethical standards? Have we seen the last of lavish gifts and sponsorship of doctors by the drug companies?

According to many consumer organisations, drug promotion in Europe today can be characterised as 'nice and friendly marketing'.¹⁵ This refers to the creation of a false sense of trust that consumers associate with branded pharmaceutical products, as a result of pharmaceutical marketing efforts disguised as genuine corporate responsibility.

How has this come about? As Health Action International – Europe observes: 'since pharmaceutical companies are not allowed to directly advertise prescription-only medicines to consumers in the EU, their attempts to promote their products have had to become more subtle.'¹⁶

Digging deeper, our team of researchers and consumer journalists uncovered support for the claim that pharmaceutical companies in Europe are now using alternate pressure points, such as patient groups, students and pharmacists, coupled with revised, and arguably unethical, marketing tactics, particularly using the internet through chat groups and product information websites.

'Back-door' marketing in Slovenia

In Slovenia, the locally-based company Lek has an advertisement on the website of a patient's group for heart diseases and Novo Nordisk has an advertisement on the diabetes patients' website. This is a kind of 'back-door' marketing since these advertisements are not as strictly regulated as the print or media advertising. Moreover, not one pharmaceutical company co-operates with the health Ministry in its healthy lifestyle promotion activities.

In addition, companies employ a range of special techniques which all aim at the same effect: to appear to offer all the available information about 'modern' diseases (especially so-called lifestyle diseases, such as stress and poor eating habits) and create a need among consumers to demand drugs to deal with the problems.

Drug promotion in Denmark

For drug promotion in Denmark, 'there are no 'grey' zones. 'It seems as if the system is functioning well', says Margrethe Nielsen, Senior Health Adviser of the Danish Consumer Council. 'But then again the industry has started to focus more and more on the diseases instead of the pharmaceuticals. The Danish Medicines Agency says that generally this is in accordance with Danish legislation.' She points out that information on diseases should not be presented by the industry but by government or neutral sources.¹⁷

Old habits

Aside from these new tactics, violations of existing drug promotion codes and regulations also occur with regular frequency, as indicated by the chart below.

These companies were involved with a total of 972 breaches of ethical drug promotion practices. Most alarming is that the largest proportion of the breaches – more than 35% – had to do with misleading drug information. Such breaches further support our claim that drug promotion does not operate with consumer interests in mind, but rather is more focussed on generating profits by maximising sales revenue.

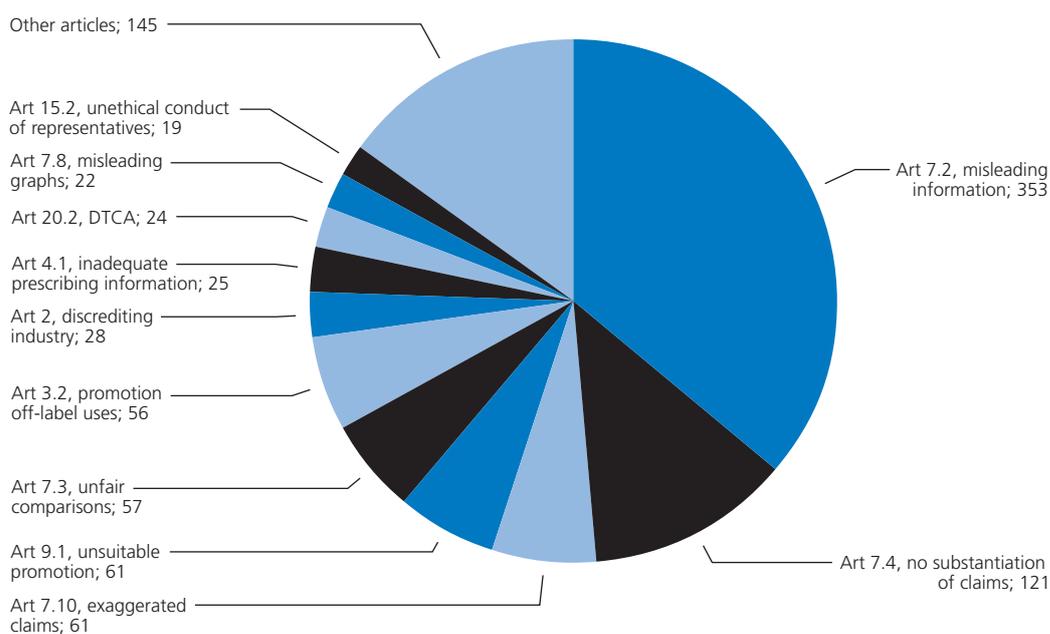
In the context of such widespread breaches, the pharmaceutical industries old and arguably poor habits with regard to marketing practices do not seem easily vanquished. The consequence is a

misleading picture of CSR among pharmaceutical companies. Specifically, if unchecked, unethical drug promotion activities could increase irrational prescribing behaviour by doctors and uninformed medicine consumption by European consumers.

Misleading advertisements

'Claims about the effectiveness and safety of drugs in promotional materials are known to be often inaccurate. In 2004, the Institute for Evidence-based Medicine performed an analysis of 175 drug advertisements received by 43 doctors in Germany. The study showed that 94% of drug advertisements were not supported by scientific evidence. Individual claims about the drugs also included benefits that were not mentioned in the articles, omitted adverse effects and other important findings, gave false descriptions of the studied patient groups or other aspects of the trial design were given, and wrongly cited figures.'¹⁸

Chart 1: Confirmed breaches of ABPI Code of Practice for 20 selected companies, 2002-2005



Source: PMCPA Code of practice review reports Feb 2002 – Aug 2005.
Calculations by ICRT research team. Multiple breaches in one case are counted separately.

Assessing CSR performance on drug promotion

Taking into account the CSR issues and the prevailing regulatory framework relevant for drug promotions, researchers considered the following assessment criteria and normative framework¹⁹ to establish the CSR performance of the companies studied:

Which industry codes on marketing does a company observe?

The reference framework for assessing this aspect of CSR performance included the following:

- The WHO Ethical Criteria for Medicinal Drug Promotion
- The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code
- The European Federation of Pharmaceutical Industries Associations (EFPIA) Code and Guidelines for Websites
- The Pharmaceutical Research and Manufacturers of America (PhRMA) Code of Interaction with Health Professionals
- The Accreditation Council for Continuing Medical Education (ACCME) Guidelines
- The American Medical Association Guidelines on Gifts
- Compliance Program Guidance for Pharmaceutical Manufacturers of the Health and Human Services Office of Inspector General (HHS-OIG)
- Various national-level codes and guidelines such as the Swiss Academy of Medical Sciences Recommendations, Farmindustria (Italian Association of Pharmaceutical Industries) Code of Professional Conduct and the German code for Voluntary Self-regulation of the Pharmaceutical Industry (Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.- FSA Code).

It is important to consider also the geographical region in which a company is committed to observing a certain code. For example, this could be Europe, or worldwide, or only in the US.

Which aspects of marketing are covered in the company's CSR policies?

The following broad aspects are distinguished here:

- Medical representatives
- Gifts and hospitality
- Promotional materials
- Disease awareness campaigns (DACs)
- Patient organisations
- Competition/antitrust.

Does the company have a general compliance mechanism for its code of conduct?

Usually companies have such a mechanism, typically including anonymous reporting lines, internal auditing on compliance and a range of possible sanctions. As most serious violations of marketing standards might also be violations of a company's general code of conduct, these general compliance mechanisms support the implementation of marketing policies.

Does the company have an additional compliance mechanism for marketing issues?

Due to their particular nature, marketing standards require additional issue-specific compliance mechanisms. These typically include special training programmes on marketing standards, clearance procedures for promotional materials and activities, and a clear attribution of responsibilities for compliance with marketing policy to managers at both corporate and national levels.

Does the company report on violations?

External transparency on marketing breaches not only allows a better assessment of a company' compliance, but is also an indicator for comprehensive policies on responsible marketing, and often come together with goals for improved compliance.

CSR performance on drug promotion

Building on the reference framework noted previously, this section summarises the primary findings of the technical research co-ordinated by the ICRT CSR Working Group. Findings on CSR performance of individual companies have been synthesised into company profiles included in Appendix 1.

In the following tables, cells that have been left blank indicate that no publicly available information was accessible to the research team, nor was it provided on request.

Which industry codes on marketing does a company observe?

Key findings (Table 3)

- All the companies are obligated by the EFPIA

code of practice, and a large majority are obligated by the IFPMA code. However, more than 50% of the companies studied do not explicitly commit to implementing either of the codes.

- None of the 20 companies studied have stated an explicit public commitment to the WHO Ethical Criteria.
- There are a wide variety of codes, from the international to regional and national levels that are applicable to CSR issues within the pharmaceutical industry. Without uniform benchmarks, it is difficult for consumers to compare CSR performance between companies.

Misleading consumer information

Denmark-based company Lundbeck, in 2002, promoted its product Cipralex as a 'purer' product than the previously marketed Cipramil.²⁰ Unfortunately for Lundbeck, it was found that the 'purity' doesn't result in greater

Table 3: Endorsement of standards for marketing

Standards	Companies																						
	Abbott	Almirall	Prodesfarma	AstraZeneca	Boehringer	Ingelheim	BMS	Eli Lilly	GSK	Johnson & Johnson	Lundbeck	Menarini	MSD	Novartis	Novo Nordisk	Nycomed	Orion Pharma	Pfizer	Roche	Sanofi-Aventis	Schering	Wyeth	
WHO Ethical Criteria	W ³																						W ²
IFPMA Code	W ³	W ¹		W ¹	W ¹	W				W ³	W	W					W	W	W ¹	W ¹	W ¹		
EFPIA Code of Practice	E ³	E	E ¹	E ¹	E ¹	E ¹	E	E ¹	E ¹	E ³	E ¹	W	E ¹	E ¹	E	E ¹	E	E ¹	E ¹	E ³	E ¹		
EFPIA Guidelines for Web Sites																		E					
PhRMA Code on Interaction	U ³				W	U				U	W						W						
ACCME Guidelines	U ³								W														U
AMA Guidelines on Gifts	U ³																						U
HHS-OIG Compliance Program											U												U
SSCI Code (Swiss)																			?				
SAMW Recommendations (Swiss)																			?				
Farindustria Code (Italian)										?													
FSA Code (German)																							W ³

Scope of application: W = worldwide, E = EU (basic assumption for EFPIA code), U = US, ? = unclear scope.

