



The Public Health Crisis in Emerging Markets

*An Institutional Investor Perspective on the
Implications for the Pharmaceutical Industry*

September 2004

PSG MEMBERS

Engagers

Co-operative Insurance Society
Credit Agricole Asset Management
Ethos Investment Foundation
Henderson Global Investors
Insight Investment
ISIS Asset Management¹
Jupiter Asset Management
Morley Fund Management
Universities Superannuation Scheme

Supporters

Central Finance Board of the Methodist Church
Legal & General Investment Management
PGGM Investments
SAM Sustainable Asset Management
Schroder Investment Management (UK)

CHAIR

Jo Allen (Co-operative Insurance Society)

STEERING COMMITTEE

Jo Allen (Co-operative Insurance Society); Jane Henshaw (Legal & General Investment Management); Olivia Lankester (ISIS Asset Management); My-Linh Ngo (Henderson Global Investors); Raj Thamotheram (Universities Superannuation Scheme).

Acknowledgements & Thanks

This report was prepared by representatives of member organisations of PSG. PSG would like to take the opportunity to thank the following:

- Representatives from the seven companies that we met between June 2003 and March 2004: **AstraZeneca plc, Bristol-Myers Squibb Company, GlaxoSmithKline (GSK) plc, Merck & Co., Inc., Novartis AG, Pfizer Inc.** and **Roche Group**.
- The **Association of British Insurers** for hosting a PSG event to debate the issues in September 2003.
- Ben Yeoh, **ABN Amro**, for meeting with the group and commenting on the report.
- **Co-operative Insurance Society (CIS)** for the design and typesetting of the report.
- **CoreRatings** for *pro-bono* analysis against the PSG framework.
- Stewart Adkins, **Lehman Brothers**, for meeting with the group and commenting on the report.
- **SAM Research** for *pro-bono* analysis against the PSG framework.
- **UK Social Investment Forum** for the provision of secretariat services from Helen Barnes through UKSIF's collaborative engagement programme, which is funded by UKSIF's premium members: Co-operative Insurance Society; Henderson Global Investors; Insight Investment; ISIS Asset Management, Jupiter Asset Management; Morley Fund Management; Schroder Investment Management; and Universities Superannuation Scheme.
- Brigitte Granville, Professor of International Economics and Economic Policy, **Centre for Business Management, Queen Mary, University of London** for commentary on the pharmaceutical sector's response to enhancing access to medicines in the developing world.
- Elizabeth Gardiner, Consultant, Health & Pharmaceuticals, for developing country market insights.

Pharmaceutical Shareowners Group
PO BOX 46118
London EC1N 7WF
www.pharmashareownersgroup.org
Email info@pharmashareownersgroup.org

Disclaimer:

As a multi-investor and collaborative project, the findings, interpretations, and conclusions expressed herein may not necessarily reflect the views of all the institutional investors involved.² The report is intended to be for information purposes only and it is not intended as a promotional material in any respect. The material is not intended as an offer or solicitation for the purchase or sale of any financial instrument. The report is not intended to provide, and should not be relied on for, accounting, legal or tax advice or investment recommendations. Whilst based on information believed to be reliable, no guarantee can be given that it is accurate or complete.

¹Effective October 2004, ISIS will operate under the name of F&C Asset Management Ltd following a merger with that company.

²Credit Agricole and CFBMC were unable to sign-off the report in the timeframe available.

CONTENTS

Foreword	1
Abbreviations	2
Summary	3
1. Introduction	5
1.1 Background to PSG	5
1.2 Engagement process	5
1.3 Scope	6
1.4 Purpose of report	6
1.5 Structure of report	6
2. Why is the public health crisis in emerging markets an issue for investors?	7
2.1 Development of global markets	7
2.2 Risks to the social contract	7
2.3 The regulatory environment and risk to pricing pressure in the USA	8
2.4 Impact on staff morale and recruitment prospects	9
2.5 Securing new markets	9
Table 1 Risks of not addressing the public health crisis in emerging markets and opportunities of doing so	10
3. Industry response to date	11
3.1 The business case for a proactive response	11
3.2 Leadership and governance	12
3.3 Mechanisms for enhancing access to products	13
3.4 Scope of access initiatives (geographical and product range)	16
3.5 Research and development	17
3.6 Collaboration and sharing good practice	18
3.7 Public policy influence	19
3.8 Transparency (performance measurement)	20
Table 2 Summary of recommendations	22
4. Conclusion	23
Appendix 1 PSG framework of best practice and current recommendations	24

FOREWORD

Despite recent declines in R&D productivity, few would question the pharmaceutical sector's role in delivering life-saving breakthroughs in medical science. Successful treatment of diseases such as cancer and heart disease is now commonplace in the western world and many causes of death have been eradicated around the globe. Yet, despite these achievements, the sector now finds itself subject to intense public criticism. This criticism spans a number of issues but a key focus has been the pharmaceutical industry's role in addressing the HIV/AIDS pandemic and wider public health crisis in the developing world. Given that resources and know-how exist, at least for many treatments, and that the industry has made great strides to provide more affordable medicines to poorer countries, investors are left wondering why the sector is still accused of 'not playing its part'.



