

## Pharmaceuticals and SRI

In this report we analyse the opportunities and risks apparent for pharmaceutical companies in addition to the 'non-financial' corporate social responsibility risks (SRI). We propose ways of valuing these factors in order to assess the companies most at risk.

### Key recommendations & forecasts

	Reuters	Year end	Recom	Price	Target price	EPS 1fcst	P/E 1fcst
AstraZeneca	AZN.L	Dec 2003	Add	£25.44	£27.00	1.83	25.91
GSK*	GSK.L	Dec 2003	Buy	£11.30	£15.20	0.82	13.74
Schering	SCHG.F	Dec 2003	Buy	€38.80	€50.00	2.52	15.43
Novo Nordisk	NVOB.CO	Dec 2003	Add	DKr274.00	DKr265.00	14.07	19.47
Novartis	NOVZn.VX	Dec 2003	Reduce	SFr56.75	SFr50.00	2.08	21.74
Roche Holdings	ROCZg.VX	Dec 2003	Add	SFr127.50	SFr120.00	4.60	27.71
Aventis	AVEP.PA	Dec 2003	Reduce	€61.10	€47.00	3.64	16.80
SASY	SASY.PA	Dec 2003	Hold	€56.00	€55.00	2.93	19.10

Source: ABN AMRO forecasts

### CSR is an issue that won't go away

The corporate social responsibility (CSR) imperative is one which, we believe, will increase in importance over time. Although an empirical link between CSR and stock performance will be almost impossible to measure, all other matters being equal, we believe companies that manage the business CSR risks better should outperform in the long run. Thus, looking at CSR could improve stock picking ability.

### Broad areas of risk and metrics

We see CSR risks as being grouped into five broad areas: corporate governance, ethics, socio-political considerations, environmental and manufacturing, and regulation and legal. We propose metrics to measure such risk, such as patent and litigation fine exposure, R&D innovation and reporting transparency.

### Conclusion

The overview of CSR is given with a view to socially responsible investment (SRI) but also for the 'non-financial risks' for any investment analyst. Pricing 'non-financial' risk is difficult. It may be beyond present valuation metrics to give it an exact quantifiable value. However, there are strong theoretical grounds for measuring these risks on a company-relative basis; in developing new metrics it will help to value the risks of a company relative to its peers. Furthermore, understanding CSR risk gives a deeper understanding of the company and the business threats it faces. We believe these types of risks warrant closer examination by analysts as it should lead to added value in investment decisions.

Disclosures and analyst certifications are at the end of the body of this research.

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### Europe

#### Sector performance

	(1M)	(3M)	(12M)
Absolute	-1.0	4.5	21.8
Absolute %	-1.2	5.5	33.8
Rel market %	-3.2	-4.5	3.8

Source: ABN AMRO

FTSE EUROTOP 300 INDEX: 1013.01

Europe Pharmaceuticals: 86.08

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This research was produced on the basis of an invitation from the Asset Management Working Group of the United Nations Environment Programme Finance Initiative (UNEP FI).

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# Pharmaceuticals and SRI

**In this report we give an overview of the challenges, opportunities and risks inherent in corporate social responsibility (CSR) vis a vis the large pharmaceutical companies.**

## Scope of report

In attempting to value CSR, this is given within a context of socially responsible investment (SRI) but also with regard to the 'non-financial risks' facing any investment analyst.

**We examine the risk of poor corporate responsibility**

## What's the point of looking at CSR and pharma?

There are broadly two good reasons for, in our view, looking at CSR:

- To improve stock picking ability and to make more money
- To contribute to a sustainable world

We believe both factors should make your life better! But can looking at CSR really help with making money? We believe it can. While the 'holy grail' of empirically linking CSR performance to financial or stock performance is something we believe is most likely to never be found (for a whole host of reasons discussed later), we believe good CSR minimises business risks. We argue that while many CSR risks are not easily quantifiable, they are certainly present, and managements that assess and minimise those risks are less at risk than those that do not. Managing these risks well could be taken as a proxy for good strategic management in general. What price you pay for that management and company is another question. Moreover, understanding these business risks should help analysts understand a company more fully.

**Managing CSR risks a proxy for good strategic management...**

**...good CSR minimises business risk**

## What does a pharma company do?

Taking a simple view, a pharmaceutical company:

- Researches, discovers and develops new drugs
- Then manufactures, sells and markets drugs under a patent

The current business model revolves around discovering drugs for commercial diseases, trying to commercialise them as quickly and efficiently as possible with the minimum amount of drop outs and then selling them under the protection of a patent for as long as possible.

## How to look at the CSR and non-financial risks

We see CSR risks as being grouped into five broad areas:

- Corporate governance
- Ethical considerations
- Socio-political considerations
- Environmental and manufacturing
- Regulation and legal

We examine the risks associated with each factor in more detail later on in this report. We go on to propose that if the risks are scored on a relative basis between companies, then better investment decisions can be made on a risk/return basis.

## Conclusion

Pricing 'non-financial risk' is difficult. It may be beyond our present valuation metrics to give it an exact quantifiable value. However, there are strong theoretical grounds for measuring these risks on a company-relative basis and this may help to value the risks of a company relative to its peers more accurately. We also suggest ways of developing those metrics.

Furthermore, understanding CSR risks gives a deeper understanding of the company and the business threats it faces. We believe these types of risks warrant closer examination by analysts and should lead to added value in investment decisions.

**Pricing 'non-financial risk' is difficult...**

**...may help to value the risks of a company relative to its peers more accurately**

**Understanding CSR risks gives a deeper understanding of the company and the business risks it faces**

# CSR risks

**We see CSR risks as grouped into five broad areas: corporate governance, ethics, socio-political considerations, environmental and manufacturing, regulation and legal.**

## Introduction

We give an overview of the challenges, breakthroughs and risks in corporate social responsibility (CSR) vis a vis the large pharmaceutical companies. We do not fully examine the biotech or healthcare subsectors, eg 'med tech', although many risks and drivers are shared between the subsectors.

The overview is given with a view to socially responsible investment (SRI) but also for the 'non-financial risks' for any investment analyst. We suggest what to look for in terms of CSR and the 'non-financial risks' and occasionally put a number on the value of such risks, but point out that by their very nature many of these risks are almost impossible to quantify accurately. We suggest scenario analysis as a possible method. This is because many of the risks are very small but carry the prospect of a catastrophic outcome. We try and suggest where companies are leading the way and in what respects. We try not to judge the companies on any metrics, as different people with diverse risk criteria will judge the companies differently, but we suggest metrics that can be explored and also highlight the limitations of this approach.

**We examine 'non-financial' risk and scenario analysis methods**

We see the CSR risks as grouped into five broad areas:

- Corporate governance
- Ethical considerations
- Socio-political considerations
- Environmental and manufacturing
- Regulation and legal

Obviously, these areas can influence each other. But, importantly they can influence how effectively a pharma company can research, produce and sell its drugs or how easily we can examine what exactly a company is doing and how it is representing its shareholders.

**We look at corporate governance, ethics, social, environmental and legal issues**

For example, in extremis, society may judge pharma companies to be too greedy. Social pressure forces governments to change the patent systems with regard to drugs. This leads to shorter patent life and less profitable companies.

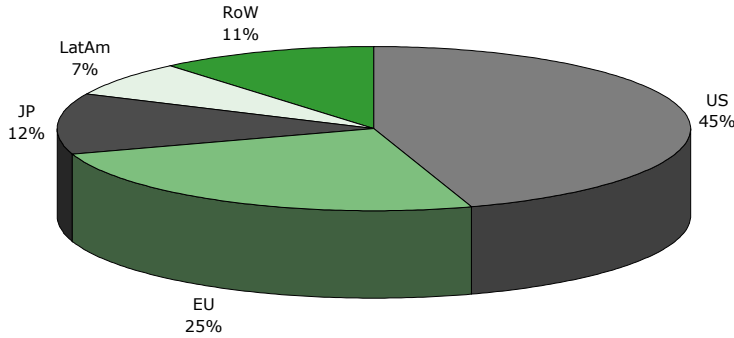
It is worth noting that presently, most observers and stakeholders see access to essential medicines as the most pressing issues facing pharma companies. However, we point out there are further risks to the industry. We shall examine these areas and how they affect pharma companies in more detail below.

**Access to medicines has been high on agenda but not the only CSR**

**Background**

For many years, the pharma industry was (and still is) immensely profitable. Today, the whole industry generates about +US\$400bn in sales annually (about 45% in US, 25% in Europe and 12% in Japan), growing at 6% pa and with EBIT margins of 25%.

**Chart 1 : Global sales split in 2003F at +US\$400bn**



Source: ABN AMRO forecasts, IMS health

However, some recent events have thrown the spotlight on the CSR risks of the industry, such as:

- Recent high-profile campaigns particularly by Oxfam and some of its peers over access to medicines in the developing world
- Controversy over negotiations on global patent treaties
- Concern over bias in research published in journals by scientists working for pharma companies
- Issues over executive pay
- Mis-marketing of drugs, and
- Manufacturing deficiencies.

Many campaigners point to the high sales and marketing spend of pharma companies at around 30–35% of sales compared with 12-18% of sales in R&D as evidence that pharma priorities are wrong (see Table 1). One could also point to the extremely high ROIC (+20%), which has been consistently high for the last 50 years, and margins (30% on EBITDA margins) a good 5–10% higher than consumer companies and 10–15% higher than retailers and auto companies, as evidence of the high profitability of the industry.

The payback for society is improved quality of life on many important metrics such as life expectancy but there is a growing minority that seems to be saying that the balance between profit and payback might be swinging too far in the pharma companies' favour. Some of the developments have been:

- Campaigns for access to medicines in the developing world
- Efforts by governments in middle income countries such as Brazil to negotiate lower prices
- Efforts by governments in Europe to regulate prices and profits
- Certain US politicians railing against the high cost of healthcare

**Recent events have thrust the spotlight onto the CSR risks of the industry**

**Table 1 : Industry P&L**

	As % of sales
COGS	12
SG&A	36
R&D	16
EBIT margin	26
Net profit margin	20

Source: ABN AMRO forecasts

This dissent ranges from the Oxfam-type campaigns in the developing world to Republican politicians in the US lobbying against the rising cost of healthcare.

