

## Always read the label

An analysis of the social and environmental aspects of the pharmaceutical industry

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## Summary

The pharmaceutical industry makes products that are of enormous benefit to society. Hardly any other industry makes such a direct contribution to saving human life. At the moment, however, the industry is suffering from a loss of confidence both on the part of investors and the general public, a problem that has been exacerbated by negative headlines about the side effects of medicines and controversial marketing practices, among other things. The industry does not make the headlines as much when it comes to environmental protection issues, but even so the production of drugs does have substantial environmental impacts. Since sustainable investment is based on the principle that social and environmental risks are economically relevant, this report studies how the pharmaceutical industry deals with these risks. In the social dimension, our analysis focuses on the two themes “Access to medicines in developing countries” and “Ethical aspects of marketing”, and in the environmental dimension on the broader issue of “Environmental aspects of production” and “Pharmaceuticals in the environment”.

Access to medicines in the impoverished regions of the world is a very emotionally charged topic. This is certainly one of the reasons why drug companies have tried to make improvements in the last two years following heavy public criticism – much of it justified. Nowadays, for example, it is standard industry practice to provide access to HIV/Aids drugs in the least developed nations and in sub-Saharan Africa at production cost, and not to enforce patents in these regions. Medicines for other diseases, such as malaria, have also been distributed, and research stepped up into neglected diseases<sup>1</sup>. Of the companies examined in this report, the best performers in this field were GlaxoSmithKline (GSK), sanofi-aventis and Novartis.

The industry also attracts criticism because of its controversial marketing practices. These include aggressive marketing of prescription drugs with the help of consumer advertising (which is permitted in the USA), gifts to doctors, off-label marketing of a drug, and a selective information policy on clinical trials. The industry is now committed to improvement in this area through self-regulation. We will have to wait and see how much drug companies change their conduct in this field. One company that does score well in this field is Roche.

The industry has reached a high standard when it comes to reducing toxic emissions and managing malfunction risks in its production plants. This is partly the result of outsourcing in the chemicals business and improvements in the eco-efficiency of production processes. The emissions created by energy consumption, emissions of volatile organic compounds (VOCs) and the waste produced are relevant to our assessment. One subject that needs further investigation is the problem of pharmaceuticals in the environment. These are

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<sup>1</sup> These include infectious and parasitic diseases that mainly affect people in impoverished regions of the world and for which no effective treatment is currently available. According to the World Health Organization (WHO), these include: sleeping sickness, Chagas disease, dengue fever, leishmaniasis, leprosy, lymphatic filariasis, malaria, river blindness, schistosomiasis and tuberculosis. HIV/Aids is also highly relevant to developing countries, but is not considered to be one of the neglected diseases, since research is driven by the market in developed countries.



excreted by humans, pass through the sewage system and end up in the environment. It is already possible to identify dozens of pharmaceutical substances in surface water, albeit in concentrations which in most cases do not pose a threat of negative effects in the short term. But knowledge of how active substances behave in the environment – environmental toxicology – is still patchy. For several years now ecotoxicology tests have been a compulsory part of the drug approvals process. Some companies are conducting in-depth research into this topic.

This report shows that it is possible for anyone guided by sustainability principles to invest in the pharmaceutical sector even though there are substantial environmental and social risks. The European drug companies are the most suitable candidates. Novo Nordisk comes top, with a “high” rating, followed by Novartis, Roche, GSK and sanofi-aventis with an “above average” rating. These progressive companies also benefit from more efficient production, a better reputation and less exposure to the risk of legal disputes. They are also helping to relieve some of the regulatory pressure on the industry and make sure that pharmaceutical companies are recognised as valuable partners for creating an efficient healthcare system.



## Introduction

The success model has started to crack

The pharmaceutical industry has enjoyed enormous success for many years: a steady flow of new medicines were launched to combat diseases, many new jobs were created and shareholders benefited from consistently high earnings growth. But cracks have started to appear in recent years. Profits have been hit by competition from generics and depleted product pipelines. The industry has also attracted criticism for various other problematic issues:

- Soaring general healthcare costs and drug prices, while the pharmaceutical industry continues to enjoy comparatively high margins
- Side effects of drugs (Vioxx, Lipobay, etc.)
- Increased reports of controversial business practices in the industry, such as aggressive marketing, trying to influence medical staff, etc.
- Denial of access to medicines for millions of people in developing and middle-income countries.

Public reputation has suffered

The pharmaceutical industry makes products that are of enormous benefit to society: hardly any other industry makes such a direct contribution to saving human life<sup>2</sup>. The results of surveys show, however, that the industry has an extremely poor reputation at the moment. According to an annual poll conducted by Harris Interactive, the industry's reputation has deteriorated dramatically in the last seven years, and is now almost as bad as the tobacco industry. Given this backdrop, it is therefore hardly surprising to hear that US film director Michael Moore is about to start work on a documentary film about the shortcomings of the pharmaceutical industry. "The environment we operate in is characterised by a loss of confidence" commented the head of Novartis, Daniel Vasella, while the CEO of AstraZeneca, Sir Tom McKillop, said that a "depressing grey mist is descending on the industry". The CEO of PhRMA, the US industry body, has confirmed that his priority is to restore the pharmaceutical industry's reputation.

Enterprise value is affected

Most of the issues mentioned are directly connected with the sustainable development of our society and also have an impact on a company's enterprise value. The purpose of this report is to examine how the pharmaceutical industry is tackling these social and environmental challenges. We believe there is good evidence – particularly in the last couple of years – to suggest that it is advantageous for the pharmaceutical industry (and other sectors) to address social demands and take them on board if they are to fully qualify for a "licence to operate".

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<sup>2</sup> The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) sees the industry's role as follows: "It should be underlined that the pharmaceutical industry's primal role and social responsibility is to deliver new, innovative medicines."

## Industry description

The pharmaceutical industry accounts for 6.2% of the total market capitalisation of the MSCI World Index, making it the third biggest sub-industry after diversified banks and integrated oil & gas companies.

This report examines the world's ten biggest drug companies and a handful of other important industry players.