The global public health crisis is now undeniably on the international political agenda. The G8 Health Action Plan, launched at the Evian summit in June 2003, emphasised the role of the pharmaceutical industry in providing solutions. A month earlier, the EU had passed a regulation aimed at preventing the diversion of discounted drugs away from developing countries. The UK's presidency of both the G8 and EU in 2005 means that focus on these issues is unlikely to dissipate, given the stated views of both the Chancellor of the Exchequer³ and the Prime Minister.⁴ Indeed, in its recent policy paper,⁵ the UK government makes explicit its commitment to encouraging commercially viable responses to the needs of developing countries. The internationally agreed Millennium Development Goals also place a strong emphasis on health outcomes including the need to tackle the burden of HIV/AIDS and other major diseases.

It is within this context that the Pharmaceutical Shareowners Group (PSG) engaged with several leading global pharmaceutical companies over the last year to discuss their responses to the global health crisis in emerging markets. Responsibility for addressing the public health issues rests primarily with governments. However, PSG recognises that there may be sound commercial reasons for pharmaceutical companies to make a proactive contribution now and in the future. This paper explores these reasons and examines company responses to date. Following the public backlash surrounding the South Africa case in 2001 and, later, the debate leading up to the WTO Cancun Meeting, we were keen to assess whether companies were now approaching these challenges proactively.

The challenges and opportunities addressed in this review are by no means straightforward and there are no quick-fix solutions. PSG recognises the scale of the challenge, welcomes the openness of companies to dialogue on this complex issue and appreciates the considerable progress they have made so far. We are grateful to the companies we met and for the valuable insights that this process has provided. PSG looks forward to continued dialogue with the companies we have met on the recommendations put forward in this paper. We also welcome debate on our proposals with other interested parties.

Jo Allen

Chair, Pharmaceutical Shareowners Group
Head of SRI Engagement Strategy, Co-operative Insurance Society

³*'Brown: let Africa have cheap drugs', The Observer, 15 April 2001*

⁴*'Blair's Aids fight rallying call', BBC News, 1 December 2003*

⁵*'Increasing Access to Essential Medicines in the Developing World: UK Government Policy and Plans, June 2004*

ABBREVIATIONS/ GLOSSARY

AAI	- Accelerating Access Initiative
ARVs	- Antiretrovirals
ATM	- Access to Medicines
BRIC	- Brazil, Russia, India and China
CEOs	- Chief Executive Officers
DCs	- Developing Countries
Emerging Markets	- There are multiple definitions, but when used in this report, this term is used as a contrast to the sector's mature markets (i.e. Northern America, EU and Japan)
EU	- European Union
FDA	- Food & Drug Administration
GDP	- Gross Domestic Product
GRI	- Global Reporting Initiative
HDI	- UNDP's Human Development Index
HIV/AIDS	- Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
IFIs	- International Financial Institutions
ILO	- International Labour Organisation
IP/IPRs	- Intellectual Property/Intellectual Property Rights
KPIs	- Key Performance Indicators
LDC	- Least Developed Country
MDGs	- Millennium Development Goals
MICs	- Middle Income Countries (as defined by World Bank)
NGOs	- Non-Governmental Organisations
PPPs	- Public-Private Partnerships
PSG	- Pharmaceutical Shareowners Group
R&D	- Research & Development
SSA	- Sub-Saharan Africa
TB	- Tuberculosis
TRIPS	- WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights
UNAIDS	- Joint United Nations Programme on HIV/AIDS
UNDP	- United Nations Development Programme
UNICEF	- United Nations Children's Fund
USA	- United States of America
VP	- Vice President
WHO	- World Health Organisation
WTO	- World Trade Organisation

SUMMARY

What is the Pharmaceutical Shareowners Group (PSG)?

The Pharmaceutical Shareowners Group (PSG) is an international grouping of 14 institutional investors that have significant exposure to the pharmaceutical sector (see www.pharmashareownersgroup.org).⁶ PSG is concerned that the sector has faced extensive public criticism over the last five years, with potential negative impacts on its reputation and licence to operate. While this criticism has spanned many issues, including drugs pricing in the USA and allegations of misconduct in areas such as clinical trials and marketing, a key issue has been the sector's response to the HIV/AIDS pandemic and wider public health crisis in emerging markets.