1) Obligation through membership of industry association, no explicit commitment.

2) Commitment stated in lobbying letter only.

3) Commitment stated in feedback to the research report, not in public communications.

Source: Industry association's websites, company websites and reports, additional company information provided by the ICRT research team.

effectiveness for patient treatments. In fact, both CipraleX and Cipramil have produced side-effects that are very common and serious, including nausea and vomiting, sleeping problems and sexual disorders. Lundbeck had not proved that CipraleX has any advantages compared with Cipramil and generic products and therefore made a misleading claim.

Which aspects of marketing are covered in the company's CSR policies?

Key findings (Table 4)

- Most companies did not have specific policy documents on marketing standards applicable to European markets.
- Disclosure of CSR information is extremely patchy across the industry. For example, the codes of Almirall, BI, Lilly and Novo Nordisk were not even publicly available. Pfizer, the world's largest and most profitable

Table 4: Marketing codes/policies and issues addressed, applicable to Europe

Criteria	Companies																					
	Abbott	Almirall	Prodesfarma	AstraZeneca	Boehringer	Ingelheim	BMS	Eli Lilly	GSK	Johnson & Johnson	Lundbeck	Menarini	MSD	Novartis	Novo Nordisk	Nycomed	Orion Pharma	Pfizer	Roche	Sanofi-Aventis	Schering	Wyeth
Relevant codes/policies																						
1 – Code of conduct/ethics	A	C	A	C	A	1	A	A	C	1	A	A	C	-	C	A	A	A	A	A	A	A
2 – Separate marketing code/policy	C	-	1	-	2	3	1	-	-	-	-	1	-	-	-	-	A	-	5	-	-	-
3 – Separate competition code/policy	C	-	-	-	C	-	-	-	-	-	-	-	-	-	-	-	A	-	-	-	-	-
4 – Combined code/policy	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	S	-	-	-	-	-	-
Marketing issues in codes/policies																						
Medical representatives	-	-	2	-	-	-	2	-	-	-	1	2	-	-	-	-	-	-	-	2	-	-
Gifts and hospitality	-	-	2	-	1	1	2	1	-	-	1	2	-	-	-	-	-	-	-	2	-	-
Promotional materials	-	-	2	-	1	1	2	1	-	1	1	2	-	-	-	4	-	-	-	-	-	-
Disease awareness campaigns (DACs)	-	-	-	-	2	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Patient organisations	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Competition/antitrust	1	-	-	-	1	1	1	1	-	1	1	1	-	-	-	4	3	-	1	1	-	-
Operational aspects																						
General compliance mechanism, linked to code of conduct	+	+	+	+	+	+	+	+	-	+	+	+	+	-	-	+	+	+	+	+	+	+
Specific compliance mechanism, linked to separate marketing code/policy	-	-	+	-	+	-	+	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-
Reporting on violations	-	-	-	4)	-	-	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-

Availability of code or policy document: A= available in full, S= summary only, C= confidential,

- = not existing or not mentioned, + = existing or mentioned.

Numbers indicate in which code/policy the issue is addressed.

1) Provided on request.

2) On direct-to-consumer communications.

3) Principles for partnering with external organisations, including patient organisations; provided on request.

4) Planned 2005 onwards.

5) German FSA industry code represents the company's internal marketing code.

Source: Company websites and reports, additional company information (see sections on each company).

pharmaceutical company, does not fully disclose its marketing code.

- Only one company (BMS) refers to its marketing codes or policies in direct communications with consumers.
- Only 2 companies have a marketing code or policy with regards to disease awareness campaigns (DACs).
- 19 of the companies do not have a publicly accessible CSR policy with regards to their interactions with patient groups.
- The majority of the companies do not make clear whether their CSR codes and policies address the conduct of medical representatives in the context of drug promotion.
- There still exist considerable differences in the normative contents and the operational structures of marketing codes. For example, the marketing codes of AZ, GSK, and, especially, Novartis provide detailed guidance on a range of issues. This contrasts with the marketing policy of Roche and the overall codes of conduct of BMS, J&J, MSD and Schering that contain mainly general principles.
- Anonymous reporting mechanisms, helplines, internal monitoring and auditing procedures, and disciplinary sanctions policies are in place in most companies. However, only the companies

with separate marketing policies, apart from Pfizer, outline additional operational procedures specially geared to drug promotion. These generally include initial and continuous training programmes and clearance procedures for promotional materials and activities.

- Only 2 companies (GSK and Novartis) are transparent in reporting the number of confirmed marketing code breaches and resulting sanctions. AZ plans to start reporting this in its next corporate responsibility report.

Which companies are transparent when disclosing financial information?

Key findings (Table 5)

- Orion Pharma was the only company that provided information on the composition of its marketing budget.²¹
- Only 7 of the 20 companies (BI, Lundbeck, Novo Nordisk, Novartis, Nycomed, Roche, and Schering) provided separate figures for marketing (or marketing and distribution) and for administration.
- Data on staff composition, another indicator for transparency, were only available for 4

Table 5: Various expenses as share of sales, and marketing staff as share of total staff, in 2004

Criteria	Abbott	Almirall	Prodesfarma	Astrazeneca	Boehringer	Ingelheim	BMS	Eli Lilly	GSK	Johnson & Johnson	Lundbeck	Menarini	MSD	Novartis	Novo Nordisk	Nycomed	Orion Pharma (see below)	Pfizer	Roche	Sanoofi-Aventis	Schering	Wyeth
Marketing and distribution (%)									23				28				29					
Marketing (%)				37										38	39							31
Administration (%)				15					15			4	6	9			4			11 ⁶		
Marketing and administration (%)	25	36	52	33 ¹	31	35	33	38 ⁵	32	42	34 ⁵	48	32	33 ⁵	30 ⁴	42 ⁷	33					
Marketing and sales staff (%)						36		44					29 ²	36 ²				34	33			

1) Marketing, selling and administration (26%) plus advertising and product promotion (7%).

2) Employee costs for sales and distribution as share of total employee expenses.

3) Employee costs for sales and marketing as share of total employee expenses.

4) This percentage relates to 'selling and general expenses'.

5) Administration plus marketing and distribution.

6) Administration and engineering.

7) Administration and engineering plus marketing.

Source: Annual reports 2004, company questionnaires. Calculations by ICRT researchers.

companies (GSK, Lundbeck, Sanofi-Aventis, and Schering).

Which companies are transparent on regulation of medical representatives?

Key findings (Table 6)

- Only a quarter of companies studied have a specific publicly accessible CSR policy on the conduct of their medical representatives.
- Half the companies have been in breach of the ABPI code of practice on the conduct of medical representatives between February 2001 and August 2005.
- The level of operational guidance to medical representatives is too varied to ensure

consistent industry standards on ethical conduct. For example, in its general code of conduct MSD prohibits representatives to recommend off-label uses, but most companies do not provide similar guidance in their codes.

Will more drugs be available OTC?

In the Czech Republic, pharmaceutical companies are very active in lobbying the regulatory bodies for prescription drugs to be reclassified to OTC status. The growing group of the OTC drugs is visible from the consumer point of view. For instance, the tag-line 'now it can be sold over-the-counter' is increasingly mentioned on promotional leaflets in pharmacies, or in television advertisements.

Table 6: Medical representatives

Criteria	Abbott	Almirall Prodesfarma	AstraZeneca	Boehringer Ingelheim	BMS	Eli Lilly	GSK	Johnson & Johnson	Lundbeck	Menarini	MSD	Novartis	Novo Nordisk	Nycomed	Orion Pharma	Pfizer	Roche	Sanofi-Aventis	Schering	Wyeth
Specific policy on behaviour of medical representatives	-	-	+	-	-	-	+	-	-	-	+	+	-	-	-	-	-	-	+	-
Controversies regarding medical sales representatives	-	-	1	+	1	1	1	-	-	1	1	-	-	-	-	1	1	-	1	1

1) Cases reported in ABPI Code of Practice Review February 2001- August 2005, not further specified in report.

Table 7: Gifts and free samples

Criteria	Abbott	Almirall Prodesfarma	AstraZeneca	Boehringer Ingelheim	BMS	Eli Lilly	GSK	Johnson & Johnson	Lundbeck	Menarini	MSD	Novartis	Novo Nordisk	Nycomed	Orion Pharma	Pfizer	Roche	Sanofi-Aventis	Schering	Wyeth
Specific policies on gifts and hospitality	-	-	+	-	+	+	+	+	-	-	+	+	-	-	-	-	-	-	+	-
Specific policy on free samples	-	-	-	-	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-
Controversies regarding free samples	+	+										+					+			
Controversies regarding seeding trials					+	+		+									+		+	
Controversies regarding gifts/kickbacks		+				1	+		1							+		1		1

1) Cases reported in ABPI Code of Practice Review February 2001- August 2005, not further specified in report

Which companies have codes on gifts and samples?

Key findings (Table 7)

- More than half of the companies have been implicated in controversies regarding their relationships to healthcare professionals between 2001 and 2005.
- Most companies have a code of conduct on business integrity, but guidance on gifts and hospitality to healthcare professionals is not always included.
- Only 2 companies (Lilly and Novartis) have a specific policy on free samples.
- Only 12 of the 20 companies have a specific policy on gifts and hospitality.

Sponsorship in Finland

Each year the Association of Finnish Advertisers publishes a barometer on sponsorship by the pharmaceutical industry. According to the 2005 figures, the companies increased sponsorship, with 89% having sponsored sports events, 50% sponsoring cultural events, and 14% sponsoring science-related events. About a quarter of the companies had sponsored social and educational events, and 11% had done so in co-operation with television, radio and films.

Which companies have codes on promotional materials?

Key findings (Table 8)

- No information was available about the European marketing policies for Abbott, Almirall, BI, Novo Nordisk, and Sanofi-Aventis.
- Only Novartis has a code that lists words and phrases prohibited in advertising materials in line with the EFPIA code.
- Just 4 companies (AZ, BMS, Novartis and Roche) describe clear corporate procedures for the approval of all promotional materials.
- An overwhelming majority of companies (17 out of 20) have been involved with publicising irresponsible or controversial promotional materials.