Companies studied		
Company	Market capitalisation In USDm	Country
Johnson & Johnson	189'920	USA
Pfizer	187'296	USA
GlaxoSmithKline	149'299	UK
Novartis	138'646	SWITZERLAND
sanofi-aventis	115'473	FRANCE
Roche Holding	98'163	SWITZERLAND
AstraZeneca	76'683	UK
Abbott Laboratories	66'152	USA
Merck & Co	61'313	USA
Lilly (Eli) & Co	60'383	USA
Bristol-Myers Squibb Co	47'156	USA
Novo Nordisk	14'606	DENMARK
Eisai Co	12'697	JAPAN

Source: MSCI/status 28 September 2005

## Sustainability issues in the pharmaceutical industry

The sustainability analysis performed on pharmaceutical companies by Bank Sarasin covers aspects such as the implementation of environmental management systems, the development of emissions and resource consumption, employment conditions, stakeholder dialogue, business ethics, relationships with suppliers and corporate governance. Appendix 1 contains an overview and description of the methodology used. The most crucial issues for the pharmaceutical industry are listed in the table below:

Key sustainability issues for the pharmaceutical industry	
Social	Environment
• Access to medicines in developing countries	• Energy consumed in production and transport
• Access to medicines for low-income persons in industrialised countries	• Emission of volatile organic compounds
• Marketing practices	• Waste
• Efficacy/tolerability of products	• Pharmaceuticals in the environment
• Research practices (clinical studies, genetic engineering, etc.)	• Environmental impact during pre-production
• Lobbying	

Source: Bank Sarasin

Major challenges: product liability, lack of innovation and generics

One of the most crucial aspects for both patients and companies is the efficacy and tolerability of pharmaceutical products, as the Vioxx scandal illustrated so clearly. In September 2004 the manufacturer of Vioxx, Merck & Co., withdrew the drug from sale after serious potential side effects came to light (increased risk of heart attack). The company is facing over 4,000 claims as a result. Other companies, such as Eli Lilly (Zyprexa) and GSK (Paxil/Serotax) are also involved in legal disputes concerning their products. Financial analysts' and media reports have provided in-depth cover of the issues of side effects and product liability. Drug companies have also been criticised for marketing "me-too" products. In recent years some pharmaceutical companies have often not launched new, innovative drugs but instead introduced products that are slightly modified copies of existing products, and then pushed them aggressively with a big marketing budget. The FDA estimates that about two-thirds of drugs fall into this category. Companies also invest a lot of money in legal action against generics manufacturers – patents on many of the most successful drugs have already expired or are about to expire in the near future.

Pharmaceutical industry does a lot of lobbying

The drug industry's influence on politicians and authorities is also criticised in connection with product approvals. Compared with other sectors in the US, the pharmaceutical industry has the highest lobbying budget and has proven to have a strong influence on the drafting of different laws, particularly through its industry associations.



Sarasin's 2004 report looked at medicinal biotechnology

Biotechnology research practices, especially using human stem cells, have also been in the public spotlight. The Sarasin report published in 2004 "Will medicinal biotechnology sustain its promise?" examined the ethical implications of genetic technologies. Apart from ethics, safety is also crucial: it is vital that genetically modified material does not escape into the environment. This area is governed by very strict external and internal regulations and the standard of safety achieved by the companies is rated as high.

Four issues in focus

This report takes a closer look at four key issues. On the social side, access to medicines in developing countries is an important theme. There is a broad public debate at the moment about the pharmaceutical industry's responsibility with respect to limited access to medicines to developing countries. Another important aspect as far as reputation and regulation are concerned is the industry's marketing practices<sup>3</sup>. On the environmental side, the broad topic of "Environmental aspects of production" is a key issue. The last issue is the potential environmental hazards caused by drug residues. Research undertaken in recent years shows that residues of various pharmaceutical substances found in commonly used drugs can be detected in the environment. The relevance of these findings still cannot be accurately assessed and therefore warrants closer inspection.

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<sup>3</sup> A survey commissioned in 2004 by GlaxoSmithKline in Europe and the USA asked 50 opinion leaders (academics and research scientists, NGOs, clients, investors, etc.) about their views on the company's social performance (environmental issues were examined in a separate survey). The most relevant issues for the respondents were access to medicines in developing countries, ethical marketing practices, competent performance of clinical studies and transparency of their results, and access to medicines for disadvantaged sections of the population in industrialised countries.

## Access to medicines in developing countries

Global imbalance

80% of pharmaceutical products are sold to just 20% of the world's population. The four most prevalent diseases in developing and emerging countries are HIV/Aids, diarrhoeal diseases, tuberculosis and malaria. These diseases alone cause millions of deaths every year, the vast majority in developing and emerging countries. Action is also required in the field of research: 90% of global research spending goes on diseases that mainly occur in industrialised nations.

Deaths worldwide caused in 2000 by infectious and parasitic diseases	
Disease	No. deaths (in thousands)
HIV/Aids	2'943
Diarrhoeal diseases	2'124
Tuberculosis	1'660
Malaria	1'080
Measles	777
Tetanus	309
Pertussis	296
Syphilis	197
Meningitis	156
Hepatitis	128
Sleeping sickness	50
Leishmaniasis	41
Chagas disease	21
Dengue fever	12
Schistosomiasis	11

Source: WHO

Who is responsible?

The fact that developing countries urgently require access to medicines is undisputed. The pharmaceutical industry can make a contribution by granting price reductions and conducting research, among other things. It is equally important for industrialised countries to make sufficient funds available<sup>4</sup>. The current situation of the Global Fund<sup>5</sup> shows that this is not yet the case. There are a number of requirements for effectively combating disease: a properly functioning healthcare system, transport infrastructure, safety, a minimum of bureaucracy and – last but not least – prevention in countries affected. This is mainly in the hands of the national governments of these countries.

Preferential pricing arrangements are becoming standard

There are basically several ways that a pharmaceutical company can facilitate access to drugs: Preferential pricing, donations<sup>6</sup>, a more flexible attitude towards patent rights and research into neglected diseases. Preferential pricing seems to

<sup>4</sup> In this context, a new form of financing is due to be employed by the International Finance Facility for Immunisation, which plans to issue bonds in order to finance immunisation and research programmes. These bonds will be covered by future payments from donor countries.

<sup>5</sup> The Global Fund is a financing organisation that collects primarily state funds for combating Aids, tuberculosis and malaria and distributes the money to individual projects.

<sup>6</sup> Donations of drugs should be made in accordance with the WHO Guidelines for Drug Donations.

have established itself as the most important measure. Medicines are now being offered to developing countries at heavily reduced prices, often at production cost. This now tends to be the case especially with first-generation antiretroviral drugs (antiretrovirals/ARVs)<sup>7</sup> or antimalarials. Prices have also been forced down by competition from generic products. In some cases the price of the drugs offered by the manufacturers of the original drug are lower than the price of generics. Where intermediaries are involved in the distribution chain in target countries, it is unfortunately impossible to ensure that the low price level is always passed on to customers – and not only in the case of Aids drugs.