PSG has a particular interest in the impact of this issue on long-term shareholder value. In March 2003, the group launched the *Investor statement and framework on pharmaceutical companies and the public health crisis in emerging markets* (see Appendix 1), which outlined our understanding of best practice based on extensive interviews with specialists from both within and outside the pharmaceutical sector. The aim of the statement and framework was to encourage companies to ensure that they were fully briefed about the risks stemming from the public health crisis in emerging markets and also to assess how well companies were managing these challenges. PSG has since met with seven global pharmaceutical companies to assess their responses and performance against the framework.⁷ We are grateful to these companies for the valuable insights that these meetings provided.

What does PSG want to achieve?

PSG members want to protect the long-term value of their investments. To this end PSG thinks it is important for investors to understand the business impact of the crisis and encourage companies to adopt best practice where this can protect long-term shareholder value. PSG does not presume to micro-manage companies and does not offer 'one size fits all' prescriptions: we fully endorse the importance of management deciding how to implement company-specific solutions that are consistent with good practice standards. Where companies are faced with demands that are not in the interests of shareholders, PSG also thinks it important that this is made clear both to company management and also to other stakeholders.⁸

Why is the public health crisis in emerging markets an issue for institutional investors?

There have been marked shifts in societal perceptions of pharmaceutical companies following the lawsuit involving 39 pharmaceutical companies and the South African government in March 2001 and the negative publicity surrounding the WTO TRIPs negotiations in 2003. A view has emerged that pharmaceutical companies have not been playing their part in tackling the public health crisis. PSG was concerned that this negative perception could have a significant impact on the sector's reputation and licence to operate with potential effects on its ability to defend the case for strong patent protection globally and to sustain 'premium' pricing in industrialised markets.

This view has been echoed by companies, many of which argue that a proactive response to the crisis is justified for several bona fide commercial reasons. These include:

- Defending the 'social contract' between governments, society as a whole and pharmaceutical companies, upon which intellectual property law and future innovation depends;
- Limiting the potential for emerging market countries to opt out of or otherwise weaken international patent treaties;
- Protecting company reputation and licence to operate with potential impacts on pricing power in the USA and other lucrative markets;
- Building political goodwill to help secure future markets;
- Improving stakeholder relations;
- Enhancing employee morale and recruitment prospects.

⁶Central Finance Board of the Methodist Church; Co-operative Insurance Society; Credit Agricole Asset Management; Ethos Investment Foundation; Henderson Global Investors; Insight Investment; ISIS Asset Management; Jupiter Asset Management; Legal & General Investment Management; Morley Fund Management; PGGM Investments; SAM Sustainable Asset Management; Schroder Investment Management (UK); and Universities Superannuation Scheme (USS).

⁷AstraZeneca plc, Bristol-Myers Squibb Company, Glaxo SmithKline (GSK) plc, Merck & Co., Inc., Novartis AG, Pfizer Inc. and Roche Group. We also attempted to meet with Aventis but, despite the company's willingness to meet with us, we were unable to schedule a meeting due to merger activities with Sanofi-Synthelabo.

⁸For example, PSG members were approached but unable to support a shareholder resolution that focused on a particular company and the pricing of specific drugs.

How have pharmaceutical companies responded so far?

Recognising that their licence to operate and reputation with regulators and consumers might be affected, most companies have responded positively. PSG welcomes the considerable progress that has been made by many companies. We appreciate that this is a very challenging area and the success of company activities is highly dependent on external factors, not least the development of adequate health care infrastructures in the poorest countries. Many companies have displayed real commitment to tackling these obstacles as well as a willingness to engage in constructive dialogue with stakeholders and we have been encouraged to learn, even in contexts that are far from ideal, how action by pharmaceutical companies can stimulate action by other important parties.

Although some companies have been actively involved in these issues for some time, PSG's judgement is that it is really only in the last year or two that this has become a matter for senior management attention and integration into core business processes. Even in the period that PSG has been working, we have noted a marked change in confidence and openness. We see these as highly positive developments and encourage companies to continue in this manner.

PSG particularly welcomes the progress made by companies such as GSK and Merck & Co., Inc. On balance, we feel these companies demonstrate many of the elements of what we consider to be an effective strategy. It is only fair to recognise, however, that all of the companies that we saw had particular strengths and, even amongst the leading companies, there were some gaps between current company practice and good practice standards.