Drug promotion is not for consumer information

In 2005, GSK was found to be giving misleading information to consumers and was fined three million Hungarian forints (\$14,100/11,400 euros) for the misleading advertising of Coldrex Maxigrip on the internet, while the Hungarian Competition Authority prohibited further screening of the advertisement. During 2003 and 2004 EGIS had advertised its product Coverex as preventing cardiovascular diseases, although this claim was not authorised.

Table 8: Promotional materials

Criteria	Companies																					
	Abbott	Almirall	Prodesfarma	AstraZeneca	Boehringer	Ingelheim	BMS	Eli Lilly	GSK	Johnson & Johnson	Lundbeck	Menarini	MSD	Novartis	Novo Nordisk	Nycomed	Orion Pharma	Pfizer	Roche	Sanofi-Aventis	Schering	Wyeth
Detailed norms on promotional materials	-	-	+	-	+	-	+	+	-	+	+	-	+	-	+	-	+	-	-	-	-	-
Explicit reference to EFPIA/IFPMA code	-	+	+	-	-	-	2	-	-	+	2	-	-	+	-	+	2	-	-	-	-	-
Approval procedure described	-	-	+	-	+	-	-	-	-	-	-	+	-	-	-	-	+	+	-	-	-	-
Controversies regarding promotional materials	+		+	+	+	+	+	+	1	1		+	+	+		1	+	+	+	+	+	1

1) Cases reported in ABPI Code of Practice Review February 2001- August 2005, not further specified in report.

2) Explicit reference to both codes.

Which companies have policies on DACs and OTC advertising?

Key findings (Table 9)

- 18 of the 20 companies do not have an explicit policy on disease awareness campaigns.
- Of the 2 companies (BMS and Lilly) that have an explicit policy on disease awareness campaigns (DACs), only Lilly provided information on criteria for interactions with external organisations, including patient organisations.

- Just one company (BMS) has a specific CSR policy on interactions with patient groups.
- Over half the companies studied have been implicated in recent marketing scandals through disguised DTCA and DACs, as well as inappropriate relations with patient organisations.

Table 9: Disease awareness campaigns (DACs) and direct-to-consumer advertising (DTCA)

Criteria	Companies																			
	Abbott	Almirall Prodesfarma	Astrazeneca	Boehringer Ingelheim	BMS	Eli Lilly	GSK	Johnson & Johnson	Lundbeck	Menarini	MSD	Novartis	Novo Nordisk	Nycomed	Orion Pharma	Pfizer	Roche	Sanofi-Aventis	Schering	Wyeth
Specific policy on DACs/DTCA	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Specific policy on patient organisations	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Controversies regarding (disguised) DTCA					+	+	+			+		+				+	+		+	
Controversies regarding DACs		+					+	+	+	+	+				+	+		+		
Controversies regarding sponsored patient organisations						+					+				+					

1) Cases reported in ABPI Code of Practice Review February 2001- August 2005, not further specified in report.

2) On direct-to-consumer communications.

3) Principles for partnering with external organisations, including patient organisations; provided on request.

Table 10: Competition issues

Criteria	Companies																			
	Abbott	Almirall Prodesfarma	Astrazeneca	Boehringer Ingelheim	BMS	Eli Lilly	GSK	Johnson & Johnson	Lundbeck	Menarini	MSD	Novartis	Novo Nordisk	Nycomed	Orion Pharma	Pfizer	Roche	Sanofi-Aventis	Schering	Wyeth
Specific policies on competition/ antitrust	+	-	-	-	+	+	+	+	-	+	+	+	-	-	-	+	+	-	+	+
Controversies regarding cartel formation or price fixing	+				+		+	+				+						+		
Controversies regarding patent manoeuvres or evergreening			+		+		+													
Controversies regarding excessive pricing or improper discounts	+	+	+	+					+											

Should consumers trust patient groups?

A Finnish survey on the patient organisations and their interactions with drug industry shows that 71% of the patient organisations say that they get financial support from pharmaceutical companies. The support included advertising in organisation magazines or newsletters, participation in organising seminars, assistance in printing costs, participation in projects, and financial donations. It also showed that 55% of the patient organisations reported that co-operation with the drug industry was either very important or important, and 33% reported that co-operation had increased during the last five years. Such relationships are not very transparent and patients attending such groups may not always be aware of the industry ties.

What are companies' records on competition?

Key findings (Table 10)

- 6 companies (Abbott, J&J, Pfizer, Schering, Wyeth, and MSD) have only general policies on fair competition.
- Only 4 companies studied (BMS, Lilly, Novartis, GSK and Roche) provide more detailed guidance and establish additional procedures for approval of certain types of business conduct that potentially restricts competition.
- GSK and BMS have by far the most comprehensive policies and address industry-specific issues such as allowing parallel importation or not cutting off supplies to competitors. This does not imply actual practice matched policies.

Footnotes

- ¹⁵ This term was coined by Graca Cabral, consumer journalist for the Portuguese Association for Consumer Protection.
- ¹⁶ See: http://www.haiweb.org/03_other_a.htm
- ¹⁷ Torsten Raagard, Danish Consumer Council
- ¹⁸ T Kaiser et al, 'Sind die Aussagen medizinischer Werbeprospekte korrekt?', *arznei-telegram*, Vol. 35, 13 Feb 2004, <www.djem.de/data/at_2004_35_21.pdf>, 30/9/05, p. 21-23; A Tuffs, 'Only 6% of drug advertising material is supported by evidence', *BMJ*, 28/2/04, <<http://bmj.bmjournals.com/cgi/content/full/328/7438/485-a>>, 30/9/05.
- ¹⁹ This assessment was performed by ICRT's team of technical researchers. The findings were compiled into a report entitled ICRT Description of CSR Issues in March 2006. P.193
- ²⁰ S Svensson, PR Mansfield. Escitalopram: superior to citalopram or a chiral chimera? *Psychother Psychosom* 2004 Jan-Feb;73(1):10-6
- ²¹ The company stated that in 2004 about half of the budget was spent on advertising costs, and the other half on detailing and disease awareness campaigns. Detailing costs included the retail value of samples, which was about 10% of all marketing costs in Europe.
- ²² Evergreening refers to the practice of obtaining patent protection for improved formulations for a 'known' drug or for using a 'known' drug to treat 'new' ailments. Source: ICRT Technical Report (2005).

Chapter 4

Conclusions and recommendations

Conclusions

Based on the research findings developed during the project, our conclusions rest on four major points:

1. Pharmaceutical companies show limited transparency in reporting key CSR information

Evidence from the project shows limited transparency among the companies studied in reporting on CSR issues. For instance, Orion Pharma was the only company that provided information on the specific composition of its marketing budget. Similarly, data on staff composition, another indicator for transparency, were only available for a handful of companies. Only two companies, GlaxoSmithKline and Novartis, report the number of confirmed marketing code breaches and resulting sanctions.

Transparency is the bedrock of good CSR practice, yet the behaviour of companies with regard to CSR policies for drug promotion show that, in general, they either do not have policies or have poor disclosure of these policies. Neither scenario is particularly encouraging for consumer confidence in industry CSR claims.

Poor transparency is an industry-wide problem
According to Slovenian consumer journalist Ursa Smid: 'Because we have two important local companies we decided to also send them

the research questionnaire, but they were not ready to answer. I must highlight that we could not get any official information from pharmaceutical producers or importers. They were not prepared to answer our letters so we have to search for information on the internet, annual reports and other public sources.'

2. New marketing tactics do not favour rational drug use by consumers

Pharmaceutical companies are now using alternate pressure points to doctors such as patient groups, medical students and pharmacists coupled with new tactics, particularly using Internet chat groups and product information websites to market their products. Other techniques involve providing disease information via pamphlets, magazine articles etc., without the company actually promoting a specific product directly to the consumer or health practitioner.

This type of 'nice-and friendly' marketing is often disguised as corporate social responsibility, and has been shown to create a subtle need among consumers to demand drugs for the conditions, while giving consumers a sense of trust in the pharmaceutical companies.

This problem is further compounded by the prevailing lack of documented promotion approval procedures for drug promotion. All companies (except Nycomed) are obligated under the European Federation of Pharmaceutical Industries (EFPIA) Code of Practice on the Promotion of Medicines to clear all promotional materials before

they are released. However, only four companies (AstraZeneca, BMS, Novartis, and Roche) describe clear corporate procedures for the approval of all promotional materials. These examples show that industry self-regulation of drug promotion is weak and does not adequately protect consumers from potentially misleading claims.

Some analysts may point to examples such as the MHRA Disease Awareness Campaigns Guidelines and EFPIA Guidelines for Internet Web Sites as proof that the pharmaceutical industry is being responsive to the need to regulate unethical drug promotion via these new forums.

However, in the former case, the guidelines only clarify the border between advertising that falls within the scope of the EU Directive 2001/83/EC, and advertising that falls outside it. It simply notes that a DAC: *'can provide a valuable source of information to the public on diseases and conditions, aid recognition of symptoms and highlight appropriate sources of advice. It should not promote the use of a particular medicinal product or products.'*

However, CI believes that such guidance, like other CSR codes, is generally weak and insufficient, as they do not add to existing legislation, and that there is no monitoring mechanism.²³ Similarly, the EFPIA Guidelines for Internet Web Sites provide guidelines for company-sponsored websites containing information on prescription-only medicinal products intended for health professionals, patients and the general public in the EU. They were adopted in October 2001 and may be enforced at the national level through voluntary self-regulatory systems, but apparently this is not currently happening as our research from Portugal on the Wyeth case shows.²⁴

Disguised sponsorship

Wyeth has a so-called 'social service' on its website, aimed at assisting women to take their contraceptive pill 'without fear and

without forgetting', through a text message (SMS), called 'Alerta Pílula SMS'²⁵ – Pill Alert SMS. Women fill out a small online questionnaire and send it to Wyeth. Women then start to receive a SMS, to remind them to take the pill. But to receive the SMS women need to have a special code given by their doctor, which is only available if they use the Wyeth product. This is not clear in the Wyeth website, which does not mention the brand of pill. This initiative is not a social service for women but a marketing device for the company. When consumer journalist Graca Cabral put this issue to Wyeth's information department, she was told: 'of course the service is only for the Wyeth pill and she should inquire with her doctor about the Wyeth pill.'