Manufacturers of ARVs offering price discounts to developing countries	
• Abbott	• GlaxoSmithKline
• Aurobindo	• GPO
• BMS	• Hetero Drugs Ltd
• Boehringer- Ingelheim	• Merck & Co. Inc
• Cipla	• Ranbaxy
• Combino Pharm	• Roche
• Gilead	• Strides Arcolab Ltd

Source: MSF

With emerging countries, prices are usually negotiated with governments and are higher than for developing countries – often about double.

Patents are controversial

Patent rights are often cited as a serious obstacle to the supply of drugs to developing countries. Over 90% of products on the WHO Model List of Essential Medicines<sup>8</sup> are no longer protected by patent, however. But drugs for treating HIV/Aids are more heavily affected by patent protection, because many of the medicines are relatively young. The current industry consensus is that patents for relevant medicines should not be enforced in sub-Saharan Africa and in the least developed countries, as specified in the TRIPS Agreement<sup>9</sup> of the World Trade Organisation (WTO).

Some companies go further in the area of HIV/Aids, by voluntarily granting production licences. GSK, for example, has granted six licences for the production of antiretrovirals in African countries: five in South Africa and one in Kenya. GSK also checks whether the partners have the necessary production capacities and can ensure consistently high quality.

Governments can suspend patents

In the case of a national health emergency, the WTO TRIPS Agreement allows developing and emerging countries to grant a compulsory licence for medicines so that they can be produced in the country locally. The least developed countries do not even need to observe drug patents up to 2016. Drug companies lobbied against these rules before their introduction, because they feared that

<sup>7</sup> Antiretrovirals usually keep the HIV infection under control at least partially and temporarily, and prevent progression of the immune deficiency caused by HIV. Limiting factors are currently the side effects associated with the drugs and the development of resistance.

<sup>8</sup> A list compiled by the World Health Organization of the most important medicines (currently around 350) for treating the world's priority diseases. The selection is based on a number of criteria: The medicines should meet the requirements of the majority of the population and be available at all times, in sufficient quantities and in suitable preparations, as well as at affordable prices.

<sup>9</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights.



frequent use of the facility would undermine patent law and make research unattractive.<sup>10</sup>

Latin American countries apply pressure

In June this year a country threatened to issue a compulsory licence for the first time: if no agreement is reached on price cuts, Brazil plans to grant compulsory licences for Aids drugs. At the end of August Brazil also announced a collaboration with Argentina on the manufacture of Aids drugs. Declaration of a national health emergency and subsequently the suspension of patents would therefore be an option. Brazil has a very well developed Aids prevention and treatment programme. Patients are treated free of charge. The drug companies affected argue that these drugs are already being supplied to Brazil at very low prices (only in Africa are the prices lower), and point out that Brazil is after all the world's ninth biggest economy. This line of argument is understandable.

India is an important producer of Aids drugs

One important development has been the introduction of a new patent law in India in 2005 that complies with the WTO Agreement. Since India has so far repealed international patent law, it has become the world's biggest producer of generics.<sup>11</sup> These legal circumstances have also enabled Indian producers (in contrast to companies in industrialised nations) to manufacture fixed dose combinations, i.e. preparations containing three active ingredients developed by different companies, in just one tablet. This will be more difficult in future. In July 2005 Roche called for the industry to work more closely together to make active substances more compatible with one another.<sup>12</sup> Products developed before 1995 are not affected and those produced between 1995 and 2005 can continue to be copied in return for a licence fee payment. 50% of antiretrovirals used in developing countries are made in India. It is feared that the prices of new drugs would rise if there were no competition from generics. In India's case it has to be said that despite its generics production, treatment of its own Aids/HIV patients is inadequate. The funding provided by the government for prevention and care is low, and infection rates are high.

#### Administering drugs in Africa



Source: Getty Images

<sup>10</sup> David Reddy, head of Roche's HIV business, made the following comment: "It's important that the environment continues to foster and reward innovation ... Without research and development, there are no drugs. The generic industry is not the answer."

GSK's CEO, J.P. Garnier, commented: "For GSK, there is no going back. But a biotechnology company might be a bit shy when thinking about whether to go into HIV research, knowing it's a political hot potato."

<sup>11</sup> Other emerging countries with generic production capacities include Brazil, Thailand and China.

<sup>12</sup> The first project involving a fixed dose combination of patented substances was launched by Merck, Bristol-Myers Squibb and Gilead Sciences in 2004.



Drug companies have responded

One of the biggest criticisms of the pharmaceutical industry is that they took too long to respond to the health crisis in developing countries after pressure from NGOs was already very substantial and their reputations had been damaged. Companies must delegate responsibilities and set up procedures to ensure they are better equipped to anticipate and deal with such issues. According to our own analysis, and also to NGOs, an improvement in drug companies' social engagement in this area was apparent from 2003 onwards.

Access for developing countries to medicines and R&D for important infectious and parasitic diseases<sup>13</sup> (HIV/Aids and diseases of TDR categories 1 and 2<sup>14</sup> / Ranked by no. of deaths), 10 biggest drug companies (plus BMS)

	HIV/Aids	Tuberculosis	Malaria	Sleeping sickness	Leishmaniasis	Dengue	Schistosomiasis
J&J		R&D					
Pfizer	Access		R&D				
GSK	Access/R&D	R&D	Access/R&D		R&D		R&D
Novartis		Access/R&D	Access/R&D				R&D
sanofi-aventis	R&D	Access	Access/R&D	Access	Access/R&D		R&D
Roche	Access/R&D		Access				
AstraZeneca		R&D					
Abbott	Access/R&D						
Merck & Co	Access/R&D						
Eli Lilly		Access					
BMS	Access/R&D						

Source: Company information

The table shows which companies already provide access to existing medicines for the most prevalent infectious and parasitic diseases in developing countries through price reductions or donations, and/or conduct research into these diseases. When rating the company we assess the breadth of coverage, the relevance in terms of number of deaths and, in the case of access, the pricing mechanisms as well.