Has the sector gone far enough?

Since reporting is not systematic or linked to discussions of investment value, this makes it difficult for investors to assess whether companies are effectively optimising opportunities and minimising risks. The industry appears to believe it is doing enough to contain risks associated with the emerging markets health crisis and is no longer on the back foot. We welcome the fact that the focus has now returned, rightly in our opinion, to governments. We are concerned, however, that the sector's approach has tended to be reactive, with companies often developing their approaches to meet specific, high-profile external events and demands. The fundamental dynamics of this crisis – namely the growing trade power of the BRIC countries,⁹ the growing burden of First World diseases in Third World countries as well as the enormous impact of AIDS – are such that the public health crisis in emerging markets is going to become a bigger challenge year on year. We did not hear a convincing story that the sector is ready for this – i.e. that it has a proactive, coherent and forward-looking approach for adapting to these new realities which is linked to overall business strategy. This may leave the sector exposed in the future.

What would a good practice strategy look like?

Based on our engagement with companies and wider discussions, we think there are eight key elements that make up a good practice strategy for addressing the public health crisis in emerging markets. These are as follows:

- **Articulate the business case:** While recognising that companies may have philanthropic reasons for their activities, a clear articulation of the business case for action and its potential impact on long-term value/risk is the essential underpinning of a good practice strategy.
- **Promote leadership at board level:** A board member or committee with specific responsibility for this area of corporate activity is critical because various aspects of corporate strategy will need to adapt to allow progress in this area.
- **Take a forward-looking approach:** A good practice strategy needs to be forward-looking and take account of evolving disease burdens and patterns of consumer demand over the next 10–20 years.
- **Objectively assess alternative options:** This should take into account factors such as such commercial sustainability, proportionality, effectiveness and risks of diversion.
- **Show flexibility and breadth:** Companies that have expertise in a range of approaches (e.g. voluntary licensing, differential pricing, donations) will be better prepared to respond to changing expectations and regulatory environments.
- **Collaborate and share best practice:** Collaborating with peers in order to deliver innovative solutions, contain the problem of 'free-riders' within the sector and generally rebuild public trust is another important criterion.
- **Demonstrate responsible use of influence in public policy:** It will become increasingly important to provide evidence that a company's public policy positions and lobbying efforts are aligned with its access targets and strategy.
- **Track performance and be transparent:** Systematic reporting of goals, objectives and activities, ideally with relevant KPIs and performance targets, and discussion of how these activities relate to core business strategy and value creation will allow for continuous improvement.

⁹*'Dreaming with BRICS: The Path to 2050', Goldman Sachs, October 2003*

PSG recognises that responding to the public health crisis in emerging markets is a dynamic issue. Through addressing the above elements as part of an overall strategy, this will help companies better articulate their approach to investors and other stakeholders, which in turn will help investors understand and support sound management decisions. PSG welcome dialogue and feedback with companies and other stakeholders on the usefulness of the observations and suggestions set out in this report.

SECTION 1: INTRODUCTION

1.1 Background to PSG

The Pharmaceutical Shareowners Group (PSG) is an international grouping of 14 institutional investors, representing *circa* £900 billion assets under management, that have a significant exposure to the pharmaceutical sector (see www.pharmashareownersgroup.org).¹⁰ As investors, we are concerned to know that pharmaceutical companies in which we currently invest (or could invest in the future) are being run with due regard to the full range of matters which define durable business success. PSG has a particular interest in how the sector is addressing the challenges related to the public health crisis in the emerging markets.

PSG dates from the March 2003 launch of the *Investor statement and framework on pharmaceutical companies and the public health crisis in emerging markets*¹¹ (see Appendix 1), which outlined our understanding of best practice based on extensive interviews with specialists from both within and outside the pharmaceutical sector. Our aim was to encourage companies to ensure that they were fully briefed about the risks stemming from the public health crisis in emerging markets and also to assess how well companies were managing these challenges. Following the announcement of the framework, the (then) 12 institutional investors supporting the guidelines decided to undertake collaborative engagement based on the framework with selected pharmaceutical companies. In order to do this effectively, they formed the Pharmaceutical Shareowners Group (PSG) with a steering committee, chair and a secretariat.¹²

1.2 Engagement process

PSG has met with seven global pharmaceutical companies (four pan-European and three USA) to assess their responses during the period July 2003 and April 2004. These were AstraZeneca plc, Bristol-Myers Squibb Company, GlaxoSmithKline (GSK) plc, Merck & Co., Inc., Novartis AG, Pfizer Inc. and Roche Group.¹³ Meetings were attended by selection of PSG members and key relevant individuals within the companies, whose job functions included Non-Executive Directors, Vice Presidents (VPs) of Corporate Affairs, VPs for Research and Development (R&D), and Senior Investor Relations representatives. We are extremely grateful to these companies for the valuable insights that these meetings provided.