In this context, we examine the key issues facing the pharma industry from a CSR perspective.

## Corporate governance

The risks and issues we see here are:

- Voting and shareholder structure
- Board structure – non-executive representation and any CSR representative
- Accounting clarity, eg stock options, pension funding, off balance sheet finance
- Political lobbying positions
- Executive pay
- Stakeholder engagement
- Sustainability policy, management structure
- Whistle-blowing procedure

Many of these issues are pertinent to all companies and corporate governance specialists can no doubt list many other issues (indeed see the appendix for ratings given by GovernanceMetrics International). However, these are issues that we believe may possibly upset investors in pharma companies.

## Voting rights and shareholder structure

Examples of notable large shareholdings or differentially classed shares in Europe include:

- Roche voting vs non-voting shares
- Novartis' stake in Roche
- Capital group stake in AstraZeneca
- L'Oreal and Total's stake in Sanofi-Synthelabo
- Family holding in Altana
- Structure of Merck Kgaa
- Bertorelli family holding in Serono
- Novo foundation stake in Novo Nordisk

Potential problems for investors include appointing new management and the formulation of new merger and acquisition strategies.

A problem might arise when one group of influential shareholders might not be acting in the best interests of the general shareholders at large.

## Board structure

The issues here will be broadly the same as for any large public company. We note that there has been a lot of noise recently about having enough non-executive representation and if that representation on the board fits the shareholder base. For

Several voting structure issues

instance, in the past, there have been certain questions raised about whether Shire had enough non-US representation on its board.

There is also the question of whether there should be anyone with overall responsibility for CSR on the board. In general, we think this is a good idea, however, the greater challenge is to filter CSR ideals throughout the whole company and if this can be achieved without someone at board level having overall responsibility, then that would probably be adequate.

## Accounting clarity

The more clarity the better! Issues in the standard accounts that we have found or that we think might cause controversy in the future for pharma companies include:

- Stock-option expensing
- Off-balance sheet finance (R&D vehicles and accounts receivable securitisation)
- Pension funding

We believe investors will want to see more accounting for more environmental and social factors. Accounting for the so-called triple bottom line. Out of the European pharma companies, Novo Nordisk is a leader in this type of accounting.

## Stock-option expensing

The question here is whether or not to expense the options through the P&L in the year that they are granted. The argument goes that this is equivalent to a salary cost to companies and should be expensed as such. Some companies, such as Coca-Cola and HSBC have already moved to this form of accounting. Perhaps partly in anticipation of mandatory accounting changes.

However, this form tends to depress the EPS of 'new economy' companies more than 'old economy' companies, as new economy companies tend to pay their employees with more stock options than old economy companies.

In this respect, biotech companies are more at risk than large pharma companies. However, even with large pharma companies there is still quite large variation. See Table 2, for an analysis of Aventis.

**Table 2: Impact on Aventis from stock option accounting**

	2002	2001
Net income (reported, €m)	2091	1505
EPS (diluted, reported)	2.61	1.89
Compensation cost net of tax using fair value (€m)	270	204
Pro forma net income (€m)	1821	1301
Pro forma EPS	2.28	1.63
Impact	-15%	-14%

*Source: Aventis 20-Fs; Aventis uses Black Scholes, 5 years life, 38.5% vol; 1.54% divi yield, 3.75% risk free rate.*

We see a 15% impact on 2002 EPS for Aventis, whereas GlaxoSmithKline (GSK) would only see a 3% impact.

The risk here is that if companies do not flag up what the EPS impact would be and how they are handling it, if accounting changes happen, the market might punish those with higher impacts on EPS.

Finally, if one believes that equity value is the discounted cash flow for all future cash flows, then stock option accounting makes no difference, as it is non-cash.

**Accounting issues including stock-option accounting and underfunded pensions**

**Debate on how to account for options**

## Off-balance sheet financing

Off-balance sheet financing is not usually an issue with pharma companies. However, there have been certain incidents over the years that we believe are worth noting.

One of the biggest episodes involved Elan and how it accounted for its R&D vehicles. Now, technically, Elan might have accounted for them correctly but the lack of clarity and the subsequent accounting problems it had cost the company dearly. Had investors had a clear picture to begin with, some of the problems might have been avoided.

The other aspect to note, is what is happening with accounts receivable. Again, it is perfectly, technically, correct to account for any securitisation of accounts receivable with notes to the accounts, but if the size and scale of it is large then it should be something investors should look at and possibly consider restating back on to the balance sheet.

## Pension funding

The state of pension funding, with new accounting rules in the UK, has also been an issue. Here we would look to companies that have large unfunded pensions to start to fund them. Aventis and Schering (which have a German legacy) are good examples and in fact both have recently started to fund their pensions.

**Underfunded pensions and return assumptions an issue**

To take Aventis as another example, it had €3.5bn unfunded in 2002 and will pay at least €1.5bn in 2003 to start to fund that gap.

**Table 3 : Pension obligations for Aventis**

€m at 31 Dec	2002	2001
<b>French companies</b>		
Accumulated benefit obligation	658	707
Projected benefit obligation (PBO)	739	814
Plan assets at fair value	51	63
PBO - Fair value	688	751
<b>German companies</b>		
Accumulated benefit obligation	2329	2481
Projected benefit obligation	2355	2517
Plan assets at fair value	170	0
PBO - Fair value	2185	2517
<b>Other foreign companies</b>		
Accumulated benefit obligation	2269	1417
Projected benefit obligation	2446	1517
Plan assets at fair value	1807	1076
PBO - Fair value	639	441
<b>Total underfunding</b>	<b>3512</b>	<b>3709</b>
<b>Under funding % pre-tax profit</b>	<b>101%</b>	<b>126%</b>
GSK Under funding % pre-tax profit	19%	7%

Source: ABN AMRO, Aventis 20-Fs

The risk here is that pension obligations are due when there is insufficient funding in place and so the cash has to come from the business or somewhere else, producing a drag on business performance.

## Global reporting initiative (GRI)

In terms of reporting on social, environmental and ethical issues, the GRI is looked at as one of the best available models. Novo Nordisk, Novartis, Johnson & Johnson, Bristol-Myers Squibb and, to some extent, Aventis are all applying GRI guidelines in their reporting.

**Initiatives to report on social and environmental factors**

However, a pharmaceutical-specific GRI framework has yet to be developed. We eventually see this or some other common framework being developed and companies that are ahead of the curve on this could benefit.

One issue that companies have raised is that so far many of the parameters selected under GRI are not very meaningful in the context of pharma. Companies are likely to remain skeptical if the parameters are not useful, but we would hope that certain sector-specific ones could be developed to make relative comparisons between pharma companies helpful.

### Political lobbying positions

Political lobbying is important, as this is where companies can influence governments most and also where matters are perceived to be most opaque at the moment. There is further discussion of this in the sociopolitical section.

**Political lobbying is important, as this is where companies can influence governments most**

If we split responsibilities into governmental ones and company ones, then many public health issues fall outside of a company's responsibilities (eg building health infrastructure, patent legislation and health education). However, companies can lobby very strongly to influence the government. Recent lobbying would probably include negotiations on global patent treaties (TRIPS negotiations, see later), however the exact position of pharma companies is often perceived to be unclear, usually due to the complex nature of the negotiations.

Lobbying could be a way of turning possible PR negatives into positives. For instance, rather than complain that there is no point providing cheap drugs to Africa because there is no distribution, or in the case of South Africa no willingness to distribute, if companies could lobby (or be seen to lobby) governments to build distribution or to provide more health education rather than, for instance, arms spending, this would show the companies in a far more flattering light.

**It could be a way of turning possible PR negatives into positives**

If companies could be seen to be lobbying for these issues and transparency is evident in key lobbying positions, then the PR and companies' reputations should be enhanced, which could (or maybe should) lead to easier negotiations with governments when it comes to regulation and pricing. Seeing what exactly companies want from governments and key public organisations would help the investor to minimise risk and give insight into what issues could be problems for companies.

Companies would point out that it's not possible to lobby without disclosing ones position. They would argue that the industry has been transparent about its position on TRIPS, but that perhaps the problem has been more that people either don't like the position, or don't understand it. For example, the recent negotiations concerning TRIPS and local manufacture related to one part of one clause (31f) of an agreement of 72 clauses, 36 pages long. It can be very difficult to get simple messages over on this level of detail when the question is a simply put: "What's your position on TRIPS?"

**Companies would point out that it's not possible to lobby without disclosing ones position**

Companies would claim they do lobby on issues beyond simply the use of products, such as education and building infrastructure. However, no government wants to be seen to be responding to pressure from a company or sector, and from the companies' point of view, blowing their own trumpets about how successful they've been in influencing a government could undermine any future efforts and be counterproductive.

### Other governance issues

- Executive pay
- Stakeholder engagement
- Sustainability policy, management structure
- Whistle-blowing procedure.

Executive pay is not an easy issue. On the one hand, one needs to reward executives enough so that they run the company to the best of their abilities but not so that they run the company for themselves rather than shareholders.

There is also a widening gap between European pay and US pay deals, with US pay deals being much larger.

Two points we would highlight: EPS is a very easy metric to manipulate, it should not be the only metric looked at and a suitable peer group should be established, probably amongst similar companies. Total shareholder return (TSR) has been a popular metric recently, but again should probably not be the only metric used.

On the other issues, needless to say, a good policy on stakeholder engagement, sustainability, management structure and whistle blowing should be in force.