3. Breaches of regulations and CSR codes occur with regular frequency showing weak industry self-regulation

In the comparative overview, it was noted that no information was available about European marketing policies for Abbott, Almirall, BI, Lilly, Menarini, Novo Nordisk, Sanofi-Aventis, and Wyeth. Almirall states that standards of conduct for medical sales representatives are included in the code of conduct, but as the code itself was not provided, this could not be verified. Lilly has a public position on DTCA only and Wyeth describes only its US marketing practices.

The absence of clear marketing policies for these companies is remarkable, given that irresponsible marketing practices form a serious, persistent and widespread problem among the entire pharmaceutical industry. This lack of commitment to adhere to internationally accepted standards of ethical corporate behaviour at the company level raises serious doubts about the strength of industry self-regulation in ensuring high rates of implementation when it comes to CSR codes.

Moreover, the sheer volume of reported breaches indicates that even the companies with apparently the most comprehensive compliance programmes

are not fully effective in preventing breaches of marketing codes. This problem extends to the biggest companies such as GSK and Pfizer.

A particularly worrying trend shown by our research is that the difference between policies and practices is often striking. It can be concluded that corrupting healthcare professionals is not an uncommon practice among pharmaceutical companies and might still be insufficiently addressed by all companies.

Landmark case on drug information in Greece

In Greece, Eleftheria Nikolopoulou entered a public hospital in 1997 with stomach trouble where she was prescribed the antibiotic Septrin by a hospital doctor. She died after a few hours. After her death, her parents began a legal battle against GlaxoSmithKline, the producers of Septrin, stating the company had neglected to include in the prescribing instructions, death as a possible counter-indication. In September 2005, the Athens Supreme Court ruled against GSK and identified the company as responsible for Eleftheria's death. GSK was ordered to pay the equivalent of 40 million drachmas (117,400 euros) to Eleftheria's family.

The issue of competition is a case in point. Evidence was found by the ICRT research team of a variety of anti-competitive strategies, including cartels, fraudulent patent manoeuvres, manipulation of reimbursement prices, improper discounts, price hikes, payments to competitors for not challenging patents, and cutting off supplies of drugs and active pharmaceutical ingredients.

Several cases of manipulated wholesale and reimbursement prices were left out of this report, as these primarily concerned fraud rather than anti-competitive behaviour itself. These actions are hardly congruent with the competition policies of the companies. However, the effectiveness of more elaborate policies remains indecisive, as BMS and GSK, despite having some policies in this respect, were among the companies involved

in various controversies regarding anti-competitive behaviour in recent years.

4. Pharmaceutical companies blur links with health researchers

Pharmaceutical companies offer health professionals a variety of incentives to promote their drugs, rather than putting consumer health and safety first. The tactics involve kickbacks, consulting agreements, releasing misleading data, promoting off-label marketing, seeding trials and other questionable pharmaceutical sales tactics.

We observed that pharmaceutical companies are assisted in these tactics by specialised medical communications agencies who recruit and train individuals, often leading doctors, specialists and academics, to promote a company's products through their work. Such individuals are designated key opinion leaders (KOLs). They may be paid by the company for their promotional efforts via presentations, research papers, conferences and debates.²⁶

The relationship between companies and KOLs is not explicitly transparent. As a consequence, consumers and patients, and in some cases health professionals, may not always be aware how motivation for individual profit could play into the drug information they receive via the KOLs. Aside from this, in cases where KOL information may appear to be 'independent' or 'unbiased' opinions, there is no real way for consumers to decipher if there is actually a conflict of interest behind such opinions.

Doctors and other healthcare professionals receive also regular visits from medical sales representatives who offer free samples of new drugs. The primary purpose of free samples is to promote new and often more expensive drugs. Research has confirmed that samples indeed influenced prescribing behaviour. The samples increased the prescription of more expensive brand-name drugs. Furthermore, when samples ran out, the induced prescription patterns were

continued and not reversed to the drug of first choice in normal circumstances.²⁷

Often payments or other favours to healthcare professionals to induce them to prescribe specific drugs are disguised in some way. For example, doctors may be paid for consulting services, to attend meetings, and to provide their opinion, while the intent of the meeting may be to promote a drug. Fully sponsored continuing medical education courses or other professional events may be organised at holiday resorts or include expensive social events. Similarly, companies often pay high amounts to doctors for enrolling patients in Phase IV trials, which can be part of a marketing strategy.²⁸

Similarly, recent studies show statistically significant bias in publications in favor of corporate research sponsors' products, when compared to publications resulting from publicly funded research on medical or health-care products.²⁹ Medical research articles are now frequently ghost written: company staff draft 'scientific' articles that are then submitted to journals listing as authors medical academics who may not have had access to all of the relevant study data, or may not even have had any direct involvement in the study. One recent estimate is that 'at least 50% of academic publications in therapeutics is now ghost written, in particular that in the most prestigious medical journals.'³⁰

All the while, consumers are in the dark about how their medicine consumption choices are the result of veiled relationships between doctors and pharmaceutical companies. We believe that doctors should have their patients' interests as a priority rather than personal profit. We found:

- Only 4 of the 20 companies studied communicate directly to consumers on their explicit guidelines for the use of medical sales representatives in drug promotion to health professionals. Pfizer, the world's largest drug company, does not do so.

- 12 of the 20 companies do not have publicly accessible codes on gifts and hospitality to health professionals.
- More than half of the companies have all been implicated in controversies regarding free samples, kickbacks, and gifts to medical professionals.
- Only Lilly and Novartis refer to the use of free samples in their codes.

Consumers are in the dark about drug company sponsorship

Portuguese consumers do not normally complain about health issues and they tend to trust in doctors without realising the hidden impact of sponsorship on prescribing patterns. In 2005 DECO, the Portuguese consumer association, received a total of 12,942 consumer complaints, of which only 110 were health-related.

Recommendations

In 1998, Health Action International published their report *Blurring the boundaries: New trends in drug promotion*.³¹ It detailed a series of problems concerned with drug promotion, similar to the issues identified in this report. In its concluding chapter, the authors observed³²:

- Globally, there is a huge imbalance in the financial resources available for promotional versus independent information. As a result, consumers and prescribers are generally subject to a positive information bias: the benefits of medicine use tends to be exaggerated and the risks downplayed.
- Codes of practice [for drug promotion] tend to be largely voluntary and are rarely enforced.
- To be effective, controls for drug promotion need to include pre-screening of printed promotional materials and active monitoring of other forms of promotion.

It is incredibly disappointing that almost a decade later, as our findings indicate, the picture of drug promotion and its control regime has hardly

changed for the better. Consumers International firmly believes that all relevant stakeholders, but particularly governments and the pharmaceutical industry, must act immediately to address the persistent roadblocks to consumer sensitive and socially responsible drug promotion.

Specifically, collective action by consumer organisations, government authorities, the EU and the pharmaceutical industry is required to:

- 1) Develop uniform guidance and indicators for CSR reporting on drug promotion.
- 2) Ensure industry compliance with existing CSR codes, norms and regulations.
- 3) Bolster existing codes with stronger guidance on drug promotion tactics involving the Internet, patient groups and disease awareness campaigns.
- 4) Implement alternatives to a pure self-regulation framework for drug promotion.
- 5) Dissolve veiled relationships between pharmaceutical companies and health researchers.

Drug companies must immediately act to:

- Adopt more comprehensive CSR policies on specific aspects of drug promotion, particularly when engaged in disease awareness campaigns, with patient groups and Internet activities.
- Improve implementation of existing CSR codes particularly via more rigorous training programmes for staff.
- Make information available to the public on reported breaches by marketing staff and follow-up disciplinary action.
- Report on precise marketing budgets in compliance with recognised international codes and norms.
- Adopt third-party independent verification procedures for checking company compliance with CSR codes, regulations and norms.
- Support the ISO process for a global SR guideline as step toward improving reporting on baseline indicators for CSR.
- Provide transparent and verifiable information

on the precise nature of relationships fostered with all stakeholders, including health professionals, pharmacists, students, journalists, clinical research organisations and patient groups.³³

At the European Union level, authorities must:

- Provide stronger monitoring and assistance to members in implementing EC directives regulating drug promotion.
- Critically evaluate the performance of the European Medicines Authority's (EMA) comparative performance on reporting on drug safety issues and violations of Good Manufacturing Practices (GMP) guidelines.
- Move responsibility for regulation of drug promotion from the Directorate General for Enterprise and Industry to the Directorate for Health and Consumer Protection which is much better suited to ensuring high standards of consumer protection.
- Support governments in the implementation of the WHO Resolution on a Global Framework on Essential Health R&D passed by the World Health Assembly in May 2006.

Governments and regulatory bodies must:

- Ensure that enforcement of existing regulations on drug promotion is stepped up, especially based on criteria outlined in the WHO Ethical Criteria for Medicinal Drug Promotion.
- Support the development of consumer information tools for CSR issues related to drug promotion.
- Develop and enforce sanctions (including revoking of business licenses) to companies that consistently breach ethical drug promotion guidelines and regulations.
- Ban all gifts awarded to health professionals from pharmaceutical companies and actors with vested interests.
- Support follow-up actions on the recently adopted WHO Global Framework on Essential Health R&D as a step forward in identifying alternatives to industry control of the health research agenda.

Consumer organisations will continue working towards improved CSR practice in the area of drug promotion by:

- Maintaining and improving their watchdog function on CSR reporting. In particular consumer organisations will develop and strengthen technical tools for monitoring CSR violations, such as the comparative CSR testing methods used by the ICRT.
- Working with consumer journalists and the media to mainstream CSR issues among consumers.
- Lobbying governments and regulatory authorities for better regulation of the use of the internet and disease awareness campaigns and patient groups in drug promotion.
- Maintaining and improving existing levels of engagement into the International Organization for Standardization (ISO) process on Guidelines for Social Responsibility.
- Facilitating consumer input into the follow-up process on the recently adopted WHO Global Framework for Essential Health R&D.

Footnotes

²³ UK House of Commons, The influence of the pharmaceutical industry, 5 April 2005, <<http://www.publications.parliament.uk/pa/cm200405/cms-elect/cmhealth/42/42.pdf>> (8 August 2005), p. 77.

²⁴ <http://www.efpia.org/6_public/Internetguidelines.pdf> (20 Sep 2005).

²⁵ "Alerta Pilula-SMS", "Deseja subscrever a função Alerta Pilula-SMS? Escolha, por favor, a modalidade que pretende" – in www.wyeth.pt

²⁶ Ibid. p. 26-27.