Access to medicines: It is possible to combat Aids, tuberculosis and malaria

All the companies studied that conduct research into and produce treatments for HIV/Aids make their drugs available at preferential prices. Although Pfizer has no antiretrovirals, it supplies its antimycotic Diflucan, to combat fungal infections caused by immune deficiency, free of charge to certain developing countries. Various drugs are also available to treat tuberculosis and malaria. Novartis has a good malaria drug: Coartem. Unfortunately in 2004 the company was unable to manufacture the quantities of Coartem agreed with the WHO. Such bottlenecks should be avoided in future. There is a drug available to treat schistosomiasis, and a generic version is used in some regions of the world. Work is under way to make the drug more widely available. According to the WHO, general action is still needed to address the problem of the availability of medicines for paediatric use. One disease that is not yet on the priority list for developing countries but whose incidence is rapidly increasing in these regions is diabetes. The Danish

<sup>13</sup> Explanation: The parasitic tropical disease leishmaniasis is transmitted by tiny flies. Dengue fever is caused by bites from mosquitoes with four different types of virus. Schistosomiasis (previously known as bilharziosis) is a worm disease transmitted via warm stagnant waters with snails acting as intermediate hosts.

<sup>14</sup> Classification system of the Special Programme for Research and Training in Tropical Diseases (TDR). Category 1: Emerging and uncontrolled diseases. Category 2: Control strategy available but disease burden persists. TDR coordinates and supports research into diseases prevalent in developing countries. The organisation was founded in 1975 by UNICEF, the United Nations Development Programme (UNDP), the World Bank and the WHO.

company Novo Nordisk, which specialises in this field, has a number of programmes to improve diabetes treatment in developing countries. In addition, the least developed countries are able to purchase insulin at heavily discounted prices. When it comes to access to medicines, the best companies are sanofi-aventis, GSK and Novartis. In general we consider the current regime – with preferential pricing for the most important Aids drugs, discounted or free medicines for other prevalent diseases and voluntary licensing in some cases – as a good basis for improving access to medicines in developing countries. In the long term it is also likely that the shortfall in drugs for treating diseases such as cancer, which have so far not been in the spotlight, will become an issue as well.<sup>15</sup>

R&D has got under way

Since 2000 there has been a substantial increase in research activities into neglected diseases, driven by a growing sense of social responsibility. At the moment there are some 60 research projects worldwide, with several targeting the same disease in some cases. 32 of these projects are being undertaken by pharmaceutical companies, and 16 of these in conjunction with state institutions (public-private partnerships). Most of the research activity is in tuberculosis, malaria and dengue fever. Here too, the same three companies take the lead. GSK and sanofi-aventis have the broadest range of research activities in these fields. In 2004 Novartis opened a research centre in Singapore that is exploring new treatments for dengue fever and tuberculosis.

People cannot afford drugs in the USA either

The US has around 45 million people with inadequate health insurance or no cover at all. This means they cannot afford the drugs they need. As a result, US senior citizen organisations in particular have exerted a lot of pressure on the pharmaceutical industry. In response, all the big drug companies have introduced price discount programmes for people on low incomes, partly as a pre-emptive move to prevent the government intervening to fix prices. Similar problems exist, for example, in Bulgaria, Lithuania and the Ukraine, due to widespread poverty and the structure of the health insurance system. In all these countries GSK offers discount programmes for low-income patients.

Business case

Credible commitment to improving access (though pricing and research) to medicines helps the industry to restore its tarnished reputation<sup>16</sup>. It also helps to protect the current patent system, because under the terms of the TRIPS Agreement countries that are short of medicines have the option, as explained earlier, of granting compulsory licences in the case of a public health emergency. By showing a commitment to emerging countries, companies can also position themselves as competent providers and partners in the medium and long-term, allowing them to participate more in up-and-coming markets. The cost of these activities is not very significant for the companies. Selling drugs at production cost in these countries does not cannibalise sales: after all, there would be no demand for the products if they were sold at market price. Spending on nonprofit-making research is tiny when compared to companies' total R&D budget. As already mentioned, access to medicines is also a social issue in

<sup>15</sup> In this context Rafael Bengoa, director of the WHO department "Management of Noncommunicable diseases" made the following comment: The struggle over Aids drugs will inevitably become a struggle over insulin and cancer drugs, too. While Aids and Sars hit headlines, he warns, "the invisible epidemics are killing more people than those".

<sup>16</sup> Paul Herrling, Head of Corporate Research at Novartis, had the following to say about research into commercially unattractive medicines for (third world) diseases: "Pharmaceutical companies tend to be very unpopular. If our social commitment helps to improve our public standing, it's certainly worth it."



industrialised countries, which is why drug companies have just launched a programme of price discounts in the US. Prices will remain under pressure as healthcare costs continue to rise.

## Ethical aspects of marketing

### High marketing expenditure

On average, pharmaceutical companies spend more than twice as much on marketing and administration as on research. This causes many critics to question the industry's sense of social responsibility. Furthermore, there are ethical and even legal problems associated with some of the marketing practices in the pharmaceutical industry. Shortcomings in this area have serious effects on the industry's reputation and on the regulatory pressure applied.

Spending on marketing and administration compared with R&D spending			
Company	Marketing and administration (USD billion)	Research and development (USD billion)	Ratio
Johnson & Johnson*	15.86	5.20	3.1
Abbott Labs	4.92	1.70	2.9
Bristol-Myers Squibb	6.43	2.50	2.6
GlaxoSmithKline	12.93	5.20	2.5
Novartis	10.41	4.21	2.5
Novo Nordisk	1.62	0.69	2.3
Pfizer	16.90	7.68	2.2
AstraZeneca	7.84	3.80	2.1
Merck	7.35	4.01	1.8
Hoffmann-La Roche	7.24	4.01	1.8
Eli Lilly	4.28	2.69	1.6
sanofi-aventis	5.59	9.26	0.6

Source: Company information

\* At 18%, a higher proportion of J&J's sales come from intensively marketed consumer products (body care and dental products) than is the case for other pharmaceutical companies.

### Doctors and patients targeted

Marketing and advertising spending on medicines is split between promotion of products to doctors and other medical personnel and advertising aimed at end users. For years, critics have complained that doctors are far too influenced by intensive marketing (visits by representatives, promotional events etc.) when they write prescriptions. In the USA, one and a half times as much is spent on advertising targeted at doctors as on public advertising. Consumer advertising of prescription drugs is only permitted in the USA (since 1997) and New Zealand. Over the past few years, expenditure on consumer advertising has increased significantly, and the pharmaceutical industry is now one of the widest users of television advertising. COX-2 preparations, which include Vioxx, are the most intensively advertised pharmaceutical products, alongside slimming and erectile dysfunction pills.