### Risks and conclusion

Many of these issues are faced by all companies not just pharma ones. Perhaps, political lobbying is the issue that is perceived to lack the greatest transparency at the moment and from which pharma companies could create some value. Better accounting for social and environmental factors will be a trend that we should see continuing. However, quantifying many corporate governance risks seems very difficult at this stage.

The risks here are mainly due to transparency and are difficult if not impossible to quantify. Qualitatively, we can suggest that better transparency and increased reporting leads to less risk. Better transparency reduces risks for investors in two ways. First, investors are in a better position to judge the risks for themselves or in other words, investors have less information risk. Secondly, it is likely that a company which reports on a subject with a great deal of transparency is not doing something that would be negative for investors. We can conclude that better transparency reduces risk but how much less risk seems an impossible question to answer.

**The risks here are mainly due to transparency and are difficult if not impossible to quantify...**

**...but we can conclude that better transparency reduces risk**

## Ethics

We believe the following pharma-specific issues might be of interest to investors from a CSR perspective:

- Animal testing
- Human clinical research practice
- Stem cell research
- Manipulation of genetic material
- Contraception (for investors with certain religious constrictions)

Here, we would like to see companies managing the risks involved. There is a risk that if companies manage these issues badly the 'license to innovate and experiment' will be hampered, leading to less invention and less profit.

**We discuss pharma specific issues - not the general issues such as human rights and supply chains**

**Animal testing and stem cell research are possible concerns**

### General guidelines

Companies should be transparent about any ethical issues they face. They should publish position papers and reports to let stakeholders know how they are dealing the issues. Engaging stakeholders in the debate and ensuring good governance procedures, possibly augmented by an ethics committee, would also be a positive.

**Position papers would be useful**

This should reduce the risk from any major misinformation problems and increased transparency should allay any fears that companies have anything to hide.

### The concerns to raise on each ethical area

Is there a report on:

- The extent of involvement and possible future involvement in the area?
- How is exposure monitored?
- How is best practice applied?

### Animal testing

It would be good to see a statement on reduce, refine and replace principles, and where possible reporting on goals reached. It should be understood that due to certain activist groups some reporting and open discussion might not be possible.

**Reduce, refine and replace principles are important to see**

### Human clinical research practice

Clear guidelines need to be adopted and overseen. The WHO guidelines for Good Clinical Practice are PhRMA's 'Principles on conduct of clinical trials and communications of clinical trial results' - two fairly well accepted sets of guidelines.

Recent issues have been:

- Being allowed to continue on a drug if a patient has tested it, even if the patient cannot then afford it (eg Novartis have been caught out on this one, with access to Glivec [leukemia] denied from a trial patient in Korea, leading to some negative publicity despite making great efforts to ensure access to Glivec for those who can't afford it)
- Ensuring patients and their legal guardians know what the trials involve (Pfizer has been caught out on this issue with drug trials in African children, where the

parents did not seem to be fully aware of the implications) particularly for trials in developing countries

- Switching patients onto a drug from a placebo/comparisons arm when it is proven to be much more useful than a placebo or comparator drug is generally overseen by an ethics committee
- Reporting on negative clinical trial results. Making sure such reporting occurs in a timely and helpful manner. There have been accusations that pharma companies 'hide' negative results

Failure to follow regulations can lead to fines.

## Stem cell research

There is a lot of background science to this subject, which we only summarise here. Please contact the authors for further detailed information.

There are three main types of stem cell and it is important to distinguish between them. They are:

- Adult
- Embryonic
- Foetal

Human stem cell research has caused some controversy. Research into adult stem cells is generally supported, eg by the American Heart Association (AHA), and not considered so controversial.

Research into embryonic and foetal stem cells is more controversial, eg is not funded by the AHA, because embryonic and foetal stem cells are pluripotent, ie they can transform into any type of cell and reproduce indefinitely. Adult stem cells are more limited in that they are only multi-potent (eg an adult skin stem cell can only ever be skin, it cannot be transformed into heart cells).

A company engaged (or intending to perhaps engage) pluripotent stem cell research should have very clear and well argued position papers as to why it is investigating these areas (eg the GSK position paper). Large pharma companies are generally not engaged in pluripotent stem cell research at this time.

## Manipulation of genetic material

This area includes:

- Transgenic animals
- Xenotransplantation

The issue is whether the scientific and social benefits of this type of research outweigh the risks. For instance, transgenic animals (a genetically altered animal) not only provides important medical insights but can also reduce the amount of animals used in research, particularly dogs and primates.

Arguments against transgenic animals include that the potential risks of transgenics to animals, humans and the environment are too great to justify their use and that transgenic animals suffer more abnormalities than regular research animals.

Transgenic animals are being developed by some companies to provide new organs for transplantation, such as kidneys, livers and hearts, this is xenotransplantation.

**Important to distinguish the different types of stem cell**

**Adult stem cells are the least controversial as they cannot transform into any type of cell**

**Embryonic and foetal stem cell research is more controversial as these cells can transform into any type of cell**

**Researching genetic modification can be controversial...**

Transgenic pigs with human histo-compatibility genes have been bred in the hope that their 'humanised' organs will not be rejected by a patient's immune system.

Most large pharma companies are involved with transgenic animals but not with xenotransplantation. In general, there is more concern over xenotransplantation than over general transgenic animal use.

Genetic manipulation can also be at the cell culture level, as well as at the organ and animal level.

Again, we suggest that companies have very clear position papers as to what they are involved in and why. This is a way in which a company can minimise its risk. A company could even afford to promote the benefits of this type of research if it wanted to be considered pro-active on the PR and reputation debates.

**...position papers would be useful**

### **Risks and conclusion**

We believe companies need to keep pushing the boundaries of science. However, science is advancing at a very fast rate. In our opinion, biological advances are occurring now at a faster rate than ever before. However, the ethical debate and particularly the ethical debate involving the general lay person is in danger of not keeping up.

**The ethical debate involving the general lay person is in danger of not keeping up**

The companies that do their best to keep the public informed and to engage stakeholders in the innovative science they are performing are best placed not to stumble at the hurdle of restrictive regulation or bad PR.

The risks here seem to be potentially explosive and should be minimised with the aforementioned steps. However, measuring the value added is again very difficult. It is virtually impossible to give a financial value to these risks with any certainty.

## Environmental and manufacturing

Many of the environmental risks are the same as those faced by many companies, such as:

- Raw material, water and energy consumption minimisation
- Pollution and waste control
- Transport and distribution effects
- Climate change

The arguments for efficient control of pollution and resource use are as applicable to pharma as they are to any company. However, until better risk metrics or pollution pricing markets evolve, it will remain difficult for us to price these types of environmental risks.

**Arguments for efficient control of pollution and resource use are as applicable to pharma as to any company**

Qualitatively one can say the better environmental, health and safety watch mechanisms and controls over and above the statutory ones, the less likely disasters with financial implications or litigation will occur. However, quite how to judge these control measures or how to price this risk is some way from being developed.

There are some factors that are more pharma-specific, such as:

- Biodiversity and biopiracy issues
- Product stewardship and disposal
- Drug manufacture and good manufacturing protocol (GMP)

Out of the non-pharma-specific risks, we mention climate change as potentially interesting. GMP risks for pharma are, in our view, one of the largest in this area.

**Biodiversity and biopiracy issues, product stewardship and GMP are all pharma-specific issues**

### Climate change

There are three broad affects on health that climate change can bring:

- Those caused by weather extremes
- Those caused by environmental and ecological change
- The consequence of displaced (and demoralised) peoples in the wake of climate change

Out of these broad categories we highlight the following as areas most likely to be in the realm of pharma companies:

- Water and food-borne diseases
- Vector and rodent-borne diseases

However, the assumptions and models that might predict what would happen to, for instance, malaria infection patterns are not advanced enough to give us detailed insights. The best estimates suggest that diarrhoeal and mosquito diseases would increase. We believe this is an area worth watching for future developments.

**Climate change could also have an impact**

### Biodiversity and biopiracy

Companies should not want to destroy any biodiversity, not only because it would look bad but also because it would deplete a resource that may well turn out to be

very profitable for them. Pharma companies are generally signed up to appropriate biodiversity policies, so we do not view this area as a risk to the pharma industry.

Biopiracy is also unlikely to be a problem for the industry. In general, companies are signed up to appropriate policies. Furthermore, if a drug developed from a unique natural source was successful, giving away some royalties would not have an adverse financial effect compared with the upside gain from developing a successful drug. We also view the biopiracy issue as low risk for pharmaceutical companies.

**Biodiversity and biopiracy probably not going to be a major problem**

### Product stewardship and disposal

The potential risk on product disposal is waste in product manufacture and water from unused products, as historically, people used to simply flush old or unused medicines down the toilet. This is now acknowledged as being less than ideal as it allows potentially active pharmaceutical products into the water system.

However, waste disposal systems and instructions to patients have improved and we do not view this as a risk. It is worth noting that active compound detection systems have improved such that, years ago, we could not detect, for example, levels of hormones in the water supply as machines were not sensitive enough. However, sensitivity is now much better and has allowed companies to be more thorough in their detection and control.

**Detection of waste material has improved**

### Good Manufacturing Protocol (GMP)

We consider breaches of GMP as potentially high risk for pharma companies. This has been demonstrated recently as Schering-Plough, Bayer and Lilly have had problems with the GMP and the FDA has imposed restrictions that have had significant financial impacts, leading to a negative share price impact.

**GMP breaches could have material impacts on pharma companies**

Schering Plough lowered its earnings estimates in 2002 after agreeing to a US\$500m consent degree (or basically a fine) with the FDA to resolve GMP issues in its New Jersey and Puerto Rico plants.

The FDA reported GMP deficiencies in 2001 and the restrictions the FDA enforced led to a negative impact for Schering-Plough until the consent degree and also arguably afterwards.

Bayer had problems with its plant where Kogenate (blood protein) was produced, which also led to loss of sales. Lilly had GMP deficiencies that led to a delay in the roll out of a new product (Xigris (sepsis), for several months).