Prior to the meetings, and to inform our discussions, PSG members undertook in-depth desk research on companies' approaches. Our preliminary findings were shared with companies as the basis for our meetings, after which we also wrote to companies with feedback.

PSG also held a seminar in September 2003 for the broader financial community. The event considered the business case for responding to the health crisis in emerging markets and explored the extent to which any risks were being factored into analysts' investment models. It also explored other challenges to the pharmaceutical sector and how companies were striking a balance between meeting philanthropic and commercial objectives. The group has also met separately with UK sell-side pharmaceutical analysts, UK government representatives and others (e.g. academics and NGOs) to advance our understanding of their positions and to inform our views.

¹⁰PSG members, September 2004 include: Central Finance Board of the Methodist Church; Co-operative Insurance Society; Credit Agricole Asset Management; Ethos Investment Foundation; Henderson Global Investors; Insight Investment; ISIS Asset Management; Jupiter Asset Management; Legal & General Investment Management; Morley Fund Management; PGGM Investments, SAM Sustainable Asset Management; Schroder Investment Management (UK); and Universities Superannuation Scheme Ltd. Assets under management statistics were compiled in Q3 2003.

¹¹This was developed by ISIS Asset Management and the Universities Superannuation Scheme, in consultation with pharmaceutical companies, other institutional investors and informed stakeholders.

¹²PSG is chaired by the Co-operative Insurance Society (CIS) and governed by a small Steering Committee comprising: Henderson Global Investors; ISIS Asset Management; Legal & General Investment Management; and Universities Superannuation Scheme Ltd. Morley Fund Management resigned from the steering committee following the departure of their former pharma SRI analyst in Oct 03. UKSIF has provided secretariat services through its Collaborative Engagement Programme since the group's formation.

¹³We also attempted to meet with Aventis but, despite the company's willingness to meet with us, we were unable to schedule a meeting due to merger activities with Sanofi-Synthelabo.

1.3 Scope

The report considers the public health crisis in emerging markets and the issues surrounding access to medicines that are relevant to research-based pharmaceutical companies producing branded, patented medicines. The subject is addressed from the perspective of institutional investors that have a long-term interest in the risks and opportunities facing particular companies and the industry as a whole. PSG has not sought to rank the seven companies we met, not least because the sector is much larger than this. Also, we acknowledge throughout the report that companies use various strategies for addressing access. As we have not concluded which approach is better on merit, it was therefore not appropriate to compare the companies that utilise different strategies.

1.4 Purpose of report

The aims of this report are threefold:

- To communicate PSG's key findings to date;
- To identify elements of good practice;
- To make recommendations to companies with reference to future strategy.

Putting a financial value on a company's response is not possible, particularly as most companies have yet to relate their approaches to core business strategy and value drivers. However, this report highlights how a company's approach can provide interesting insights into the quality of management and strategic thinking as well as the robustness of internal risk management systems. It particularly focuses on issues that could impact the profitability of the sector as a whole and could therefore affect sector weightings as well as stock picking decisions. It is, therefore, likely to be more relevant to investors that take a fundamental and more holistic, long-term view than those that have a straightforward trading approach.

1.5 Structure of report

- Section 2 discusses the industry context and why this is an issue for investors.
- Section 3 discusses the industry's response to date and makes recommendations for further action.
- Section 4 draws some conclusions and outlines what investors consider to be important elements of an effective strategy for addressing the public health crisis in emerging markets.

SECTION 2: WHY IS THE PUBLIC HEALTH CRISIS IN EMERGING MARKETS A MATERIAL ISSUE FOR INVESTORS?

2.1 Development of global markets

Investors have a long-term interest in the development of a stable and prosperous global market. This goal could be fundamentally undermined by the increasing burden of ill health in the developing world. Although considerable progress has been made over the last 25 years, a large proportion of the world's population still lacks access to basic health care and some 38 million people were living with AIDS in 2003, all but two million of them of working age.¹⁴ A recent report from the International Labour Organisation (ILO) claims that GDP growth in Asia is already being impacted by AIDS with the worst still to come.¹⁵

PSG believes that the main responsibility for ensuring healthy populations lies with government, and improving access to health care requires funding, political will and proven infrastructure.¹⁶ However, PSG also recognises that there may be sound commercial reasons for pharmaceutical companies to make a positive contribution to achieving this goal. These are summarised in Table 1 at the end of this section and discussed in more detail below.