### Expensive gifts are no longer the order of the day

For a considerable time it was common practice for doctors in particular to receive what were in some cases lavish gifts from pharmaceutical representatives. Over the past few years, such practices have been the subject of ever closer scrutiny, and now the industry associations have introduced codes of practice (e.g. the EFPIA Code of Practice on the Promotion of Medicines), that regulate such matters in detail and can be described as strict. The promotion of what are known as "off-label uses" of medicines also causes problems and is under scrutiny by the US judiciary. The term "off-label" means that medicines are being marketed for fields of therapy for which they have not been approved. The US legislature allows doctors to prescribe drugs for any indication, but prohibits companies from promoting such use. Last year for example, Pfizer was fined USD 430 million because the company (or rather its predecessor Warner-

Lambert) had marketed the drug Neurontin for fields of therapy for which it was not approved.

Advertising with side effects

For years, critics have been pointing out that intensive marketing has caused too many people, including increasing numbers of young people, to obtain prescriptions for painkillers, for example. In the case of Vioxx, the associated risks have now become clear. As the plaintiffs in the first Vioxx damages case in July of this year emphasised, the advertising influenced consumers through misleading statements. Surveys have shown that the credibility of such advertising has now reached an all-time low.

Voluntary code of practice within the industry

The industry has reacted with the planned introduction at the beginning of 2006 of the Guiding Principles for direct-to-consumer advertising of prescription medicines by the US industry association PhRMA. By introducing these Guiding Principles, the industry is seeking to prevent legal guidelines being introduced to restrict advertising activity. Critics maintain that this voluntary code of practice does not go far enough, and in some respects simply replicates legal guidelines. In the meantime, the latest figures in relation to the consumer advertising of pharmaceuticals and various statements from representatives of the industry make it clear that advertising spending is now falling again.

Medicine prices highest in the USA

The past few years have seen a great deal more criticism about the high prices of medicines. Although the industry emphasises that medicines only account for around 10% of total health costs, they do represent the fastest growing cost area. In contrast to the situation in Europe and most other countries, the US Government scarcely intervenes in medicine pricing, resulting in high prices. As prices are lower in Canada, consumers have met their needs through Canadian online pharmacists or by simply crossing the border to buy their medicines. Pharmaceutical companies strongly resist parallel imports.

Investigations by the judiciary

The US Department of Justice is currently investigating 150 cases in which pharmaceutical companies, among others, are accused of having defrauded government health supply programmes by charging excessive prices, while granting wholesale distributors huge unpublished discounts. According to the Department of Justice, pharmaceutical companies by now represent the largest group appearing in the fraud cases, both in terms of their number and of the fines involved. In the past, the US pharmaceutical industry has paid huge fines and settlements for illegal marketing practices, amounting to USD 2.2 billion between 2000 and 2003. No other industry was forced to dig so deep into its pockets. As an example, AstraZeneca paid out USD 355 million on one settlement in 2003. The company was accused of having supplied doctors with free samples of the drug Zoladex, for which the doctors subsequently charged.

A topical example is the case brought by the California Attorney General against 39 pharmaceutical groups for inflated medicine prices. The defendants are accused of having defrauded the health insurance fund Medi-Cal (California's state health insurance fund for those on low income) to the tune of hundreds of millions of dollars over a period of years, by making false statements in relation to average wholesale prices, on which the refunds for medicines are based. Many medicines were allegedly supplied to doctors, pharmacists and hospitals at significantly lower prices. The Attorney General is seeking to reclaim hundreds of millions of dollars and also to impose fines of up to three times the amount of the actual loss on the defendants if they are found guilty. The accused companies include Amgen,



Aventis, Baxter, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck KGaA, Mylan, Novartis and Schering-Plough. Roche for example is not being sued. A total of 16 other federal states have already filed actions on the same grounds.

Results of clinical studies published

Clinical studies are an integral component of pharmaceutical research. The communication of (positive) results (also in relation to products that are already on the market) represents an important marketing tool. In 2004, a case was brought in the USA against GlaxoSmithKline for having allegedly suppressed negative results in relation to the side effects of antidepressants on young persons. GSK has declared itself willing to pay a settlement amount of USD 2.5 million, and has since then published all the results of clinical studies. In the meantime the industry associations have agreed on the (voluntary) publication of the results of clinical studies. It would appear that most companies will go along with this. In addition to GSK, Roche was also quick to offer access to a corresponding Web-based database. Critics are also seeking extensive reforms in the structure of the clinical studies.

Ethical marketing remains a challenge

Virtually all the companies analyzed by us have come under criticism, to differing degrees, for controversial marketing practices. Frequent legal disputes make this significant in both financial and reputational terms. In relative terms, Roche, Novo Nordisk, Eisai, Novartis and sanofi-aventis came out best. Roche for example does not focus on mass products, but on products such as cancer drugs, which differ significantly from other preparations in terms of their effect. This focus means that their marketing expenditure can be relatively low. Other companies have also announced their intention to invest more in research for innovative products with a specific focus. It remains to be seen how this strategy will be implemented.

## Environmental aspects of production

Over the past two decades, the industry has made significant progress in the areas of pollutant emissions and hazardous incidents, thanks to extensive outsourcing of the chemicals business and considerable improvements in the eco-efficiency of production processes.

Environmental impact comes mainly from emissions

According to AstraZeneca's environmental analysis of its own business activities, contributions towards the greenhouse effect and waste production have the greatest impact. An analysis of emissions by Roche has shown that the emissions emanating from energy consumption (NO<sub>x</sub>, SO<sub>2</sub> and CO<sub>2</sub>) and the emissions of volatile organic compounds (VOCs)<sup>17</sup> have the most serious impact on the environment. VOCs are used as solvents during production. Roche for example emitted 1,000 tonnes of VOCs in 2004.

High quality standards in production



Source: ©ImagePoint.biz

Transport and electricity consumption are the main contributors to the greenhouse effect

What are the principal generators of emissions? 20% of AstraZeneca's greenhouse gas emissions for example are accounted for by the combustion of fossil fuels during production, 22% come indirectly from electricity generation, 21% from business travel and transportation and, due to AstraZeneca's specific product range, 37% are generated by the propellants contained in inhalation products. The latter are also responsible for the emission of ozone-destroying substances. Their significance is however becoming less marked, as alternative propellants are increasingly being used. A life cycle analysis of the drug Exelon,

<sup>17</sup> VOCs react with nitrogen oxides under the effect of sunlight in the atmosphere close to the ground to form ozone (summer smog).

conducted by Novartis and focusing on energy consumption, has shown that transportation of the drug by air makes the greatest contribution towards the associated energy consumption. Roche's CO<sub>2</sub> emission account for 2004, which does not however include emissions from transporting products, confirms the significance of electricity consumption.