**GMP deficiencies can lead to fines, delays of new product approvals and the halting of product supply**

In our view, GMP risks are one of clearer cut and higher risk elements of the pharmaceutical industry.

### How to measure GMP risks

This is extremely difficult to forecast going forward. We certainly know they exist and we might be able to have a 'qualitative feel' for the risk, but we believe a forecast going forward is almost impossible.

One way we could pick up a hint of the risk exposure is to track FDA warning letters, which can be found in the public domain. If the matters raised on these letters are not addressed, then a Form FDA-483 can be issued which takes the matter to a more serious level and might have a financial impact.

## INVESTMENT VIEW

However, forecasting whether the issues on a warning letter will be addressed adequately is almost impossible and every year most pharma companies will have a warning letter that pertains to some aspect of its operations.

Another way to look at it is to look at historical warning letters and score the severity and number that a company has in any year and use that as a proxy for risk. This method will not accurately capture risk in the future but might be a reasonable first estimate. The likely error in this method is that companies that have been severely stung once will probably (or rather should probably) upgrade their systems so that it doesn't happen again.

### Risks and conclusion

Many of the risks in this area are sustained risks that could have an explosive impact if not managed carefully but are in general quite small. The one risk to monitor more carefully, in our view, is GMP risks. However, forecasting GMP risk is very prone to error and extremely difficult to do accurately but we do suggest two methods (highlighted above) focusing on what actions the regulatory authorities (particularly the US FDA) have taken.

**Number of GMP deficiencies can be scored to estimate GMP risk**

**Environmental risk more explosive than sustained**

## Regulation and legal risk

Regulation risk is a big factor for pharma companies. However, it tends to affect the industry as a whole rather than individual companies and varies in each geographic region.

**Regulation risk tends to affect the whole industry**

Legal risk comes mainly in the form of litigation, either on patents or from some form of negligence. In this respect it overlaps with environmental (eg fines for pollution), manufacturing and business ethics (eg mis-marketing or anti-competitiveness) risks.

**Legal risk is mainly in the form of litigation, either on patents or from some form of negligence**

We provide an overview of some these risks.

### Regulators and government – innovation the key

There is some overlap between what the government controls and what regulators control. However, we separate them out in this report and analyse the situation from the perspective of the government under the socio-political section.

The three main regions for regulation are the US (FDA), Europe (EMA) and Japan. These regulators control what is allowed on to their markets, whether drugs should be recalled and the quality of those drugs (hence the overlap with manufacturing and environmental risk).

Aside from fines and restrictions due to GMP deficiencies, some of the main risks are:

- Non-approval of a drug
- Recall of a drug
- Delay of a drug's launch

The non-approval of a drug can be a significant blow for a company and for smaller companies can lead to most of its value being de-rated.

We can assess this probability by looking at clinical trial data and the likely data package going to the regulators. The standard probability of success is between 85% and 95%. However, there are cases when we can forecast a lower degree of success.

Regulators (and analysts!) look for a good balance on efficacy vs safety. Innovation is also key (and as we see later on with pricing pressure from governments, it is also key there), as drugs showing great innovation can be granted a priority review and pass by the regulators quicker. They can be also awarded orphan drug status, which is similar to additional patent protection.

**Good risk/reward profile crucial**

One risk we see developing here is on sufficient safety data, particularly for so-called 'me-too drugs'. These are drugs that do not show significantly better efficacy or safety than those currently on the market. We believe the regulators are increasingly slow to approve these drugs and are waiting to be absolutely sure of their safety before passing them.

One argument has been that 'me-too drugs' are less risky to bring to market than drugs that are new in class. This is because many of the class effects of the drug have already been studied and to some extent validated. There is also an argument that there is less commercial risk as the market for the 'me-too drugs' has also been developed somewhat .

However, the regulatory risk of delay seems to be getting higher with these types of drugs, for the previously mentioned reasons. All of the last 10 drugs that went to the regulators with a novel mode of action have made it to the market compared with only about 85% for those with an established mode of action.

If you examine the average approval times for new drugs at the FDA, they have increased from 1999. The number of priority reviews has also fallen between 1999 and 2002.

**Table 4 : FDA approval times**

	1999	2000	2001	2002	2003F
Priority reviews	19	9	7	6	9
Standard reviews	16	18	17	10	11
Total NME approved	35	27	24	17	20
Average approval time	12	16	19	23	18

*Note: Approval time is calculated from first submission not from last re-submission  
Source: FDA*

The situation at the FDA is something of a reflection of the pressures on the industry. Fewer NMES have been submitted, hence fewer approvals. An increase of 'me-too drugs', or perhaps an increase in the efficacy/safety hurdles from the FDA, has led to increasing delays (often via multiple approvable letters rather than full approvals).

The stance of the regulators towards the industry often seems to depend on many factors, ranging from the political implications to the type of innovation being done.

**Measuring the risk**

There are ways of getting an estimate of the risk involved. One can look at the current average rejection rate of the FDA or other regulator and then at the available data vs other drugs to assess whether it is more or less likely to receive approval or a delay. One can calculate that by therapy area, for instance, there is evidence that cardiovascular drugs are generally more successful than nervous system drugs.

One could develop this into an approximate NPV by taking the risk and potential future values and applying an appropriate discount rate.

However, generally, on a relative basis, a drug or project is simply assigned a more qualitative risk, eg more or less likely for a delay or non-approval by the FDA.

**Litigation risk**

Litigation is costly in legal fees and potentially more costly in damages or lost patents. Here we highlight some areas that have been costly for companies but note it is often the result of negligence in other areas of the business that culminates in litigation risk:

- Environment/manufacturing
- Competition
- Marketing ethics
- Drug safety issues
- Patents

The risks are mainly covered in more detail elsewhere in this note, however, we provide a summary here.

**Table 5 : Average pipeline risk**

Phase	Probability to market
Pre-clinical	<1%
Phase I	10%
Phase IIa	20%
Phase IIb	40%
Phase III	70%
Submission	90%

*Source: ABN AMRO forecasts*

**Litigation is costly in fees and also in possible fines**

## INVESTMENT VIEW

Most pharma companies have some ongoing environmental litigation. Many also have ongoing investigations into anti-competition issues or drug marketing issues. Almost every pharma company has some current patent litigation and is probably the highest (and most variable) extra-financial risk most analysts examine.

Occasionally a drug safety issue will occur, for example and most recently Bayer with Baycol (anti-cholesterol) where the drug was withdrawn from the market due to safety concerns. However, in most cases, the pharma companies settle either with the authorities or patients, and the cost will not be too great. However, if a company can be proved to be negligent, eg in the case of Wyeth (formerly American Home Products) and the Fen-phen diet pill, the cost can move into the billions.

## Social-political

There are several factors that could be considered socio-political CSR, including:

- Access to medicines
- Political lobbying
- Bribery & corruption
- Child labour
- Community giving
- Community initiatives
- Corporate governance
- Equal opportunities
- Health & safety
- Human rights
- Labour standards
- Supply chain management

We will focus on access to medicines and political lobbying as two areas pertinent to pharmaceuticals. Lobbying seems to be understudied and access to medicines is one of socially responsible investors' biggest concerns.

**Access to medicines is one of socially responsible investors' biggest concerns**

Before we move on, we mention working conditions and labour standards. Although we have found no direct evidence, there are anecdotal accounts that better working standards (and health & safety) lead to better workforce efficiency. However, this would be very hard to measure and difficult to measure financially, except to say it seems obvious that a happy workforce is a better workforce, all other things being equal!

### Political lobbying

Political lobbying is a very murky area. By its very nature it is secretive and opaque. However, we believe the lobbying power and how pharma influences governments (and regulators) is probably one of the single most important factors influencing the industry and potentially influencing global healthcare concerns.

Certain commentators will argue that governments are stronger than corporations and that recent arguments proposing that 'big business' is now more powerful than governments are overstated. Governments control the law that companies have to operate in and can always change laws and regulations.

However, pharma companies are uniquely positioned to lobby and influence the key decision makers concerned in healthcare policy in governments worldwide and so swing the laws and regulations potentially in their favour.

When we discuss the access to medicines problem, we highlight that many responsibilities would likely be assigned by citizens as government responsibilities (eg developing healthcare infrastructure) not pharma companies'. However, as we argue that pharma companies are uniquely positioned to lobby and influence key decision makers, so companies able to lobby governments to shoulder those responsibilities.

**Important to distinguish responsibilities**

Areas companies must have influence over include:

- Government policies on pricing and patents
- Policies on healthcare infrastructure
- Donations from Western governments to the developing world

We are unsure what influence pharmaceutical companies have on government policies and patent treaties, but we believe it seems reasonable to expect they have it.

Pharma companies were key to changing the US regulatory system to speed up FDA review times and pay for those reviews to occur.

**Pharma companies were key to changing the US regulatory system to speed up FDA review times**

Although we cannot know for sure, pharma companies presumably had an influence on the US decision to take Brazil to the WTO over its laws regarding generics, importing and pharmaceuticals. We do not know if pharma companies also had an influence on the US government subsequently deciding not to pursue the matter.

Pharma companies can decide where to locate their R&D and its spend, presumably influencing decisions at local government as well as national governmental level.

Pharma companies influenced the wording and scope of the TRIPS agreement and thus on global patents rights as they now stand.

The donations by certain pharma companies, or personal donations by CEOs of pharma companies, have also been highlighted recently (eg Pfizer's CEO's donations to Bush).

All of these factors must have a massive effect on the way industry is allowed to operate. Yet investors really have no idea how each company stands (apart from the statements presented by industry bodies such as PhRMA). It would be extremely useful to know the flavour of lobbying positions and the tack companies are taking. Investors could then decide whether such positions are justified and useful or perhaps detrimental. Should pharma companies be lobbying the French Government to increase generic utilization and not be lured by reference pricing rather than lobbying against both ideas? We are unsure. But, certainly knowing a company's position would be useful in many ways.