"... disease can destabilise economies and entire political systems... the very legitimacy of the global system depends on the good health of the poorest, most vulnerable people."

Laura Tyson, Dean, London Business School and member, Commission on Macroeconomics and Health

"By 2015, the economic returns of scaling up health interventions for the world's poor would be at least six times the cost of scaling up, and will not only lift millions of people out of poverty, but will also boost the global economy."

Daniel Cohen, Professor of Economics, Ecole normale supérieure, Paris and member, Commission on Macroeconomics and Health

"The balance of power in world trade is changing, and the leading countries will need to adapt to new challenges. One of those challenges will be to understand and respond to the needs of developing countries, particularly the poorer ones, for the benefit of the entire trading community."

House of Lords Select Committee on European Union (Sixteenth Report), June 2004

"According to the National Intelligence Council's excellent study on the epidemic, most of the growth in [AIDS] cases in the coming years will be centred in ...India, China, Brazil, and Russia. Not surprisingly, one of the most divisive current issues in WTO negotiations is the question of loosening patent restrictions on AIDS-treatment drugs so that these states can stem this rising tide without bankrupting themselves."

The Pentagon's New Map: War and Peace in the Twenty First Century, Thomas P Barnett, G.P. Putnam's Sons, NY, 2004, p.55

2.2 Risks to the social contract

The pharmaceutical sector's business model depends upon strong patent protection as a reward for investment in high risk research and development. The patent system is a 'social contract' between society and pharmaceutical companies, bestowed by governments as a reward for discoveries that deliver improved public health. This contract is therefore dependent, at least in part, on the continued perception that the industry's contribution to society is worth the costs imposed by protected pricing.

PSG is concerned that this 'value-for-money' equation has been increasingly questioned with public criticism of the industry escalating over the last five years. The risk is that this could undermine the social contract that is so critical to the industry's success. While this criticism has spanned many issues, including drug pricing in the USA and allegations of misconduct in areas such as clinical trials and marketing, a key area has been the sector's response to the HIV/AIDS pandemic and the wider public health crisis in emerging markets.

¹⁴UNAIDS 2004 Report on the Global AIDS Epidemic.

¹⁵HIV/AIDS and work: global estimates, impact and response, ILO, 2004

¹⁶See, for example, the Commission on Macroeconomics and Health: <http://www.cmhealth.org/>

The lawsuit involving 39 pharmaceutical companies and the South African government in 2001 and the negative publicity surrounding the TRIPs negotiations in 2003 was associated with a marked shift in societal perceptions of pharmaceutical companies.¹⁷ In particular, a common view emerged that pharmaceutical companies were not ‘playing their part’ and were overly restricting access to their drugs through excessive prices.

If this perception persists and develops, there is a risk that emerging markets may opt out or otherwise decrease their commitments under international patent treaties. This risk has been highlighted in press commentaries and by key opinion formers including pharmaceutical CEOs and senior USA government representatives. Consensus is growing fast that multi-lateral trade agreements should be more responsive to the legitimate needs of emerging market countries. While the probability of a complete overhaul of the intellectual property regime is low, the potential consequences would be ‘catastrophic’ for the sector and hence this risk warrants active management.¹⁸

“If they don’t get ahead of this issue, the hostility that generates could put at risk the whole intellectual property rights system.”

Robert Zoellick, USA Trade Representative, Testimony to US Congress, 7 March 2001

“If I don’t supply Africa, governments will license our intellectual property to others who can.”
Miles White, CEO of Abbott Laboratories, ‘Benevolence and the bottom line’ Financial Times, 14 July 2004

“The lesson is that the pharma industry depends not only on the ability of its scientists to come up with new therapies but also the co-operation of governments to turn medicines into money. The costs of maintaining this co-operation are not trivial.”

‘Benevolence and the bottom line’, Financial Times, 14 July 2004

“The companies have much to lose as the international community grows restless. At stake is the very patent protection system that allows them to control drug prices. They want to keep the power of pricing their products, they must bend for a true international crisis.”

David Kessler, Former FDA Commissioner, National Public Radio, 19 February 2003

“The pharmaceutical industry has made great strides to provide more affordable medicine to poor countries but we need to make it the norm, not the exception.”