²⁷ RF Adair and LR Holmgren, 'Do drug samples influence resident prescribing behaviour? A randomized trial', JAMA, Vol. 118 (2005), p. 881-4n

²⁸ M Angell, *The Truth About Drug Companies: How They Deceive Us and What to Do About It*, New York: Random House, 2004 .p. 139.

²⁹ S Krinsky, *Science in the Private Interest*, Lanham: Bowman & Littlefield, 2003

³⁰ D Healy,, *Let Them Eat Prozac*, Toronto: James Lorimer and Co., 2003 p.14. In:

http://www.ecclectica.ca/issues/2005/3/index.asp?Article=2#_edn13

³¹ Barbara Mintzes and HAI-Europe. *Blurring the boundaries: New trends in drug promotion*, 1998. See: <http://www.haiweb.org/pubs/blurring/blurring.intro.html>

³² Ibid.

³³ Many alternatives exist on ways to reduce the dependency of health researchers on funding from pharmaceutical companies and need to be explored further by all stakeholders involved.

Appendix

Company profiles of CSR performance in drug promotion

Abbott

What they do

- In an advertisement for Tarka (verapamil/trandolapril) in Germany in 2004, Abbott claimed a certain reduction in blood pressure demonstrated in an eight weeks trial involving 391 participants. However, 124 of these participants left the trial before the end of the eight-week period. Most were actually excluded from the trial after four weeks because the drug was ineffective.³⁴
- In 2001, TAP, a joint venture of Abbott and Takeda Pharmaceuticals of Japan, was forced to pay \$875 million to resolve criminal charges for fraudulent drug pricing and marketing of Lupron, a cancer drug.³⁵
- In 2004, TAP also settled a class action lawsuit in the US on the same charges by paying \$150 million to the defendants.³⁶
- Authorities in Portugal fined Abbott in 2005 for forming a cartel with five other pharmaceutical companies (J&J, Bayer, Menarini, Pharmaceutica Quimica). Abbott had to pay the largest fine to date of 6.8 million euro.³⁷
- In 2004, a lawsuit was brought against TAP claiming that the company used unfair promotional pricing for Prevacid, used for heartburn.³⁸

What they say

- According to Abbott, they comply with all laws.³⁹
- Abbott's Code of Business Conduct provides guidance on compliance with competition and anti-corruption.⁴⁰
- The code provides guidance on legal compliance

and a reference for standards on gifts and hospitality, and has a system for employees to obtain further guidance and report suspected violations.

What's the problem?

- Guidelines on gifts and hospitality to health professionals in other countries are not publicly available.
- Although Abbott stresses that the Code of Business Conduct is a global policy and applies to all countries,⁴¹ specific norms for outside the US are not specified in the code itself.
- No public information was found on norms or procedures for advertising and promotional materials.
- Verification and certification of compliance on the Code is done by the company itself.⁴²
- No information was found on specific norms for disease awareness campaigns or interaction with patient organisations. It is not addressed by their Code of Business Conduct.

Almirall Prodesfarma

What they say

- Almirall states that it is committed to promoting medicines in accordance with self-regulation standards.
- The company has a code of ethics that includes ethical standards in advertising, in line with the codes of the EFPIA and the Spanish industry association Farmindustria.⁴³ The code focuses on interactions with healthcare professionals

and other third parties⁴⁴ and includes ethical standards in advertising.⁴⁵

- A confidential reporting structure exists for reporting code violations.

What's the problem?

- No public information was found for Almirall on competition policies. They are internal documents only.
- Neither the EFPIA Code of Practice of Farmindustria code explicitly address ethical practice for disease awareness campaigns (DACs) and interaction with patient organisations.
- Company standards regarding the conduct of medical sales representatives and gifts and hospitality to health professionals could not be confirmed as the company's code of ethics is not publicly available.
- Details on code violations were not provided to researchers.

AstraZeneca

What they do

- In 2004 AZ organised an event to promote its drug Crestor, which included tickets for a musical. The meeting constituted a violation of the Code on the Promotion of Medicinal Products.⁴⁶
- In another case, the company provided airfare and accommodation for doctors to attend a conference on bipolar disorder in Cannes on the French Riviera and was put on probation by Dutch authorities for violating the Code on the Promotion of Medicinal Products.
- In 2004, the Dutch Code Commission ruled AstraZeneca's promotion of Nexium was in violation of the Code on the Promotion of Medicinal Products.⁴⁷
- The Dutch Code Commission in 2004 found AstraZeneca's claims in its promotion of Seroquel unjustified, not based in two relevant studies and therefore misleading.⁴⁸
- Pfizer filed a complaint about the promotion of AstraZeneca's drug Crestor in 2004. The Code

Commission ruled that the promotion contained some misleading claims.⁴⁹

- In 2000, the European Commission started an investigation into patent manipulations of AstraZeneca for its ulcer treatment Losec (omeprazol). In 2003, the Commission reached the preliminary conclusion that AstraZeneca had seriously abused its dominant market position and misused patent rules. In 2005, the Commission confirmed its findings on the antitrust case and imposed a fine of £40 million (about 60 million euros). Some observers considered this to be far below the profits obtained by the illegal practices.⁵⁰

What they say

- According to the company, to avoid repetition of violations of ethics in marketing all employees must now pass an exam on the code of conduct.⁵¹
- National Codes of Marketing and Sales Practices are in place in all AstraZeneca's 53 marketing companies, and 50 of them updated their code during 2004.⁵²
- In 2003, AstraZeneca revised the marketing code, introduced a global confidential helpline,⁵³ and included marketing and sales practices in its Global Corporate Responsibility Priority Action Plan.
- The company reports on the following relevant Key Performance Indicators (KPIs): number of local AZ codes in place, and from 2005 onwards the number of confirmed breaches, through internal procedures or external complaints.⁵⁴

What's the problem?

- The AstraZeneca Code of Marketing and Sales Practices does not contain detailed normative guidance.⁵⁵
- The company's global marketing codes do not mention any specific principles with regard to DACs or sponsoring of patient groups, but indicates that from time to time regulatory guidance on specific issues, such as internet and consumer oriented communications, will be issued.⁵⁶

- AstraZeneca's code of conduct or CSR website section do not include specific norms on competition. As the company does not disclose its national marketing and sale codes, it is not clear whether these address the issue of competition.

Boehringer Ingelheim

What they do

- In Latin America, Boehringer Ingelheim has been heavily advertising medicines containing dipyrone (metamizol) to the general public, such as Anador in Brazil. In high income countries, the drug is regarded a high-risk painkiller and is prescription-only.⁵⁷
- The BUKO Pharma Campaign nominated Boehringer Ingelheim in 2005 for the Public Eye Award, an award for irresponsible business behaviour. In a summary to the nomination, BUKO Pharma stated the company had produced ineffective and hazardous drugs, used unethical marketing methods, sold sub-standard goods to developing countries and valued intellectual property over access to medicines. The claims were based on research done by BUKO Pharma.⁵⁸

What's the problem?

- Boehringer Ingelheim has no policy on marketing practices that is publicly available.
- In the Netherlands, there is an internal policy with guidelines for compliance with the Dutch Code on the Promotion of Medicinal Products, governed by the Stichting Code Geneesmiddelen Reclame (CGR). After BI was fined in 2002 by the CGR, the internal guidelines became stricter. Violations of the code are reported in the company's annual report.⁵⁹
- There is no information on a marketing policy for the rest of Europe.
- Boehringer Ingelheim has no public policy on competition.

BMS

What they do

- In 2002, BMS published page-wide advertisements for the prescription drugs Zerit, Videx and Sustiva in German lifestyle magazines. In reaction to a complaint by the consumer organisation Verbrauchszentralen Bundenverband, the company stated that the advertisements were a mistake and intended for magazines for healthcare professionals. Yet after this, another advertisement to the general public was published. This announced a new formulation of Zerit, to be launched in 2003, although advertisements for products that have not yet been approved are not permitted, even in communications to healthcare professionals. Government authorities refused to impose a punishment.⁶⁰
- Between 2001 and 2003, BMS reportedly received one warning letter and two untitled letters from the US FDA in the context of allegedly false or misleading promotional materials for Pravachol.⁶¹
- In 2004, the Dutch Code Commission for the Code on the Promotion of Medicinal Products ruled that BMS had promoted its schizophrenia drug Abilify on the basis of unproved effectiveness claims and ordered the company to stop the misleading promotion.⁶²
- In 2005, the Dutch Code Commission for the Code on the Promotion of Medicinal Products ruled that BMS was conducting inappropriate post-marketing research for Abilify. Participating doctors received 100 euros per enrolled patient or a free three-year Pharmaphone magazine prescription, although the research protocol was vague, did not meet research quality standards, and lacked a clear objective. The commission ordered BMS to stop the seeding-trial and to send rectifications to participating health care professionals.⁶³

What they say

- BMS's Standards of Business Conduct and Ethics contain guidelines on marketing, gifts

and entertainment, and competition. The code notes that advertising 'should always be truthful and specific claims must be fair and substantiated'.⁶⁴

- Outside the US, BMS corporate standards contain additional guidelines against corruption of government officials, but not on marketing practices.
- There is also a separate corporate Fair Competition Policy.
- A Corporate Compliance helpline exists for questions about the company's Standards of Business Conduct and Ethics and for anonymous reporting of violations.
- The company states it has a zero tolerance policy regarding illegal inducements, including entertainment, trips, gifts and fees for health professionals.⁶⁵
- BMS recently adopted a Direct-To-Consumer Communications Code, outlining its position on DTCA, DACs and consumer information in general.

What's the problem?

- The Fair Competition Policy is not publicly available.⁶⁶
- Compliance with the standards is internally monitored by various corporate departments.⁶⁷
- The company's standards of business conduct do not contain additional norms or guidance on the conduct of representatives, apart from those on offering gifts and entertainment.
- BMS does not describe any criteria for DACs. The company's Standards of Business Conduct and Ethics and the PhRMA code do not address these issues.
- No information was found on how the commitments in BMS's Direct-To-Consumer Communications Code are incorporated in the company's operations.