Taking it a step further, should pharma companies be lobbying the western governments to increase donations to the developing world healthcare cause? Are they lobbying for this already, if so, why aren't they shouting louder? Would these donations then go on to build the healthcare infrastructure and develop the market, bringing long-term benefits to the pharma company?

**Should pharma companies be lobbying western governments to increase donations to the developing world healthcare cause?**

We are unsure as to how pharma companies can better communicate their lobbying positions. However, we suggest devoting some space in position papers on points that investors are most concerned about or where a company is lobbying hardest.

### Risks and conclusion

We are unsure what the risks to revealing such positions so openly are, except that, of course, it reveals a company's hand. However, this increased transparency will be to the gain of an investor, who should be able to better analyse a company and hence lower an investor's risk.

## Access to medicines

The disease burden in developing countries is huge compared with the developed world. Many people die from diseases that have cures and there are many diseases in the developing world that have no cure and little research being done.

**The disease burden in developing countries is huge compared with the developed world**

Pharma companies are increasingly being seen as key players in solving this disease burden and over recent years the industry has been targeted as being part of the problem (in terms of pricing and patents), not part of the solution. However, the situation is complex.

Over 90% of the products on the WHO list of essential medicines are off patent, suggesting patents aren't necessarily the problem (HIV is the exception) but certainly pharma companies could do more to help the industry's PR (especially given the high public and political awareness of HIV). The financial analysis of the situation is yet again virtually impossible. But we do examine reputation risk and the possible opportunity of emerging markets.

**Over 90% of the products on the WHO list of essential medicines are off patent**

## Tackling the disease burden

There are many problems to solve and the issues need to be confronted on many levels. However, we believe most of the problems stem from one factor:

**Most of the problems stem from poverty**

- **Poverty:**

So, in our view, the first pillar to any solution (and we don't think it is controversial) is to provide

- Money

This can in turn create

- better healthcare infrastructure, distribution, education

and buy drugs and vaccines, either through cost-priced drugs donated/licensed by big pharma or

- generics

The solution is relatively simple then. Lots of cash, build infrastructure and education and then use medicines through that infrastructure. The problem then is a lack of cash, because the developing countries do not have it (or use it on problems) and the developed countries do not want to donate. Given that the obvious solution seems to be unavailable in today's sociopolitical environment, we examine the other factors contributing to the problems.

Many factors influence access to effective medicines, including:

- Quality of diagnosis
- Accurate prescribing
- Selection, distribution and dispensing of medicines
- Drug quality
- Capacities of health systems and budgets
- Lack of research and development (R&D)
- Price of drugs

In developing countries, infectious diseases are responsible for almost half of all deaths and half of all infectious disease deaths are caused by HIV, tuberculosis and

**In developing countries, infectious diseases are responsible for almost half of all deaths**

malaria. These three diseases cause about 5m deaths a year, mostly in the developing world.

The top developing world disease problems are:

- HIV
- Malaria
- Tuberculosis
- Onchocerciasis
- Lymphatic filariasis
- Leishmaniasis
- Diarrhoeal diseases
- Schistosomiasis
- Sleeping sickness

The limiting problems with these diseases are either a lack of a cure (and perhaps more importantly, lack of research into a cure) or lack of ability to get the appropriate medicines to patients – although price is a factor.

**The limiting factor with these diseases is either a lack of a cure or lack of ability to get the appropriate medicines to patients...**

There is the very emotive argument of many people dying in the developing world on the one hand, and profiteering drug companies on the other, but in our view the case is not that clear cut. It depends on whose responsibility you think it is.

**...although price is a factor**

Also, for the most PR-sensitive disease, HIV, there is no cure. All the drugs in the world will only slow down the progression of the disease. If the pandemic is to be cured, it will only be done through better education and infrastructure, not through drugs.

**Who is responsible?**

To pinpoint who should be doing what, we must try and decide who is responsible, as well as what is important:

**We must try and decide who is responsible as well as what is important**

**Table 6 : Influences and responsibilities**

Government	Pharma	Corporates	Society
Infrastructure	Lobbying government	Education	Education
Education	Patents	Help in distribution?	lobbying government
Patent law	Pricing	Donations?	Donations?
R&D/tax incentives	R&D		
Donations?	Donations?		

Source: ABN AMRO

As we discussed previously, pharma companies are in a unique position to lobby governments on these matters. However, ultimately many of the responsibilities come down to the government.

**Companies beholden only to shareholders**

Indeed, on one of end of the scale one could argue that drug companies are only responsible to their shareholders and that the pharma companies’ responsibility is to develop profitable drugs and then sell them to maximise shareholder return (if that is what shareholders wish). It is then society’s responsibility to ensure access, eg western governments to bulk buy drugs and distribute them to Africa.

At the other end of the scale, one could argue that pharma companies are global citizens and have a responsibility to try and ensure access to drugs the world over.

**Pharma companies are global citizens**

## INVESTMENT VIEW

In reality, we believe a balance will need to be struck where companies can be profitable while still maintaining a corporate citizen role and influencing governments and society as to the responsibilities they should shoulder.

We can't give an answer to the question of responsibility posed here. However, we can see that there is big risk that the healthcare situation in the developing world could get worse and worse and one day society might ask what humans were doing when the largest human healthcare crisis in the world was developing.

**One day society might ask what humans were doing when the largest human healthcare crisis in the world was developing**

## Patents and prices

### The philosophy behind patents

Patents are a government's way of giving an inventor ownership of his or her creation. For a certain period of time, patent-holders are allowed to control how their inventions are used, allowing them to reap the financial rewards of their work.

The philosophy behind patents is that it is almost a social contract between inventor and society. The incentive to invent, to prove ideas and things of use to society. Patents are, most people agree, crucial for innovation.

**The philosophy behind patents, is that it is almost a social contract between inventor and society**

However, the risk to pharma patents is that if companies are seen to be reneging on that social contract, ie pharma company inventions, then the drugs are not going to help society (because a country is too poor to afford them) and then a country's society might opt out of the patent treaties and the whole patent system falls apart.

This is very unlikely, but given that it would have such catastrophic implications we believe it would be sensible for pharma companies to minimise this risk at all costs.

### Other protection

As well as patents, there are certain exclusivities given in some countries, eg orphan drug exclusivity in the US and EU, that can enhance protection. Also, more relevant to the developed world, pharma companies use strategies with varying degrees of success to defend their profits, for example:

**As well as patents, there are certain exclusivities given in some countries**

- New indications;
- Reformulation;
- Switching to newer products;
- Filing new patents;
- Paying off generics;
- Court procedures; and
- Joining in the generic market.

### Patents as a barrier – a red herring?

As we have already argued, money, not patents, appears to be the rate-limiting step in the issue of access to medicines in the developing world.

However, could restrictive patents be an issue at all, or simply a red herring?

We note that essential medicines are rarely patented in developing countries. Some 99% of drugs on the WHO's list of 325 essential drugs are off-patent, those for HIV being the biggie. It would seem that patents are quite far down the chain in preventing access to medicines. Indeed, in poor countries, and for poor patients in rich countries, patents are valuable because they produce innovation. Patents make differential pricing easier, which in turn means richer people tend to pay more and offsets the cost for poorer people, whether inter- or intra-country.

**Restrictive patents - a red herring?**

That is not to say that pharma companies could not do more if they so wished. Voluntary licensing of patents or transferring of IP and useful technology to developing countries would be of great benefit to the developing world. It might also help spur some of the infrastructure building that is required.

## The risks from patents: parallel imports and potential patent treaty meltdown

We have already highlighted the main risk to the industry from patents. That is, if pharma companies are perceived to be breaking the 'social contract' behind patents, ie that pharma companies are profiteering from their drugs and not giving back to society, then certain countries might decide to opt out of TRIPS or global patent treaties and the whole patent system comes down.

We view this risk as small but potentially catastrophic.

On the other end of the argument, there is the risk of cheap drugs in the developing world being imported back into developed markets. However, we also view this risk as small and (at least for the HIV class) of limited impact.

Parallel imports can be minimised by taking some appropriate measures, such as different packaging (GSK has made this recent point). And earlier analysis by the author suggests that financial loss, even if reimportation did occur, would likely be low (maximum \$40m over the five major HIV players if a huge amount of HIV reimportation occurred in Africa) given the likely reimportation rates.

**Risk from parallel imports can be minimised**

## The NGOs and a different view

The view from many NGOs is different. While some, like Médecins Sans Frontière's 'equity pricing' strategy, have quite a developed plan that includes trying to use market forces eg bulk buying, others seem to argue that patents increase the cost of medicines in developing world countries and are therefore pretty much a bad thing in the developing world.

**Some NGOs argue that patents increase the cost of medicines in developing countries**

Oxfam, for instance, argues that "WTO patent rules are set to restrict further poor peoples' access to life-saving medicines by raising their price" and that the "high price" of AIDS drugs means "only a tiny minority of people in poor countries receive treatment".

We would suggest that this view oversimplifies matters (as we have already argued) and indeed might be counterproductive in getting essential medicines to poor countries. We believe patents don't necessarily mean raised prices (particularly for essential medicines, which are often not patented) and the patent incentive is crucial for developing new drugs. Readers can examine the arguments and draw their own conclusions.

**We would suggest that this view oversimplifies matters**

However, Oxfam does highlight the power of US trade agreements with developing countries and the power of the pharma lobby. Oxfam goes on to argue that companies "should [lobby] in a legal, transparent and non-coercive manner that respects commitments on human rights and development".

This highlights our view that pharma companies could do well to lobby in a more transparent fashion and avoid some of the negative PR and risks involved in being opaque.

## Summary

Patents have the effect of stimulating high levels of research and development that are allocated to the discovery and development of new drugs, but they can also lead to higher prices set for the drugs discovered than would otherwise be found.