Roche 2004 CO <sub>2</sub> emissions (in 1000 tonnes)	
Natural gas	245
Oil	65
Coal	72
Waste	12
Electricity (and district heat)	483
Car fleet	52
Business travel (flights)	71
Sewage treatment	14
<b>Total</b>	<b>1,014</b>

Source: Roche

Environmental protection is firmly rooted within the companies

Most of the companies that we analysed have achieved a high to very high standard in the management of their environmental risks. Environmental, health and safety management systems are in place throughout most of the groups and detailed environmental data are recorded. Following significant reductions in the output of pollutants in the eighties and nineties, it has now become more difficult to achieve such sizeable reductions. However, further improvements in efficiency are possible. Since suppliers and contract manufacturers are such a feature of the industry, it is also important to require them to take responsibility for environmental protection. Most companies do have such procedures in place. There is a clear need for action to reduce the highly environmentally relevant effects of product transportation and the use of company vehicles and business travel, as described above.

New production methods bring environmental benefits

Further improvement of environmental performance may be possible through the broader use of biotechnology production methods<sup>18</sup>. The benefits of these methods were also confirmed in the Sarasin report "Will medicinal biotechnology sustain its promise?" which was published in 2004. The production of pharmaceutical substances with the aid of genetically modified plants is for the most part still in the research phase. We believe there are still a few unanswered questions in relation to acceptance by society (see GM foods) and environmental compatibility.

<sup>18</sup> Use of micro-organisms or cells of higher organisms as a basis for the industrial production of, for example, fine chemicals, enzymes, food additives and pharmaceutical ingredients.



## Pharmaceuticals in the environment

The active ingredients of pharmaceuticals enter the environment through production, seepage from household waste tips and bodily excretions, the latter being by far the most significant entry route. The desired mechanisms by which the medicines take effect within the body frequently mean that the active substances contained in medicines are often not metabolised or are only partly metabolised by the body. X-ray contrast media or cancer treatments, for example, are intended to have longer-lasting effects. As an example, in Germany around 31,000 tonnes of human therapeutic drugs and 2,500 tonnes of veterinary drugs are used every year. Over 2,700 ingredients are used in human therapeutic drugs. The acute toxicity of pharmaceuticals makes them some of the most extensively investigated materials, but there has been very little research on the effects of low but continuous exposure in terms of human toxicology and environmental toxicology.

Are medicines ingested whilst swimming?

In sewage treatment plants, most pharmaceuticals remain undegraded or are only partially degraded, but are not completely retained in the plant. A number of studies have shown that as a result, since the start of the nineties, evidence has been found of 100 active ingredients in surface water. These are most frequently painkillers, lipid reducers, anti-convulsive drugs, antibiotics and beta blockers. A survey conducted in Germany in 2003<sup>19</sup> found residues in surface water of 44 of the 89 pharmaceutical substances investigated. The Environment Agency (of England and Wales) also conducted a survey in 2003 and discovered pharmaceuticals in the aquatic environment.<sup>20</sup> The quantities of pharmaceutical substances carried in water courses are by now similar to those of plant protective agents.

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<sup>19</sup> National and Regional Committee for the Safety of Chemicals: Pharmaceuticals in the Environment – Evaluation of the survey results; Environmental Authority, Hamburg 2003

<sup>20</sup> Targeted Monitoring Programme for Pharmaceuticals in the Aquatic Environment, Environment Agency



Source: ©ImagePoint.biz

No problem (yet)

No relevant quantities of pharmaceuticals have so far been found in ground water or in the drinking water supply. The concentration of pharmaceuticals in surface water is well below the concentrations present during therapeutic application in the human body. However, in the case of hormones, antibiotics and cytostatic drugs, their specific effect may be assumed to give them relevant potential for endangering the environment. Initial changes, caused by hormones and hormonally active substances<sup>21</sup>, were seen in fish in the proximity of sewage treatment plant outflows, in that male rainbow trout began to produce precursor substances for egg yolk production. No further negative effects on water-based flora and fauna have been found to date. However, we still have inadequate knowledge about the environmental behaviour and ecotoxicology of pharmaceutical substances.

Licensing authorities lay down requirements

The question of whether comprehensive ecotoxicological aspects can be incorporated to a greater extent into the development of medicines is critical. Restricting the product benefit, in this case the effectiveness and tolerability of a medicine, raises problems. The licensing authorities have been laying down requirements for a number of years. An environmental assessment was integrated into the licensing procedure within the EU as early as 1993. This focuses on acute toxicity, and there are no plans to refuse to grant licences in the event of a potentially serious negative environmental impact. These guidelines are being revised, partly on the basis of the EU-financed research programme ERAPharm. The US licensing authority, the FDA, has required an environmental assessment since the late seventies.

Research by the pharmaceutical industry

Most pharmaceutical companies are merely researching this topic and emphasise that they do not at present anticipate any negative impact on humans or animals. GSK for example has however progressed somewhat further. In 2004, with the aid of Pharmaceutical Assessment and Transport Evaluation Models (PhATE) developed by the US industry association PhRMA, the

<sup>21</sup> Even some chemicals that are not used in pharmaceutical substances are hormonally active. These include for example bisphenol A, tributyl tin (in paint used on ships) and phthalates.



company undertook an environmental risk assessment on 40 active substances. PhATE is based on consumption data relating to these substances and on population distribution and hydrological models, thereby enabling estimation of concentrations in the environment.

Novartis has already screened its product range for ecotoxicological risks and has improved access to the associated data for product development purposes. Sanofi-aventis has conducted ecological life cycle analyses for its main products, with particular consideration to the possible effects of residues in the environment.