Supachai Panitchpakdi, Director-General of the World Trade Organisation and member, Commission on Macroeconomics and Health

2.3 Risks in other regulatory environments

In addition to the risk to the patent regime, PSG is concerned about the possible spillover effects on pricing power and regulatory regimes in other markets. In particular, we are concerned that if the sector does not address challenges related to emerging market countries well, the attendant controversy could fuel the public trust deficit that already exists in mature markets.¹⁹

This could exacerbate already intense pricing pressures in the USA, where a significant and vocal minority argue that current pricing levels are not justified. An erosion of confidence in the companies making branded drugs could cause USA patients to further question the value of contributing to their drug costs, particularly the so-called ‘me-too’ drugs.²⁰

A bigger public trust deficit could also have knock-on effects on the wider regulatory environment governing critical areas such as drug approvals as well as in areas where a good reputation delivers direct benefit (e.g. recruitment of patients for clinical trials).²¹

¹⁷In March 2001, a case brought by a number of multi-national drug companies and their subsidiaries was due to be heard by the South African courts. The case challenged the constitutionality of the South African Medicines Act 1997 on various grounds, including that it contravened South Africa’s international obligations under the TRIPs agreement. The case was portrayed as an attempt by the companies to prevent cheaper medicines being made available to patients. The challenge was withdrawn by the companies in return for the South African Government agreeing to apply the 1997 Act in accordance with its international obligations. Companies involved in the S African case included: GlaxoSmithKline, Merck, Bristol-Myers Squibb, Roche, Novartis and AstraZeneca. (PSG has since met with all of these companies.)

¹⁸Ben Yeoh (ABN Amro pharmaceutical analyst) research note, ‘Pharmaceuticals and SRI’ February 2004, supports this argument.

¹⁹“Activist accusations may take on huge proportions, perhaps beyond all rationality from a company’s point of view, if, in the eyes of the public, they are connected to other events.” *Managing outside pressure: strategies for preventing corporate disasters*, M Winter and U Steger, John Wiley & Sons, 1998, p.47.

²⁰‘Me-too’ drugs are drugs that are similar to many already on the market.

²¹‘A cure for clinical trials’, McKinsey & Co (2002).

"...I need to balance the demands from the Board...with the needs of patients, customers, colleagues, business partners, and governments and communities.... Realistically, to build Pfizer's value over the long-term, I must negotiate trade-offs among these various stakeholders.

Hank McKinnell, Chairman & CEO, Pfizer Inc, to the Council of Institutional Investors, 4 September, 2003

"The point is, you cannot have maximum profits as the single goal; you have to do something society wants and you'll be paid off."

JP Garnier, CEO of GlaxoSmithKline, Management Today, "The MT Interview," 1 March 2004

2.4 Impact on staff morale and recruitment prospects

PSG is concerned that this issue, if not addressed properly, could also have a damaging effect on staff morale and recruitment prospects. The pharmaceutical industry, like other knowledge-based industries, faces real challenges recruiting and holding on to key staff. The sector increasingly seeks to recruit the best and the brightest on the basis of 'wanting to make a difference'. Such staff are well known for being sensitive to criticisms from friends and family about working for 'unethical' or 'uncaring' companies.²² And as drugs companies recruit more people from emerging markets, especially those where there are significant talent pools from good educational systems (e.g. India, China), this issue may have greater salience in the future.

"We could hire almost anybody we wanted for 10 years because of the feeling in the company."
*Roy Vagelos, Former Merck & Co., Inc. CEO, Wharton Knowledge, June 2004 commenting on the impact of the company's decision to donate Mectizan.*²³

"You don't need a PhD in social psychology to see that employees at any company – especially a company whose business is human health – like to see their employer behave well."

'Benevolence and the bottom line', Financial Times, 14 July 2004

2.5 Securing new markets

While the market opportunities may be very small in the poorest countries, there are significant opportunities in emerging markets. While the global pharmaceutical market is growing at a constant rate (9.4% for 2004), the pace of growth in Latin America and the Asia/Africa/Australia market outstrips that of developed markets at 16.2% and 10.6% respectively, with emerging economies such as China, Mexico, Brazil, Turkey and India recording greater than average growth.²⁴

It is important for companies to establish good relationships with the governments of these countries to help secure future markets and enable them to compete effectively with generics whose penetration of these markets is already strong. A coherent strategy for enhancing access to drugs may be an important factor in building these relationships.

²²A recent employment survey suggests that this may currently be of more importance to European than American staff. *Taking the Industry's Pulse: 5th Annual International Employment Survey, Jan 03, Maribel Rios, Pharma Technology Europe.*

²³Throughout this report, company examples have been used to illustrate or reinforce some of the points we make. We have selected noteworthy examples from the companies we met with. The choice of examples is by no means comprehensive and, given the process undertaken, should not be assumed to indicate that this represents best practice for the sector.

²⁴IMS Health, March 2004.