Eli Lilly

What they do

- Published data for Lilly's antidepressant Prozac

claimed that the drugs reduces the likelihood that people will harm themselves. However, data from clinical trials indicated the opposite, namely that people continue to harm themselves.⁶⁸

- Oekom Research also indicates that Eli Lilly is criticised for a history of poor transparency and secret settlements on alleged side effects of Prozac.
- Regarding DACs, Lilly's code of conduct states that attempts to influence media coverage of certain therapeutic areas and treatment alternatives is allowed, but that there should be no attempt to control the content of articles and broadcast programmes, unless these are clearly identified as owned or sponsored by the company. The code also states that educational grants or charitable contributions may never be given to any customer in exchange for prescribing or recommending a product,⁶⁹ but this seems not to cover patient organisations.
- In Spain, Autocontrol judged in 2005 that Lilly had violated articles 5 and 7 of the Farmindustria Code. It had illegally disguised promotional efforts for its drug Cialis and promoted it to the general public. The company was fined the minimum amount of 6.000 euros.⁷⁰

What they say

- *'Lilly takes very seriously any suggestion that we suppress safety data. You may be aware that in January 2005 the British Medical Journal published an article, claiming to have in hand missing documents which allegedly showed that Prozac is linked to suicide and that Lilly attempted to minimise this information in the 1980s and 90s. After conducting their own investigation into the matter, BMJ acknowledged that Lilly had acted properly in relation to the disclosure of information. BMJ published a formal apology to Lilly and retracted its allegations.'*
- Lilly states it actively participated in the development of the PhRMA code and was among the first companies that adopted it.⁷¹
- The company established 10 principles for direct-to-consumer advertising (DTC).⁷² The link

in Eli Lilly's GRI index on 'advertising policy and procedures' refers to this information. Violations of the code of business conduct have to be reported and employees can use a special anonymous telephone line.

- Lilly's code of business conduct includes standards of conduct for medical sales representatives and
- norms on gifts and hospitality, educational grants, discounts and product samples.⁷³

What's the problem?

- Marketing is not addressed in the company's Corporate Responsibility principles.
- Apparently an internal approval system for all promotional materials exists, ⁷⁴ but information about this system was not publicly available.

GSK

What they do

- Before GSK's anti-depressant Paxil was approved for use against 'social phobia' in 1999, the company organised a large public awareness campaign about the condition, renaming it 'social anxiety disorder'. GSK has been accused of grossly exaggerating the numbers suffering from this condition, leading to much higher sales of Paxil and inappropriate drug use.
- In 2000 GSK's drug Lotronex had been approved by the FDA for women with irritable bowel syndrome. Months after approval, reports about side effects were sent to the FDA. GSK then voluntarily withdrew the drug from the US market. Patient groups, including at least one funded by GSK, wrote letters to the FDA demanding the drug be re-approved. GSK also sponsored the International Foundation for Functional Gastrointestinal Disorders. Its president Nancy Norton spoke at advisory meetings organised by the FDA in order to assess the safety concerns surrounding Lotronex, without revealing that the foundation

received significant amounts of money from the pharmaceutical companies, including GSK. At the time of her appearances, the industry was reportedly funding the foundation in the order of \$600,000 a year.⁷⁵

- In 2001, GSK was warned several times by the FDA to change its promotion activities in the context of Avandia.⁷⁶
- In 2002 German authorities started an investigation against GSK for corruption of at least 1,600 doctors.⁷⁷
- In February 2003, Italian authorities started an investigation against GSK for corruption of over 4,000 doctors. The total value of illegal gifts was estimated at 228 million euros from 1999 to 2002. These incentives suggest that doctors would have prescribed 7-8% more GSK products each than otherwise would have been the case.⁷⁸
- Promotional materials for GSK's antidepressant Paxil claimed that the drug reduces the likelihood that people would harm themselves. However, data from clinical trials indicated the opposite, namely that people continue to harm themselves.⁷⁹
- In 2005 the Dutch Code Commission ruled that GSK had made unjust claims about the necessity of using Seretide in the treatment of COPD in its promotional materials and violated the Code on the Promotion of Medicinal Products.⁸⁰ The Commission also showed that GSK had provided unclear and misleading information for Avandamet and Avandia in a mailing to healthcare professionals and ordered the company to stop these practices.⁸¹
- In May 2004, GSK was accused of fraudulent manoeuvres to extend patent protection over its anti-depressant Paxil and its antibiotic Augmentin, in order to prevent competition from generics.⁸²

What they say

- GSK's 'Employee guide to business conduct' includes a company-wide policy on 'Pharmaceutical Marketing and Promotional Activity', which applies to all employees and agents. It also includes guidelines on competition law.

- Since December 2003, GSK also has regional marketing for Europe, the US, Japan and the rest of the world (International). During 2004, the regional codes were translated into major languages and distributed throughout the company. For 2005, GSK planned to harmonise different regional codes where appropriate.⁸³
- GSK's European code is accompanied by a quarterly reporting mechanism where national divisions report breaches of the code and actions that have been taken to prevent recurrence.⁸⁴
- Sales and marketing employees receive training on appropriate marketing practices and their obligations under GSK's marketing codes. This includes initial and refreshes courses. New staff have to pass a test on the code of practice.
- In Europe, over 10,000 sales and marketing staff were trained in the marketing codes in 2004.

What's the problem?

- Despite the training on GSK's codes, during 2004, 87 employees were dismissed or agreed to leave the company voluntarily as a result of breaches of sales and marketing codes. In addition, there were 109 cases of other sanctions against employees including written warnings, remedial training and fines.⁸⁵
- GSK's global policy on pharmaceutical marketing and promotional activities is short and general in nature with no detailed guidance.
- The GSK European Promotion of Medicines Code of Practice states that promotional material for prescription drugs should only be distributed to healthcare professionals.⁸⁶ However, it does not contain a policy on disease awareness campaigns or sponsoring of patient groups.

Johnson & Johnson

What they do

- In 2004, Johnson & Johnson's Polish unit was fined 3.8 million zlotys (approximate 1 million euro) by the country's competition authority for abusing a dominant position for the dialysis drug Eprex.⁸⁷

- In 2005, authorities in Portugal fined Johnson & Johnson 360,000 euros for forming a cartel with five other pharmaceutical companies (Abbott, Bayer, Menarini, Pharmaceutica Quimica) for 36 bidding processes to supply 22 hospitals in Portugal.⁸⁸

What they say

- Johnson & Johnson's ethical code and policy on business conduct contains general principles on marketing.
- The company's policy on business conduct mentions that 'usual forms of entertainment such as lunches or dinners as well as occasional gifts of modest value' in business relationships are allowed.⁸⁹
- Johnson & Johnson's ethical code states that medically relevant product information should be fair, balanced and comprehensive.⁹⁰
- The company's policy on business conduct requires compliance with national competition and antitrust laws in each country.⁹¹

What's the problem?

- A further description of marketing policies is not publicly available
- Johnson & Johnson is not a direct member of the IFPMA and therefore the company and its subsidiaries are not automatically committed to the IFPMA code.
- The company code does not provide precise norms on gifts and hospitality to healthcare professionals.
- The code does not set specific norms or provide further guidance on product information, and it is not clear whether it covers all promotional materials (such as internet chat groups etc).

Lundbeck

What they do

- In England in 2002/2003, Lundbeck was found guilty misleading advertisements accompanying the launch of Cipralex.⁹² Cipralex is a newer version of the company's older antidepressant

Cipramil, but contains exactly the same active ingredient.⁹³

What they say

- Lundbeck has an overall code of conduct for medical representatives. Lundbeck states that it is focused on being responsible, and therefore '... each subsidiary's specific code of conduct for medical responsibility is developed locally in order to comply with all national sales and marketing rules and restrictions.'⁹⁴

What's the problem?

- No information was found the implementation mechanisms accompanying Lundbeck's country-specific codes of conduct for medical responsibility.
- Lundbeck discloses only global distribution costs, not a regional or country breakdown. In 2004 total distribution cost was 2,290 million Danish Kroners (approximately 305 million euros).

Menarini

What they do

- According to *El Nuevo Diario* Menarini raised its prices in Nicaragua in 2005 by 16-25%, including medicines which had no generic counterpart available in Nicaragua. Pharmacists said that they doubted if the price increase was authorised by the Ministry of Promotion, Industry and Commerce (MIFIC) in Nicaragua.⁹⁵

What they say

- Menarini states that the price increase was authorised in Nicaragua: '*Menarini got an official approval for some price increase by the MIFIC. In our case, the price increases were partially compensating a big loss registered on the exchange rate US\$/Euro during the last years. The date of authorisation is 2 August 2005. The date of implementation is 10 August 2005. Our affiliate in Nicaragua has duly informed all the local customers of this price increase and the relevant authorisation by MIFIC.*'⁹⁶

- The company states it strictly observes the marketing codes of EFPIA, IFPMA, and the Italian industry association Farmindustria,⁹⁷ It explains: '*The Menarini Group has to date distinguished itself by a long tradition of respect for the current norms and laws governing pharmaceutical and diagnostic business, particularly for those of an ethical nature. ...No violations or potential violations are allowed or accepted. Within this basic framework: In 2002 Menarini Group started a huge project to re-define all the Group's rules (Policies and Procedures). Within this project we had been defined two procedure to cover: (a) the compliance with Article 81(1) of the EC Treaty; (b) The respect of free competition laws (in particular for diagnostic market). In 2003 Menarini adopted a new Company Ethical Code that defines the fundamental ethical value on which the Group is based and ...covers topics like: duties of the head of companies and employees, conflict of interests, relations with external entities...*'
- Menarini's ethical code includes a section on compliance with competition laws. It prohibits exchange of information or agreements with competitors regarding, for example, pricing policies, sales conditions, markets or production costs that might restrict free competition.⁹⁸

What's the problem?

- Both the Ethical Code and the mentioned procedures are not public documents. Therefore, they are not disclosed in the group website or in other paper-based documentation.⁹⁹
- With regard to gifts and hospitality, the code focuses on relations with government officials and suppliers, and does not provide specific norms on relations with healthcare professionals.¹⁰⁰
- The company does not refer to the EFPIA, IFPMA and Farmindustria codes in its own ethical codes or in publicly available policy information. No further information on responsible marketing policies was found or provided.

- Menarini's ethical code does not set specific standards for the behaviour of medical sales representatives.
- No relevant public information was found on Menarini's policy on DACs and interaction with patient organisations.