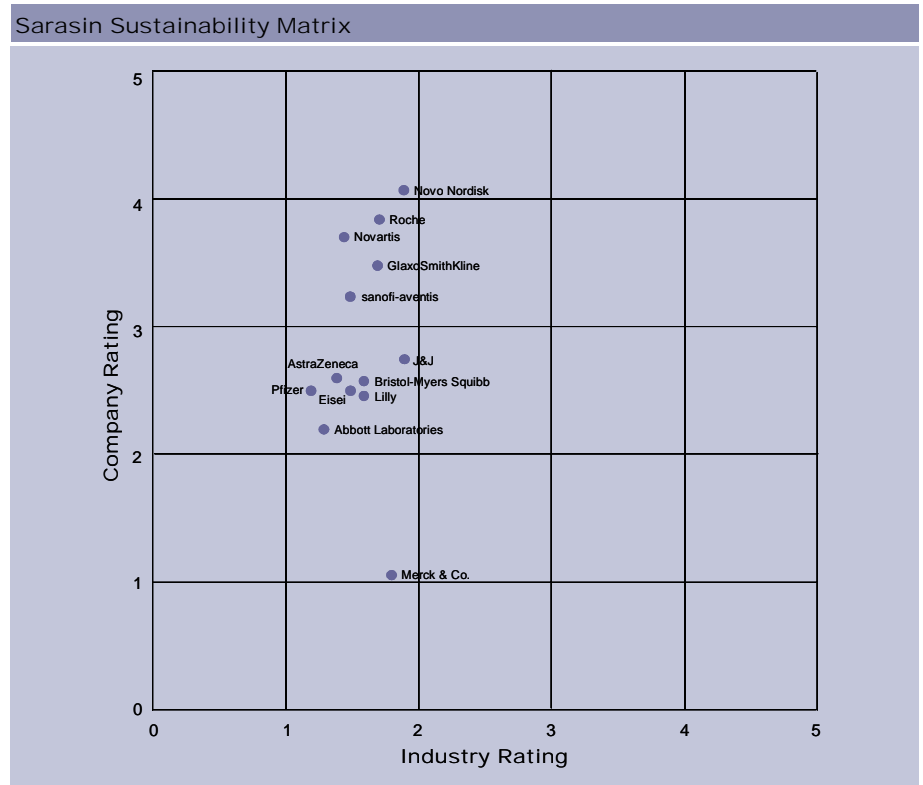
These problems do not affect pharmaceutical companies that specialise in natural herbal remedies and homeopathy. These include both the French listed companies Boiron and Arkopharma.

Risks for the industry?

Based on the present status of research, there would not appear to be serious environmental or health risks. However, any future evidence of pharmaceutical substances in groundwater and drinking water could trigger regulatory and legal consequences for the companies concerned. Technical advances are likely to make it possible to provide evidence of increasingly low concentrations, which will then beg the question of whether the pharmaceutical companies have done everything possible to develop environmentally friendly active ingredients. At all events, this topic remains distinct from problems such as tobacco and asbestos, due to the small environmental effects ascertained to date and the high social benefits of pharmaceutical products.

## Results of the company evaluation

The evaluation of the companies' environmental and social performance is based on a proprietary valuation methodology developed by Bank Sarasin. A detailed description of the methodology and its application to the pharmaceutical industry is provided in Appendix 1.



Source: Bank Sarasin

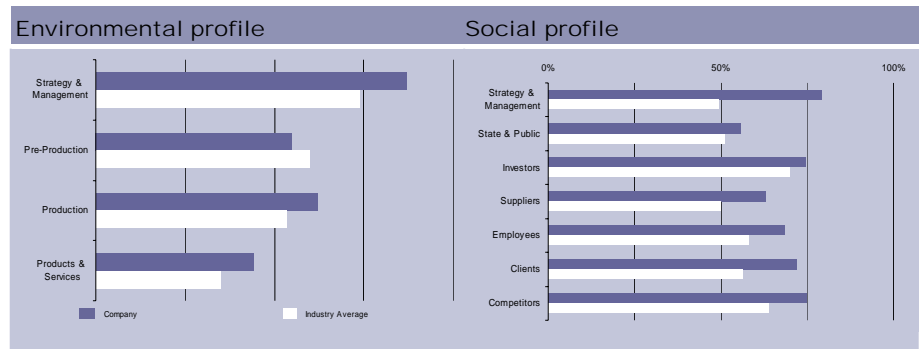
Europeans are leaders

European drug companies have the best sustainability profile. Novo Nordisk came top, with a “high” sustainability rating, followed by Novartis, Roche, GSK and sanofi-aventis with an “above average” rating. The US company Merck & Co. comes last, despite its commendable price discount programme for HIV/Aids drugs for developing and emerging countries. Negative factors include the product liability risks (Vioxx), controversial marketing practices in some cases and a disappointing score on the environmental front.

High standard of environmental protection

In general the pharmaceutical industry achieved a high standard of environmental protection on average. This is clear from the next figure, which shows the average of the pharmaceutical industry (on the environmental and social profile of Novartis). Management structures, reduction of emissions and resource consumption, as well as environmental requirements for suppliers and contract manufacturers, are all at a high level on average. “Products”, a criterion that has a relatively small weighting, mainly comprises the indicators research and measures for monitoring drug residues in the environment, as well as the production of herbal and homeopathic remedies. This is still a relatively new

criterion and big pharmaceutical companies hardly produce the type of products mentioned, which tends to keep the average low.



Source: Bank Sarasin

Positive...

In the social domain, there has been an improvement since around early 2004 in the level of access to products for developing and emerging countries, as already mentioned. Employment conditions in the companies are relevant, considering the “war for talents” in the industry, and reveal a high level compared with other sectors. The percentage of qualified staff is comparatively high and the pharmaceutical industry has continuously increased its headcount in the past few decades. However, some US companies have now started to cut jobs – especially on the sales front – following product recalls and depleted product pipelines. A wholesale relocation of production to low-wage countries is not so much an issue in the pharmaceutical industry as it is in the upstream chemicals business, for example. The level of corporate governance is good on average in the companies studied.

... and negative effects on social performance

Social ratings were often negatively affected by unethical marketing or competitive practices, as well as product liability issues. Social requirements for suppliers regarding workplace health and safety do exist for the most part, but little consideration is currently given to aspects that are particularly relevant to suppliers in emerging markets, such as hours of work, freedom of association, etc.

Opportunities for investors in sustainability

This report shows that it is possible for anyone guided by sustainability principles to invest in the pharmaceutical sector. The industry is exposed to significant environmental and social risks, but some companies have proven that it is possible to minimise these threats.