**Critics of the drug industry emphasise the high prices that are charged and discount any health gains arising from pharmaceutical research**

Critics of the pharmaceutical industry emphasise the high prices that are charged and discount any health gains arising from pharmaceutical research. In contrast, the industry's defenders emphasise the latter set of issues but not the former.

Of course, we believe both are important; and it is this conflict that has been running centre stage. However, it must be put into the context of the wider problems and issues of access to medicines.

## Pricing

The issue of patents is interlinked with the issue of pricing. As we argue that patents are not necessarily making drug prices inaccessible for poor countries, then it is more a matter of a lack of pricing flexibility. Part of the problem is that pricing is a complex issue even in developed markets.

**Part of the problem is that pricing is a complex issue even in developed markets**

A lack of patents in a poor country may not cause prices to drop. The situation is different in a rich country such as the US, where there is a lot of competition and the barriers to generic entry and sales are small (after patent protection ends).

The barriers to selling even generics in poor countries could be still a lack of money and a lack of infrastructure to buy, prescribe and distribute those drugs.

### Differential pricing – part of the solution?

However, differential pricing can be useful, in our view. It is on this point that the pharma companies might need to be pushed further (as companies see no benefit in it, only the risk of parallel imports) and different strategies might be necessary.

**Differential pricing can be useful and has been successful for many years**

One partial success story here might be in the world of vaccines. Vaccines are helpful in relieving the disease burden. Unlike AIDS drugs, vaccines are preventative. For many years (20+), the pharma companies involved in vaccines have been offering low-cost vaccines to buyers on behalf of developing countries. These buyers, often NGOs, are adept with pricing issues and can deal with the pharma companies successfully. The situation is helped by the fact that parallel importing for vaccines can be easily controlled.

A step forward from vaccines pricing is the more recent not-for-profit pricing of many HIV drugs by several companies. Market conditions for vaccines make it relatively easy to price differentially. It's much more complex for ARVs and other medicines, but shows that segmenting the market in this way is possible.

**Not-for-profit pricing of HIV drugs, another step forward**

In effect, we believe this is the developed world subsidising the cost of drugs for the developing world, which might rest uneasily with those in the developed world who feel they can not afford the drugs they want. One can argue that differential pricing is already established. In all industrialised countries there are various prices for the same drugs, mainly as a consequence of market-regulator interaction. We feel key to further acceptance of differential pricing between the developed and developing countries is the acceptance of high prices in developed countries. Here, there's still much lobbying to be done by the industry and NGOs to convince governments and the public of this.

Differential pricing might be achieved then by sophisticated bulk buyers. It is possible that some form of international expert group can assist in estimating marginal costs and thus facilitate negotiations favourable to developing nations. The industry may find it difficult to discuss and negotiate this issue, simply because co-operative industry discussions of price issues are competition law violations. Or there may be long-term, large-scale arrangements such as those emerging under UNAIDS.

**Key to further acceptance of differential pricing is the acceptance of high prices in developed countries**

Certainly, there is scope for differential pricing and this might be useful, not so much for the essential medicines already off patent (although we suspect there might be some benefit there), but more for the emerging chronic diseases such as cancer and cardiovascular diseases, or possibly even depression, a disease typically seen as a rich nation's illness.

### What do the drug companies have to gain?

Probably not a lot, in terms of financial value. Then again, if parallel imports are kept to a minimum, the pharma companies do not have a lot to lose either.

Pharma companies could gain in the fragile 'reputational' value that people talk about but can never really calculate. However, potentially more importantly being shown to be good and helpful for developing countries should help to ensure that schisms in the patent systems do not occur and that the catastrophe of countries pulling out of patent treaties is averted.

We would suggest that minimising this risk is enough for pharma companies to more actively engage in differential pricing solutions, particularly when the marginal cost is low.

### Conclusion

Patents and pricing are interrelated. However, the focus on patents being 'bad' is, in our view, somewhat misplaced. We believe patents enable differential pricing, which we see as a key part of the solution.

Patents can and do encourage innovation. We disagree with those who categorically state that patents increase prices for essential medicines. However, to retain a 'licence to innovate', pharma companies need to be perceived as pricing fairly to poor countries (much like those involved in vaccines do).

Differential pricing remains a key tool. We believe governments and NGOs need to work together to buy in bulk, negotiate marginal cost prices, ensure distribution and prevent parallel importing.

The gain is almost impossible to price; however, reputational risk could be lowered and the risk to patent treaties minimised.

### Solutions

Much valuable work has been done by the WHO, economists and policy makers on possible solutions. We summarise some ideas and conclusions here.

Almost everyone points to poverty as the major root problem. After poverty, there is the access to medicines problem (already discussed), then the issue of a lack of research into developing world diseases.

In terms of access to medicines, the following will, in our view, need to be the foundation for any long-term solutions to the problem:

- Continued differential pricing helped by bulk buying;
- Continued building of infrastructure and education;
- Further public-private partnerships (discussed later); and
- More money.

Only education and preventive measures can ever 'cure' pandemics such as AIDS in the foreseeable future. Only money can buy the infrastructure. Drugs bought at preferential prices and in private-public partnerships (PPPs) should help the problem.

### Research into developing against third world diseases

The economic problem here is that R&D into developing world diseases does not generally pay off. One solution for this is to make it pay off in terms of economics. However, there are also other problems:

- Poor expected market returns;
- State of the science;

**If parallel imports are kept to a minimum, the pharma companies do not have a lot to lose**

**We believe patents enable differential pricing, which we see as a key part of the solution**

**The economic problem here is that R&D into developing world diseases does not generally pay off**

- Insufficient access;
- Fear that IP protection will be inadequate; and
- Identifying priorities.

### Expected market returns not economically viable

Markets for these types of new medicines are small, whereas developing costs are just as large as for a 'developed world drug'. Currently it is not financially feasible for industry to match the level of research investment that is socially justified.

### State of the science is too undeveloped

The lack of understanding of a disease, coupled with the complexity of the science involved, makes the prospect of finding new cures very uncertain and risky. This lack of understanding limits the R&D investment that is prudent for a profit-maximising industry to undertake.

### Insufficient access

Weaknesses in physical, medical, political and financial infrastructure is a disincentive to develop new products to enter such countries. (While the focus is on access to medicines, it is very often the case that other preventive measures are more appropriate, as well as more cost effective, eg mosquito nets and condoms, which should not be forgotten.) Inadequate resources for delivering healthcare, purchasing medicines, vaccines and other technology put off R&D.

**Weaknesses in physical, medical, political and financial infrastructure is a disincentive to develop new products to enter such countries**

### IP protection inadequate

There could be a fear that if compulsory licenses are issued for, perhaps, a malaria cure, then no financial benefit would be gained.

### Identifying priorities

Insufficient information about patient populations and the effectiveness of existing products makes it difficult to identify priority markets.

### Solutions and successes

Several solutions have been proposed, most of which have gone through WHO papers in some form. There have been broadly labeled push and pull mechanisms. Push programmes are those that provide direct funding for research through, for example, grants to industries or government labs.

**Table 7 : Push mechanisms**

Mechanism	Issues to consider
Research in university and public labs	Essential for basic research Less suited to human clinical trials
R&D tax credits	Widely used to encourage R&D Only incoming earning companies benefit
Public investment in applied research	Eg AIDS vaccine initiative Hard to pick 'winners' Danger of politicising funding decision Difficult to shut down failed programmes
Sharing R&D costs between companies	Implies sharing returns Applicable to pre-competitive research Antitrust difficulties
Post phase II support	Depends on disease and location
Fast track regulatory review	Helpful but in itself not enough to spur R&D

Source: WHO; we suggest interested readers consult Sachs and papers from the WHO Commission on Macroeconomics and Health.

Pull incentives are designed to create or secure a market and so improve the likelihood of a return on investments. Because pull mechanisms reward output, they cost nothing unless a usable product is created.

**Incentives designed to create or secure a market and so improve the likelihood of a return on investments are useful**

**Table 8 : Pull mechanisms**

<b>Mechanism</b>	<b>Issues to consider</b>
Extension of patents or exclusivity on new product	Used with success in orphan drugs  Open to 'abuse' such as the paediatric extension use Exclusivity on a low-return product is not attractive
Extension of patent on alternative product	Refers to products in industrialised countries Potentially very attractive to established countries Politically very challenging Burden placed on patients for a different medicine (maybe offset by subsidises)
Tax credit on sales	Spreads cost burden Attractive to legislators Advantages to both seller and buyer
Purchase commitment	Theoretically attractive Creates market where one did not exist Precedent exist outside medicine Helps address price component of access problem May be best combined with increased purchases of existing products

*Source: WHO; we suggest interested readers consult Sachs and papers from the WHO Commission on Macroeconomics and Health.*

### Private-public partnerships (PPPs)

R&D PPPs, such as the Medicines for Malaria Venture, might also be a good model. They are an important way forward in helping distribution and other infrastructure problems. Indeed, Oxfam has said "PPPs have played a striking role in preventative health – most notably in vaccinations".

PPPs are an easy way forward for companies and the one they tend to advocate the most; however, they are too often ad hoc and are not reported in an easily accountable manner. We believe it would be better if PPPs were given a more structured role within a pharma company's business.

### Some successes and opportunities

PPPs have certainly had some success. Indeed, partnerships from pharma companies with other private companies, eg mining companies in Africa, have been productive. Other PPPs (most pharma companies have a few PPPs) have also been helpful, for instance in vaccines for malaria and TB.

Differential pricing in vaccines continues and some progress has been made.

Paragraph 6 of Doha Declaration on TRIPs & Public Health has been resolved and a compromise on compulsory licenses for export has been reached (essentially it is now easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves). Mainly because of this resolution we do not discuss the issues in much detail here but refer the interested reader to previous analysis from this author and to [www.wto.org](http://www.wto.org).

Emerging markets might be considered a limited opportunity, but we believe China and India may begin to look a lot more attractive in the medium term. Indeed, Novartis's CEO at an analyst meeting in January 2004 suggested China as a market opportunity. This may spur more R&D in these countries, which in turn may help R&D and access to essential medicines.