MSD

What they do

- A major controversy regards misleading information on the drug Vioxx, which was an issue even before the drug was withdrawn because of safety concerns. In 2001, the FDA warned Merck for: 'having engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed ... and thus, misrepresents the safety profile for Vioxx.'¹⁰¹
- In Spain, Autocontrol judged in 2005 that MSD had violated article 3 of the Farminindustria Code, by providing misleading and unfounded information in promotional materials for its drug Fosamax. The company was fined the minimum amount of 6,000 euros.¹⁰²

What they say

- The Merck Code of Conduct includes standards on fair competition, advertising ('honest communication'), gifts and hospitality, including invitations to conferences and symposia. Each section describes norms for employee conduct and provides specific questions and answers to illustrate the application of these norms. Apart from the corporate marketing norms in the code of conduct, the company provides information on marketing standards for the US only.¹⁰³

What's the problem?

- No information was found on norms on gifts and hospitality for outside the US, or the implementation of such norms.
- No information was found on specific company policies on DACs and interaction with patient organisations. The Merck Code of Conduct does not address these issues.¹⁰⁴

Novartis

What they do

- The Berlin medical journal *arznei-telegramm* accused Novartis in 2002 of omitting unfavourable results in the publication of a study of the drug Diovan, in order to make the efficacy of the drug appear better than it actually was. The same journal also accused Novartis of illegal marketing practices and creating expectations of efficacy that could not be met.¹⁰⁵
- In 2002, the Swiss consumer protection agency *Stiftung für Konsumentenschutz* criticised Novartis for misleading consumers. Novartis had stated in its sales promotion that its drug Mebucasol F was new on the market, but the active ingredients would be the same as those of an older but cheaper drug, Sangerol.¹⁰⁶
- There have been cases of celebrities who were paid large fees to mention the benefits of specific brand-name drugs in TV programmes, without disclosing they received a financial reward for these stories. Novartis used this type of unethical advertisement for its drug Visudyne in March 2002.¹⁰⁷
- In 2000 Novartis started a DAC about the nail infection dermatophyte in the Netherlands. At the same time Novartis sent promotional mailings to doctors, reminding them the only product on the market to treat dermatophyte was Novartis's Lamisil. The commercials increased visits to doctors by 50% and raised sales for Lamisil from 15 million euros in 1999 to 32 million euros in 2001.¹⁰⁸ Prescriptions by doctors for this condition increased from 7 to 15 per thousand patients. The Dutch Code Commission ruled Novartis' promotion of Lamisil was in violation of the Code on the Promotion of Medicinal Products. Novartis appealed the decision, claiming the name of the product was not mentioned in the commercials, which only explained symptoms of the condition. The company won the appeal, but stopped the campaign after heavy protests from doctors. Prescriptions written for the

infection then dropped to the former level.¹⁰⁹

- In 2005 in Spain, Autocontrol ruled that Novartis had violated the Farmindustria Code by relying on insufficient and insignificant sources for comparing its drug Myfortic to Roche's Cellcept in promotional materials.¹¹⁰
- In 2004, a class action lawsuit was filed in the US against Novartis accusing them of providing fraudulent kickbacks, discounts and rebates to encourage pharmacy benefits managers to put its drugs on their formularies. The case is still pending.¹¹¹

What they say

- Novartis adopted has a new global Marketing Code in 2003. It has ten main principles that supplement industry codes and national legislation. Pharma Novartis (the branded prescription drugs division) has its own Pharma Promotional Practices Policy and Guidelines.
- The Novartis Pharma policy includes detailed guidelines largely in line with the EFPIA code, including for example the prohibition of certain words and phrases in advertisements. In contrast to most marketing codes, Novartis' promotional practices policy also provides some guidance on the provision of free samples and includes a compliance checklist.¹¹²
- More stringent local codes or requirements take precedence over the global policy.
- Regarding internet promotion, the Novartis Pharma Promotional Practices Policy and Guidelines state that: 'appropriate measures must be taken so that only the audience targeted gets full access to the information.'¹¹³
- Novartis expressed the intention to improve compliance with codes during 2005.¹¹⁴

What's the problem?

- By 2004, over 90% of marketing and sales staff were trained on adherence to the code and 11 internal audits on marketing practices were conducted. Nevertheless, violations of the marketing code and code of conduct in 2003 and 2004 resulted in the dismissal of over 100 employees.

- No specific information on CSR policies for DACs and interaction with patient organisations was found.
- A separate Novartis Internet Code exists, but was not available to the researchers for review.

Novo Nordisk

What they do

- In 2004 the Dutch Code Commission of the Code on the Promotion of Medicinal Products ruled that promotion material of Novo Nordisk for its drug Levimir (insuline detemir) was based on false claims and that the provision of free samples constituted an illegal promotional activity. NovoNordisk claimed that since it was not a member of Nefarma, the Dutch industry association, the Commission could not rule in this case. The Commission considered itself competent to rule and ordered NovoNordisk to stop the promotion and issue rectifications.¹¹⁵
- Novo Nordisk is one of several pharmaceutical companies under investigation for illegal activities related to public tenders in Brazil in which it is alleged that businesses conspired with Health Ministry officials and others to inflate the prices of ministry purchases, including insulin. The company commissioned an external study, which concluded that Novo Nordisk employees had not participated in illegal acts.¹¹⁶

What they say

- The company states that it adheres to 'the Helsinki Declaration and relevant international and national standards and codes for advertising'.¹¹⁷
- Novo Nordisk states it does not report on the number and types of breaches of advertising and marketing regulations, as the data does not exist in aggregated form. The company will not consider reporting the data until it is possible to give a complete overview.

What's the problem?

- Although Novo Nordisk has a comprehensive

public CSR policy covering most issues, it does not include marketing. However, the Helsinki Declaration defines rights for patients participating in clinical trials and does not set standards for marketing practices. The company does not mention to which other standards it refers.

- As Novo Nordisk is not affiliated to the IFPMA, the company is not obliged to follow the IFPMA Code in all its operations.
- No information was available on marketing policies, implementation, or performance.
- No information was available on standards of conduct for medical sales representatives, on norms for gifts and hospitality, advertising standards, standards for DACs and interaction with patient organisations.
- No information was available on competition policies. The issue might be included in Novo Nordisk's Code of Ethics, but the code was not publicly available for review.

Nycomed

What they say

- In its annual report, Nycomed states the following: *'We acknowledge the need for professional integrity in our relationships with our customers. It is the responsibility of the general managers in each Nycomed market to ensure the appropriate conduct of marketing and sales activities. To further support this, a corporate project has been initiated to develop and implement a Code of Conduct encompassing all Nycomed business.'*¹¹⁸
- Nycomed states that is committed to implementing the EFPIA code of practice through local memberships of pharmaceutical industry associations,¹¹⁹ and is currently developing a code of conduct that covers marketing and sales practices.¹²⁰

What's the problem?

- Currently the company does not have a code of conduct for medical representatives.

- No further information was found the operational aspects of Nycomed's policy on responsible marketing and the company's implementation of the EFPIA code of practice.
- No further information was found how proposed marketing codes would be implemented.

Orion Pharma

What they say

- Orion states about its marketing policy: *'The Company has a code of conduct in Finland for the medical representatives and we offer our personnel "Best Practices Training" in many issues worldwide. In Finland the system is that a sales representative has to pass an examination to act as a sales rep (RLE examination).'*¹²¹
- The company has had a follow-up questionnaire where doctors had an opportunity to evaluate the skills of the sales representatives, followed up by a sustainable feedback programme and a training programme implemented during 2002-2004.¹²²
- Orion reports that its total promotion and marketing costs in 2004 were 18.2 million euros, including samples and salaries. About half of the marketing budget consisted of advertising costs and the other half of detailing and disease awareness, which, according to the company, were difficult. The total retail value of samples was approximately 1.85 euros.¹²³

What's the problem?

- No information was found the norms included in the code of conduct or training of representatives.
- It is not clear whether norms for responsible marketing and sales practices were included in training programmes, or whether they focussed on technical skills only.
- With total pharmaceutical sales of 514 million euros, the stated expenses for marketing are only 4% of sales, which seems extremely low compared to other companies. The reason for the low marketing expenses is not known.
- Orion has a code of conduct in Finland,¹²⁴ which

was not publicly available.

- No policy information for Orion Pharma was found on the following issues: codes of conduct for medical representatives, gifts, relationships with health practitioners and patient groups, or disease awareness campaigns.

Pfizer

What they do

- In 2004 Pfizer pleaded guilty on charges of falsely marketing its epilepsy drug Neurontin for off-label uses.¹²⁵
- In 2004, in the Netherlands, the Code Commission on the Code for the Promotion of Medicinal Products judged Pfizer had made misleading claims about the safety of Lipitor in its promotion materials.¹²⁶
- The Dutch Code Commission granted a complaint filed by a doctor against Pfizer in 2004. The doctor complained about an invitation that he had received from Pfizer for a information meeting about Celebrex. Pfizer promised to cover expenses by giving 200 euro for doctors signing up to the meeting.¹²⁷
- In two advertisements for Norvasc (amlodipin) in Germany in 2004, Pfizer omitted important findings from the ALLHAT-study that was referred to. It claimed 'equal value' of Norvasc when compared to diuretics, although this could not be concluded on the basis of the research findings.¹²⁸ The American College of Cardiology (ACC) co-operated with Pfizer and issued a statement urging doctors to stop the use of the competing drug Cardura.¹²⁹
- Published data on Pfizer's anti-depressant Zoloft has claimed that it reduces the likelihood that people will harm themselves. However, data from clinical trials indicated the opposite, namely that people continue to harm themselves.¹³⁰
- The MHRA ruled that in a promotional letter, sent to healthcare professionals in the UK in November 2004, information about Celebrex was not balanced or accurate. The MHRA required that Pfizer would send a corrective statement, but after a publication by the MHRA

on the use of selective COX-2 inhibitors in general, this requirement was dropped.¹³¹