## Appendix 1

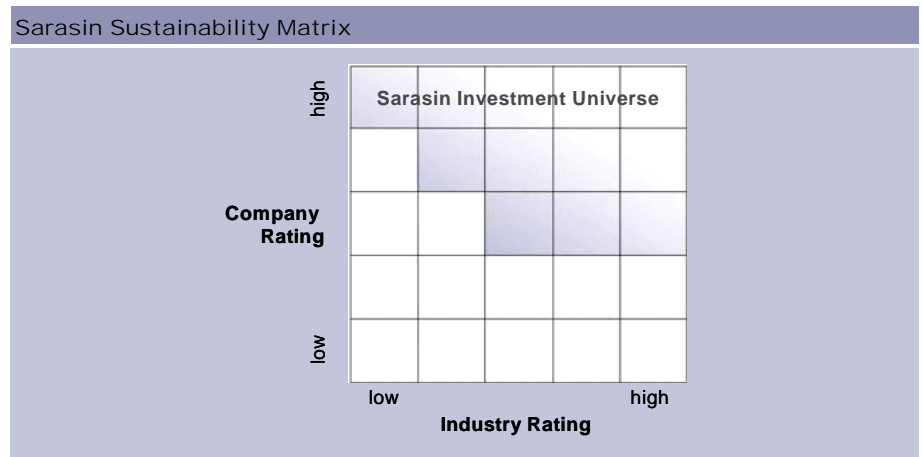
### Sustainability analysis methodology

Matrix combines industry and company rating

Our environmental and social analysis of companies is based on a proprietary valuation method developed by Bank Sarasin. It incorporates two dimensions which are combined in the Sarasin Sustainability Matrix®:

- ◆ **Industry rating:** Comparative assessment of industries using selected environmental and social criteria,
- ◆ **Company rating:** Comparative environmental and social analysis of companies within their industry.

Only the companies positioned in the Sarasin investment universe (shaded) qualify for Sarasin sustainability funds.



Source: Bank Sarasin

Main criteria for the industry rating

The industry rating is an aggregated assessment of the extent to which an industry creates environmental and social risks. We examine a total of four risk categories:

- Consumption of resources: Use of natural resources (especially fossil fuels and water)
- Emissions: emission of air pollutants and creation of waste
- Employment conditions: Influence on employment and work conditions (health & safety, salaries, employee rights)
- Other potential sources of social conflict: impacts on society as a whole, especially harmful and ethically controversial production methods and products, political lobbying and exercising of financial power, corruption and business ethics, activity in countries with low social standards (globalisation).

The industry risk exposure is derived from the characteristic product spectrum of an industry. We take the entire life cycle of products into account here, from the production of raw materials to the manufacture, use and eventual disposal of the product. Our industry rating focuses on the risks, as already explained. We do not take into account the positive contribution an industry makes to sustainable development (e.g. through its products).

Environmental and social risks of the pharmaceutical industry			
Criteria	Phase in the product life cycle		
	"Pre-Production"	Production	Product use
Consumption of resources	●	●	
Emissions	●	●●	
Work relations	●●	●	
Social potential of conflicts	●	●●	●

Source: Bank Sarasin

Overall industry rating

When it comes to environmental risks, the most relevant aspects are the emissions produced by energy consumption, emissions of VOCs and the solid and liquid waste produced. The relevant social risks are in the efficacy/tolerability of products, ethically controversial research methods (e.g. use of stem cells from embryos), access to products for the financially disadvantaged and business ethics. All in all, the sustainability rating of the pharmaceutical industry is "below average".

Main criteria for the company rating

When rating individual companies, we look at how they deal with sector-specific environmental and social risks and how they exploit the associated opportunities. The main criteria are identical for all industries. They are compared with the sector average in the company's environmental and social profile and then aggregated into an overall rating. The weighting of the main criteria and the selection of the subcriteria are industry-specific.

The next table contains an overview of the criteria and their weightings, as well as the most important indicators that underlie the criteria.

Sample criteria and weights for the environmental rating of pharmaceutical companies			
	Main criteria	Weight	Key indicators
<b>Environmental profile</b> <b>40%</b>	Strategy & Management	20%	Integration into business strategy and organisational structure, planning and control processes, quality of reporting
	Pre-production	25%	Environmental requirements for suppliers and contract manufacturers
	Production	45%	Reduction of energy consumption (production, transport, business travel) and air & water emissions, avoidance of hazardous substances and prevention of plant malfunction
	Products & Services	10%	Research into and measures to prevent drug residues in the environment, production of homeopathic and herbal remedies, more environmentally friendly packaging

Source: Bank Sarasin

Sample criteria and weights for the social rating of pharmaceutical companies			
	Main criteria	Weight	Key indicators
<b>Social profile</b> <b>60%</b>	Strategy & management	20%	Integration into business strategy and organisational structure, planning and control processes, quality of reporting
	Govt. & general public	30%	Developing countries' access to medicines, research into neglected diseases, lobbying
	Investors	5%	Composition of the board of directors, voting rights, quality of financial reporting
	Suppliers	5%	Requirements for working conditions, transparency of selection process
	Employees	10%	Health & safety, work/life balance, redundancies, training and professional development opportunities, employee surveys
	Clients	25%	Efficacy and safety of products, ethical marketing practices, production of generics
	Competitors	5%	Hostile takeovers, price fixing, patent disputes

Source: Bank Sarasin

Controversial activities

Certain business activities which are not deemed to be compatible with sustainable development (e.g. armaments, nuclear energy, tobacco, pornography) can lead to the exclusion of companies from the Sarasin sustainable investment universe. The Fund's Advisory Council makes this selection for our retail funds Sarasin Sustainable Equity and Sarasin OekoSar Portfolio. In the case of the pharmaceutical industry, we exclude reproductive cloning, therapeutic cloning and genetic modification of germ cells.

Information sources

The company rating is based on the company's own details, a worldwide press search and information from independent institutions. We do not use standardised questionnaires.

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## Publications

Covered Bonds	The Sustainability of Covered Bonds. Klaus Kämpf, July 2005
Country Sovereign Bonds	Emerging Country Sovereign Bonds: A Sustainable Investment? Michaela Collins, June 2005
Financial Institutions	The Sustainability of Public Financial Institutions. Klaus Kämpf, March 2005
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Performance	Share Performance and Sustainability – Does environmental and social performance have any influence on share performance? Eckhard Plinke et al., September 2002
Food	How sustainable is the food industry? A study of environmental and social performance in the food and beverage industry. Matthias Fawer/Christoph Butz/ Catrina Vaterlaus-Rieder, August 2001
Forestry	Are the founders of sustainability true to their roots? An overview of the forestry and paper industry. Christoph Butz/Catrina Vaterlaus-Rieder, July 2000

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