Advances have been made in the developed world, too. Orphan drug status has encouraged R&D into niche diseases in the US, Europe and Japan. Drug discounting for the poor and elderly has or will be increased in the US.

## Conclusion

In terms of implementing many of the suggested solutions, money and political will power are still required, in our view. Some progress has been made but it has been slow. Many of the issues raised here might not be seen as direct responsibilities of pharma companies and they might have relatively little to gain. In all likelihood, we believe progress will continue to be slow. In terms of AIDS funding in 2001, the UK (the biggest G7 giver) gave \$147m, about half the budget for a film like *Titanic*. Germany gave \$3m. The very poor countries can currently afford to spend only about \$10 per person per year on health (according to WHO). These sums from western governments are not enough if they want to make a difference – but possibly western society does not want its governments to help Africa while health problems exist domestically.

It is pertinent to note that Bill Gates gave \$150m to the vaccine fund in 2001, outspending all of the G7 countries in terms of donations. About 45% of African children who could be easily vaccinated are not, for lack of money. It depends on society's priorities, but if world health is supposedly one of them, there is still some way to go.

**Money and political will power are still required to implement these solutions**

**Very poor countries can currently afford to spend only about \$10 per person per year on health**

## Pricing the risk – the holy grail

Here we turn our attention to trying to price the risk on some of these CSR risks. In our view it is impossible to come up with any type of NPV value on such risks.

We also find, at least to our knowledge, that there is a lack of metrics to help price such risks. Similar problems exist in terms of pricing pollution and similar factors. We are unsure where better metrics are to spring from – perhaps first from academic economists.

We look at some factors that might affect the entire industry. We examine ways of assessing risks between companies on a relative basis and discuss if reputational risk is in practice a useful metric. We try to analyse the quantification challenge and highlight how much work needs to be done in developing better and more valuation metrics in this field. Readers should bear in mind that standard valuation tools such as DCF and PE ratios are themselves flawed in many ways and even the pricing of something such as a bond (with reasonably predictive cash flows) is prone to error. The difficulty in pricing reputational and other CSR risks given the quantification challenges on a standard DCF for a company cannot be overstressed.

We also look at scenario analysis as a possible useful tool.

**Pricing the risk is almost impossible**

## CSR and financial gain: Problems and solutions

Many investors are seeking to prove (or disprove) a correlation between good CSR and financial performance or stock market performance. On an empirical basis, this seems to us almost impossible.

There is no established way of measuring CSR and even less of a method for putting a value on it. For example, take transparency of accounts. How does one measure this empirically? Number of non-compulsory disclosures made? Even if this was a good measure, when trying to correlate it with stock performance there will be myriad of confounding factors.

**Many investors are seeking to prove a correlation between good CSR and stock market performance...**

**...On an empirical basis, this seems to us almost impossible**

Depending on the time frame, one cannot even necessarily correlate low or high PE with under- or outperformance of a stock. However, PE can be a useful metric in addition to all the others because a low PE could imply that the market does not rate a company's growth prospects, and this is useful to know.

Similarly, although empirically trying to correlate good CSR with stock price performance is beset by so many flaws and problems it seems almost pointless to attempt, it does not mean that CSR cannot also be a useful metric.

### Measuring CSR

First, what makes up good CSR for a sector would need to be determined, and then how to measure it. Ideally, one would want measurable empirical factors, eg carbon dioxide emission numbers. However, many of these measures are hard to obtain and even harder to then scale, to be able to compare two companies with different businesses.

A relative measure is what we want, a measure that can be used to compare companies. However, we have already shown that empirical measures in this field are problematic, but perhaps we can use the analyst's knowledge to compile a metric.

Returning to transparency (if we decide that transparency is a key CSR metric), rather than try to invent an empirical one, which probably wouldn't have much useful practical basis, we can score one out of 10 on a company-relative basis.

For example, Company (Co) A reports using a GRI-based system and voluntarily discloses many useful facts but doesn't set CSR targets. Co B sets CSR targets, discloses some noncompulsory information and does not use GRI-based accounting. Co C reports a standard set of report and accounts.

As analysts, we view Co A as more transparent than B and B more than A. So we score them 8, 7 and 5, respectively. However, other analysts might view B as better than A because CSR targets might be more important to them and thus could produce a different relative score.

Whatever the preference, from this analysis, all other things being equal, we would prefer to invest in Co A than Co C. This is because it has better transparency, so there is less risk that our models will be wrong or of there being some important information we might have missed.

To recap:

- Decide on CSR risks; and
- Score the risks on a relative basis.

Then, we could even weight the risks according to what we believe to be more important. For example, for pharma see Table 9.

**What makes up good CSR for a sector would need to be determined...**

**...and then how to measure it**

**A relative measure is what we want**

**We can score a company out of 10 on a relative basis**

**We could even weight the risks according to what we believe is most important**

**Table 9 : Relative CSR scoring**

Company	Transparency	CSR goals	Litigation risk	GMP failure risk	Total	Rating
A	8	6	3	5	22	
B	6	7	5	5	23	
C	6	5	5	5	21	
D	4	5	8	2	19	
Weighting	2	0.5	1.5	1		
A	16	3	4.5	5	28.5	A
B	12	3.5	7.5	5	28	A
C	12	2.5	7.5	5	27	B+
D	8	2.5	12	2	24.5	C

Source: ABN AMRO

As can be seen, all other valuation metrics being equal, we would prefer Co A to Co D. We found GMP failure risk hard to differentiate between the companies, except for D. This could be because only D has had any failures in the past five years.

Co B scores most highly in terms of raw numbers, but because we view transparency as by far the most important CSR metric, Co A scores higher on a weighted basis.

In some ways, this is a similar process to credit scoring. And like bonds, one could maybe then assign the companies a CSR rating such as A or B+. We believe this is similar to what some SRI investors already do.

**This is a similar process to credit scoring**

IF this process is done with a view to the extra risks that a company is taking on, then all other things being equal this measure could be useful as a valuation metric eg, if Co A and Co D have the same PE and valuation multiples, they both trade at 15% discounts to a calculated DCF. If an investor is thinking of buying one over the other, if our assumptions are correct, Co A should in the long run be the better investment because it is less exposed to CSR business risks than D.

That's the theory. Still, it is not that easy to put into practice and it is only relative within one sector. Comparisons between companies in different sectors are still difficult (much the same way as PE comparisons between sectors is often difficult).

Deciding what CSR risks are relevant is also hard. This is something investors should seek to develop in dialogue with pharma companies. Still, we would like to offer at least four metrics to consider.

**Consider these metrics:  
Transparency,  
Patent risk,  
Innovative R&D  
GMP risks**

**Transparency.** Measured by how much useful noncompulsory information is given. GRI reporting will be a useful yardstick. Taking a consensus of analysts' views will probably help smooth out analysts' bias. For instance, we would rate GlaxoSmithKline's transparency better than Sanofi-Synthelabo's and we would suggest this would not be a controversial statement among analysts. However, deciding between GSK and Novartis would be harder. If in doubt, we suggest an equal weighting between companies.

**Patent litigation risk.** This is often measured by analysts outside of the CSR sphere. It can be measured in terms of sales expected to be lost to generics as a percentage of this year's sales, and can be split into what is often termed 'hard' and 'soft' risk. Hard risk is the sales that most people agree will be lost. Soft risk is if there is a generic challenge but analysts do not expect the pharma company to lose. These numbers could then be ranked and scored accordingly.

**R&D into innovative drugs.** It is hard to measure the quality of an R&D pipeline. Some analysts try to judge a pipeline on a risk-adjusted NPV value. This gives a good sense of the value of a pipeline but is prone to a lot of model error. One way to look

at innovation would be to look at the percentage of disclosed drugs with novel modes of actions compared with non-novel. Or, if the percentage of drugs in developing world diseases appears to be a better metric, that could be used. Regardless, scoring the innovation in a pipeline would be a useful exercise.

**GMP/environment and litigation risks.** This is hard to measure. However (much like insurance companies) basing some measure on previous fines and claims could be an indicator. As we have argued, this might not necessarily be a predictor of forward looking risk but it is a good first estimate. We suggest taking the value of fines and claims (rolling over the past three or five years) as a percentage of EBIT or percentage of net income as a measure. We previously discussed using more complex measures using FDA warning letters, which would also be possible but correlates less clearly with financial effects.

Other factors that might be scored could be reputation, the percentage of sales in emerging markets, or any other factors we have already discussed (see Appendix for further factors).

These factors might then be scored with other factors as in the following (dummy) table.

**Table 10 : Multi criteria analysis**

Company	Revenue growth	Gross Margin expansion	EBIDTA margin expansion	Capital turnover	Spread	Invested Capital growth	Overall score
AstraZeneca	XXXXX	XXX	XX	XXXXX	XXXX	XXXX	XXXXX
Roche	XXXX	XXXXX	XXXXX	X	XXXXX	XX	XXXXX
Sanofi-Synthelabo	XXXXX	XXXX	XXXXX	XXX	XXX	XX	XXXX
GlaxoSmithKline	XXX	X	XXX	XXXXX	XX	XXXX	XXXX
Schering	XX	XX	XXXX	XXX	XXXXX	XXX	XXX
Lundbeck	XX	XXXXX	X	XXXX	X	XXXXX	XXX
NovoNordisk	XXX	X	XX	XX	XX	XXXXX	XX
Novartis	XXXX	XX	X	XX	XXX	XXX	XX
Shire	X	XXXX	XXX	XXXX	X	X	X
Aventis	X	XXX	XXXX	X	XXXX	X	X

Source: ABN AMRO, xxxxx = better, x = less good

**What else does CSR affect?**

Having already established that there is a strong theoretical link between good CSR management and minimising business risk (which should lead to better financial performance, all other things being equal), we discuss what other elements CSR affects. This would mainly be summed up in the rather all-encompassing idea of reputation. However, CSR in some ways also affects credit ratings and insurance premiums. In fact, knowledge of what risk insurance companies are pricing would be one measurement to consider.