- Pfizer has sponsored an Impotence Association campaign in which the logo of Pfizer figured prominently on the advertisements. The UK Prescription Medicines Code of Practice Authority (PMCPA) ruled that this was inappropriate and could encourage patients to ask doctors specifically for Viagra.¹³²
- In 2004, Pfizer was criticised by the Federation of German Consumer Organisations for illegal direct-to-consumer advertisements in newspapers, in contravention of German drug regulations. According to the NGO, Pfizer claimed that Sortis was the best cholesterol-lowering medicine available.¹³³
- In 2005, the Dutch Code Commission (CGR) ordered Pfizer to shut down a website about erectile dysfunction that it sponsored, because the company was promoting of its prescription drug Viagra to the general public.¹³⁴
- In Spain, Autocontrol judged in 2005 that Pfizer had violated articles 3.8 and 7 of the Farmindustria Code. It had made an unfair comparison between its drug Viagra and Eli Lilly's Cialis and illegally promoted the drug to the general public. The company was fined 90.000 euros.¹³⁵
- In September 2005, the Prescription Access Litigation project (PAL) filed a class-action lawsuit in the US, accusing Pfizer of a deceptive advertising campaign for Lipitor.¹³⁶

What they say

- CSR policies on drug advertising, business integrity in general, and competition are described in Pfizer's Policies on Business Conduct.¹³⁷ They apply to worldwide operations.
- In a letter to the UN High Commissioner for Human Rights, Pfizer states it follows the WHO's Ethical Criteria for Medicinal Drug Promotion and the IFPMA Code of Pharmaceutical Marketing Practices.¹³⁸
- A compliance hotline exists and is operated by a third party. Compliance with the Policies on

Business Conduct is the primary responsibility of the Corporate Compliance Officer and the Corporate Compliance Group.¹³⁹

- Pfizer's 'Policies on Business Conduct' explicitly prohibit 'payments of any kind to any person... to obtain advantage in selling goods'.¹⁴⁰
- The issue of free samples is shortly addressed in Pfizer's 'Key principles guide'.
- Pfizer's conduct code prohibits 'false or misleading advertising' and 'unfair comments' about the products of competitors.¹⁴¹
- In the 'public policy' section on its website, Pfizer includes the issue DTCA.¹⁴²

What's the problem?

- Only a summary of Pfizer's CSR policies are publicly available and they do not provide clear information on company CSR practices.
- On issues like DTCA Pfizer also refers to public policy documents.¹⁴³ However, the company does not describe how these specific standards are integrated in company policies and implemented
- The key principles guide, which covers the issue of free samples, apparently only applies to Pfizer's operations in the US.¹⁴⁴
- Pfizer's journal *Creating Access to Innovation* contains the dubious statement that free drug samples increase 'the likelihood that the right drug will be prescribed'.¹⁴⁵
- On the issue of DTCA, the company only refers to articles and other documents commenting on the issue and, more specifically, defending DTCA on its website. It can be concluded that Pfizer strongly supports DTCA.
- No policy information on DACs and interaction with patient organisations was found.

Roche

What they do

- In 2002 and 2003, Roche reportedly received one warning letter and one untitled letter from the FDA in the context of allegedly misleading promotional materials and patient-directed

videos concerning its cancer drug Xeloda.

According to the FDA, Roche failed to present risk information, overstated the efficacy of the drug, made unsubstantial superiority claims and omitted material information about the limitations on the drug's approved indications.¹⁴⁶

- In 2004 the Dutch Code Commission of the Code on Promotion of Medicinal Products (CGR) ruled that Roche had violated the code in its promotion material of the drug Aleve Feminax. According to the Commission, Roche's claims that Aleve was more effective than other pain killers were not based on sufficient scientific evidence. The Commission ordered Roche to stop the promotion and issue rectifications.¹⁴⁷
- In 2005 the Dutch Code Commission of the Code on Promotion of Medicinal Products (CGR) ruled that Roche had violated the code with a compensation scheme and promotional letter for Bondronat.¹⁴⁸

What they say

- For marketing practices in general, Roche refers to national legislation and several industry guidelines.
- Roche has internal guidelines on legal compliance of promotional activities, which clearly define the responsibilities of various managers and teams. All promotional activities need to be cleared for compliance by local divisions.¹⁴⁹
- Roche claims to have a policy in line with the IFPMA and EFPIA codes, and standards for the conduct of medical sales representatives should therefore be similar to the standards in these codes.
- Roche has guidelines on business integrity that include dealings with customers and other third parties.¹⁵⁰
- Regarding hospitality, some guidance on restrictions is offered in the internal Guidelines for Roche's Involvement in Medical Meetings. These include the general norms that hospitality must be 'always subsidiary to the main, scientific purpose' and 'of a reasonable standard'. Examples of more detailed norms are the

exclusion of persons accompanying health professionals from hospitality and maximum expenses for dinners and honorariums.¹⁵¹

What's the problem?

- It is Roche's policy not to disclose information on breaches of marketing codes.¹⁵²
- Roche does not provide further details how the IFPMA and EFPIA codes are implemented.
- Roche's CSR policies do not contain detailed guidelines on gifts to healthcare professionals.
- Roche's guidelines on legal compliance of promotional material state that all data available on a product must be fully exploited.¹⁵³ It is not clear how this should be interpreted. It could mean for example that information on adverse drug effects should not be concealed, but it could also refer to data useful for marketing only. The company does not provide further details.

Sanofi-Aventis

What they do

- In an advertisement for Plavix (clopidogrel) in Germany in 2004, Sanofi-Synthélabo stated that the treatment was recommended for 'at least 12 months'. However, the source that was cited mentioned 'at least 9, possibly also 12 months'. Sanofi Synthélabo also mentioned exaggerated mortality risks by wrongly presenting figures from another source.¹⁵⁴
- Aventis claimed blood-pressure dependent risk reductions in advertising material for Delix (rampiril). However, this effect could not be concluded from the article that was provided as the source for the claim.¹⁵⁵
- In November 2002, the European Commission concluded that Aventis Pharma and Rhone-Poulenc Biochimie had unlawfully fixed prices of methylglucamine between 1990 and 1999, and fined the companies 2.85 million euros after granting a 40% reduction to reward them for their co-operation throughout the investigation.¹⁵⁶

What they say

- According to the Oekom Research, a booklet on promotional practices to uphold WHO, PhRMA and IFPMA marketing codes is being finalised and will be provided to all employees worldwide.
- Before the merger, Aventis had internal guidelines for promotion, based on the IFPMA and PhRMA codes, and a global compliance policy. Sanofi-Synthelabo had a brochure called the Ten Commandments of Pharmaceutical Advertising.¹⁵⁷

What's the problem?

- Currently Sanofi-Aventis does not have a public policy on responsible marketing practices.
- The issue is not addressed in the company's Annual or Sustainable Development reports 2004 or on its website.
- Gifts to healthcare professionals are not addressed in the company's financial code of ethics.

Schering

What they do

- In April 2002, Schering launched Yasmin in the UK, claiming, in an advertisement to healthcare professionals, that the medicine was 'the pill for well-being and that 'Yasmin is different in many ways. It has been shown repeatedly to have no associated weight gain. In addition, Yasmin has a demonstrable effect on PM [pre-menstrual] symptoms and on skin condition ...Women feel well in Yasmin. Make a difference to their lives and prescribe Yasmin.' The magazine DTB published a review of Yasmin in August 2002, which concluded that the claims were misleading: 'we believe that the claim that Yasmin "is the pill for well-being" is unjustified and misleading and should be withdrawn.' In response, Schering threatened to sue DTB for defamation. Prompted by DTB's article, the PMCPA began an investigation and concluded in September 2002 that Schering had breached the Authority's Code of Practice on 11 separate counts.¹⁵⁸

- According to Oekom Research, Schering's US subsidiary Berlex received a warning letter from the FDA in 2003 regarding a misleading advertisement for the contraceptive Yasmin. According to the FDA, the 60-second TV ad entitled 'Goodbye Kiss' was misleading because it made implied clinical superiority claims to other combination oral contraceptives and minimised the important risk information that distinguishes Yasmin from other combination oral contraceptives. As a result, the television ad reportedly raised significant public health and safety concerns

What they say

- In Germany, where the company's headquarters are located, the company joined the so-called Freiwillige Selbstkontrolle der Arzneimitte lindustrie (Voluntary Self-control of the Medical Industry – FSA).
- Schering takes the FSA standards as its internal marketing code. Schering further comments: 'The implementation of the revised EFPIA code had to be completed by its members by 1 January 2006. These standards are valid for all Schering AG and its European subsidiaries.'¹⁵⁹
- Schering's Code of Ethics includes general principles on anti-corruption. It states that no employee is allowed to offer any kind of benefit to business partners which might (appear to) compromise the ability make objective and fair business decisions.¹⁶⁰

What's the problem?

- No company-specific information was found on advertising standards. This issue is not addressed in Schering's Code of Ethics or in the German FSA code.¹⁶¹
- Schering's Code of Ethics refers to applicable antitrust, competition and fair trading laws. However, the code does not provide further guidance on how these principles are put into practice.¹⁶²
- Although Schering describes the rules of the FSA code as strong,¹⁶³ it should be noted that they are weak compared to other national

codes. The company's commitment to implement the revised EFPIA code is much stronger and would imply a stricter internal marketing code.

Wyeth

What they do

- During 2005 in Portugal, Wyeth developed and promoted a so-called 'social service' on its website, aimed at assisting women to take its contraceptive pill 'without fear and without forgetting', through a text message (SMS), called 'Alerta Pílula SMS' 164 – Pill Alert SMS. However, this service is only open to women using the Wyeth product, after receiving a special code given by their doctor. This is not clear in the Wyeth website, which does not mention the brand of pill. This initiative is not a social service for women but a marketing device for the company.

What they say

- Wyeth's Code of Conduct provides guidance on compliance with competition laws and contains general principles on advertising and relationships with healthcare professionals. For example, it states that promotional materials must accurately and fairly describe the company's products and not be false, misleading or deceptive.¹⁶⁵
- The company also produced Wyeth AntiTrust Compliance Guidelines, which are available on its website.
- Wyeth provides brief guidance for compliance with competition laws in its Code of Conduct. The code includes agreements with competitors on prices, output, geographic markets, terms, and sales policies.¹⁶⁶
- All employees worldwide have to report violations of Wyeth's code of conduct.

What's the problem?

- No detailed information was found on Wyeth's marketing policies for European markets.
- Guidance on reporting of violations of the

company code of conduct contain few guidelines for promotional practices outside the US

- No information was found on Wyeth's standards of conduct for medical sales or on norms for gifts and hospitality applicable in Europe.
- DACs and interaction with patient organisations are not addressed in the code.¹⁶⁷

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