**Reputation**

Reputations are fragile, like hand blown Venetian glass.

More pragmatically, reputation risk could be defined as the current and prospective impact on earnings and capital arising from negative public opinion. This affects the ability to establish new relationships or services or continue in existing relationships. This risk may expose the institution to litigation, financial loss or a decline in its customer base. It is extremely difficult to measure. Managing reputation involves monitoring stakeholders and public opinion, identified and prioritising risks and opportunities, analysing gaps and launching responses, implementing the strategies and actions and remonitoring the situation.

Reputations are fragile

Reputation risk could be defined as the current and prospective impact on earnings and capital arising from negative public opinion

The reputational risk to actual pharma sales is probably relatively small. If patients are dying and only one drug will save their lives, they are unlikely to refuse on the grounds of a company with a dubious reputation. However, it could affect the large customers, eg governments and insurers, a little more, particularly when it comes to negotiating on price and other matters.

Reputation will likely affect a drug company most in terms of its personnel. If a company wants to be able to recruit the best people, the best managers, the best scientists, then we believe it will need a good reputation. Considering that pharma companies are built on the foundation of discovering new drugs and this relies on good science and good scientists, then we think to achieve its long-term aims a company will need to keep up a good reputation or it will fail to attract the scientists it needs.

**Reputation will likely affect a drug company most in its personnel**

Measuring reputation is difficult and putting a value on it even harder. Reputation can be blown apart in a day and even most surveys that try and solicit opinion on reputations can often be faulted.

To roughly estimate reputation, we would again suggest a relative scoring given by a broad range of stakeholders, if practical. Otherwise, a few analysts' opinions might need to be relied upon, which could easily not reflect a company's true reputation.

In practical terms, if many of the other aspects of this analysis are addressed, then reputation will probably be addressed, too. Pharma companies might have been relatively slow to pick up on public opinion and the factors that might be denting their reputations. Recent events have made matters better, but further measures will probably be needed if reputational risks are to be further minimised.

**In practical terms, if many of the other aspects of this analysis are addressed, then reputation will probably be addressed**

### Scenario analysis and stress testing

Scenario analysis could be a useful tool but does have limitations. It can be used to plan 'what if' scenarios:

- What if there were no patents in Africa?
- What if prices were reduced by 25%?

The impact these scenarios could have then be modeled. However, the likelihood of such a scenario is then hard to determine. For instance, we have described the possibility of the weakening of worldwide patent treaties, possibly sparked by a backlash against big pharma not doing enough in the developing world. We can also model that scenario leading to a potential 20% derating of the sector and a market that goes into contraction. However, we cannot easily assign a probability to it. We know it's unlikely, but is it a 1% chance or a 0.1% or a 0.00001% chance?

**Scenario analysis could be a useful tool but does have its limitations**

Modeling scenarios is useful in examining the upside and downside impacts of different decisions and outcomes. Unfortunately, without knowing how likely a scenario is, the modeling has more limited use.

### Conclusion

There is merit in developing further metrics to value companies. These metrics based on CSR measures are most useful when they are relative and when they have some empirical part to them. However, most metrics we discuss still have modeling and analyst risk because they will be based on an analyst's assumptions.

Still, all other metrics being equal, we believe CSR valuation tools can help investors make money and contribute to sustainability. They can also highlight areas that companies could improve upon if they so wished.

**We believe CSR valuation tools can help investors**

We believe further work needs to be done in developing metrics. Collaborations between those working in a financial valuation field, those in CSR and companies should prove fruitful.

## Looking forward

Social and environmental factors affect the businesses of pharmaceutical companies, although the link is not often clear. Drug companies have come some way to better transparency and to better deal with CSR concerns.

Investors and companies have more to do. We believe developing metrics will be useful in terms of valuation tools. Companies continuing to increase transparency, increase innovation and show awareness of CSR issues are likely to be rewarded in the long term, in our view. Moving towards more GRI-like reporting will help, but it will require developing a culture both at companies and with investors of aiming for goals socially, environmentally and economically – the triple bottom line.

Given the links between minimising CSR risks and minimising business risks, we think moving towards accountability on the triple bottom line will make better companies and, it is hoped, a better world.

**Given the links between minimising CSR risks and minimising business risks, moving towards accountability on the triple bottom line will make for better companies**

## Further CSR factors to consider

### Factors to look at in triple bottom line reporting and GRI principles.

Aside from the economic factors, these factors might be of interest:

- Corporate governance;
- Risk and crisis management;
- Strategic planning;
- Environmental policy/management, performance and reporting, eg resources, wastewater, by-products, emissions, number of animals used in testing, biodiversity;
- Corporate citizenship/philanthropy, eg donations of preferentially priced drugs, value of PPPs, number of LDCs in which the company operates, number of LDCs buying under best possible pricing or preferential pricing;
- Stakeholders' engagement, eg presence of committee or management in charge;
- Labour practice indicators and human capital development;
- Social reporting, and health and safety, eg male/female ratios, employee turnover rate, injuries, talent attraction and retention;
- Standards for suppliers;
- Customer relationship management; and
- Self-reporting surveys, eg percentage of employees who agree that social and environmental factors are important for a company, who agree that management lives up to core values, that trust management.

GRI reporting principles are:

- Transparency;
- Inclusiveness;
- Auditability;
- Completeness;
- Relevance;
- Sustainability context;
- Accuracy;
- Neutrality;
- Comparability; and
- Clarity.

# Why this report?

**This research was produced on the basis of an invitation from the Asset Management Working Group of the United Nations Environment Programme Finance Initiative (UNEP FI).**

We were invited to:

- Identify the specific environmental and social issues likely to be material for company competitiveness and reputation in the chemicals, consumer electronics, and pharmaceuticals sectors.
- Identify and, as far as possible, quantify their potential impact on stock prices.

The AMWG includes the following 12 firms with combined assets under management of US\$1.6trn.

## Table 11 : Asset management firms supporting the AMWG

1. Acuity Investment Management Canada
2. BNP Paribas Asset Management France
3. Calvert Group Ltd. USA
4. Citigroup Asset Management USA
5. Groupama Asset Management France
6. Morley Fund Management United Kingdom
7. Nikko Asset Management Japan
8. Old Mutual Asset Management South Africa
9. San Paolo IMI S.P.A. Italy
10. Storebrand Investments Norway
11. ABN AMRO Bank N.V. Brazil
12. HSBC Asset Management International

*Source: Asset Management Working Group*

For more information visit: [www.unepfi.net](http://www.unepfi.net) or contact Jacob Malthouse at: [jacob.malthouse@unep.ch](mailto:jacob.malthouse@unep.ch).

# GovernanceMetrics International ratings

GovernanceMetrics International's (GMI) overall global rating, for which they have sole responsibility, is based on over 600 metrics (encompassing board accountability, financial disclosure and internal controls, shareholder rights, remuneration, market for control and corporate behaviour). Ratings are relative to a global universe of 2100 companies with a scale of 1.0 (low) to 10.0 (high) with a median rating of 6.5. For more details see [www.gmiratings.com](http://www.gmiratings.com). When GMI change their rating we will show the updated score in our next published research report on the company.

**Table 12 : GovernanceMetrics International ratings**

AstraZeneca plc	7.5
Aventis S.A.	6.0
Glaxo SmithKline plc	7.5
H. Lundbeck A/S	5.0
Novartis AG	6.5
Novo-Nordisk A/S	6.0
Roche Holding AG	4.5
Sanofi-Synthelabo	5.0
Schering AG	6.0
Serono S.A.	4.5
Shire Pharmaceuticals Group plc	7.5
<b>Sector Average</b>	<b>5.6</b>

Source: GovernanceMetrics International

## Recommendation structure

For large cap, sector-based research we apply a three-stage recommendation structure: a combination of the analyst's view on the stock relative to its sector and a call on the sector relative to the market. Taken together these imply a view on the stock relative to the market as shown in the table. The sector call is the responsibility of the strategy team in co-operation with the analysts (and is described on the back page). This process ensures a consistent, balanced distribution of recommendations and forces an analyst to have clearly differentiated views on the stocks in his/her universe.

Stock vs sector	Sector (vs market)		
	Overweight (>10%)	Neutral ( $\pm$ <10%)	Underweight (>-10%)
Buy (outperform >15%)	Key Buy	Buy	Add
Add (outperform <15%)	Buy	Add	Hold
Hold ( $\pm$ <5%)	Add	Hold	Reduce
Reduce (underperform <15%)	Hold	Reduce	Sell
Sell (underperform >15%)	Reduce	Sell	Key Sell

For stocks which do not fit neatly into a sector paradigm, we show only a target price and an absolute recommendation consistent with this view.

### Target prices

The target price is the level the stock should currently trade at if the market accepted the analysts' view of the stock, provided that the necessary catalysts are in place to effect this change in perception within the performance horizon. In this way, therefore, the target price abstracts from the need to take a view on the market or sector. If it is felt that the catalysts are not fully in place to effect a re-rating of the stock to its warranted value the target price will differ from 'fair' value.

### Performance parameters and horizon

Given the volatility of share prices and our predisposition not to change recommendations frequently, the relationship between the current and target price, on the one hand, and the performance parameters shown in the table above, on the other, should be interpreted flexibly. Performance in this context only reflects capital appreciation and the horizon is 6 to 12 months.

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### Recommendation distribution (as at 24 Feb 2004)

	Global total (IB%)	Europe total (IB%)
Buy	412 (26)	209 (44)
Add	386 (24)	232 (35)
Hold	354 (20)	187 (33)
Reduce	195 (14)	143 (17)
Sell	68 (21)	39 (36)
<b>Total (IB%)</b>	<b>1415 (22)</b>	<b>810 (33)</b>

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