Table 1: Risks of not addressing the public health crisis in emerging markets and opportunities of doing so

	Risks	Opportunities
<i>Preserving the social contract</i>	Damage to reputation with various stakeholders, particularly governments, resulting in risks to social contract underpinning the patent system and wider licence to operate.	Build/enhance reputation with governments. Protect social contract and integrity of the intellectual property system.
<i>Ensuring a favourable regulatory environment</i>	A perceived lack of response by pharmaceutical companies may damage their relationship with international and national regulatory bodies that control the IP, pricing and drug approval frameworks. Spillover to more mature, profitable markets, where healthcare providers may be more aggressive in calls for downward pricing if the sector is not seen to be acting responsibly elsewhere. Progressive responses can alter the political mood in companies' favour.	Achieve a favourable regulatory environment. Help protect pricing power in premium markets.
<i>Securing new markets</i>	Endanger ability to enter and establish a presence in future markets by failing to establish good relations with host governments and wider stakeholders.	Facilitate entry and secure future markets. Build goodwill with governments. Leadership gains resulting in commercial benefits.
<i>Enhancing staff morale and recruitment prospects</i>	Damage to staff morale and ability to attract & retain employees, especially 'knowledge workers'.	Enhanced employee morale and recruitment prospects.

SECTION 3: INDUSTRY RESPONSE TO DATE

This section outlines key findings from our research including detailed meetings with seven companies. Based on what we heard, it provides an analysis of companies' responses and makes recommendations for further action. It is structured as follows:

- The business case for a proactive response
- Leadership and governance
- Mechanisms for enhancing access to products
- Scope of access programmes (geographical and product range)
- The role of research and development
- Public policy influence
- The benefits of collaboration
- Transparency (performance measurement)

3.1 The business case for a proactive response

Company responses

While most companies indicated that they felt a moral responsibility to respond and were acting because it was 'the right thing to do', every company also agreed that the global health crisis represented a potentially material risk.

Company assessments of materiality varied according to their product mix, geography and projected product portfolios.

It is notable that no company judged the supply of essential medicines in the poorest countries (e.g. LDCs and SSA) to be a business opportunity in the short or even medium term. Most companies focused on the lack of public sector funding and infrastructure as the main barrier to growing these markets. According to one executive, "...governments simply do not have the national budgets to purchase such drugs and therefore companies cannot depend on LDCs for revenue generation." There was little discussion about the private sector market for pharmaceutical products in LDCs and SSA and whether this presented significant opportunities.

This aside, there was a high level of consensus about the potential significance of the issue and the business case for a proactive response. All companies mentioned at least one or more of the following drivers:

- Defending the 'social contract' between governments and pharmaceutical companies, upon which intellectual property law and future innovation depends;
- Limiting the potential for emerging markets to opt out of international patent treaties;
- Protecting company reputation and licence to operate with potential impacts on pricing power in the USA and other lucrative markets;
- Building political goodwill to help secure future markets;
- Improving stakeholder relations;
- Enhancing employee morale and recruitment prospects.

The last point was emphasised by almost all companies, particularly in relation to research staff. One company said that the integration of 'ethical' issues into company strategies was useful for seeking to create a shared mission and culture, particularly during periods of organisational change (e.g. recent mergers and acquisitions).

With regard to political goodwill, some companies have recognised that positive engagement on emerging markets strategies can be an advantage. We heard that politicians and multi-lateral agencies have been less inclined to criticise the sector as a result of its taking a more pro-active stance.

The general consensus seemed to be that significant progress had been made, that the industry was no longer on the back foot, and that attention had shifted back to governments.

PSG view

PSG concluded that companies generally share our concerns about the impact of the crisis on the sector's licence to operate and see sound commercial reasons for taking a proactive approach.

It is difficult for investors to assess whether companies are managing this issue effectively since reporting is not systematic or linked to discussions of investment value. Similarly, few companies have attempted to monitor the impacts of their activities on value drivers such as relationships with regulators and staff morale/recruitment. This may be, in part, because company responses have tended to be initiated as public affairs or philanthropic projects rather than being integrated into core business strategy.

While we broadly agree that the risks would seem to have been contained for the time being, we are concerned that the sector's approach has tended to be somewhat reactive. While there are plenty of examples of good practice initiatives, what is often lacking is a coherent and forward-looking approach that is linked to overall business strategy and takes account of the evolution of disease burdens and patterns of political power and consumer demand over the next 10–20 years. In particular, PSG found little evidence that companies routinely consider access issues in the planning, launch and marketing of new products. This may leave particular companies, and therefore the sector as a whole, exposed in the future.

In terms of the specific issue of staff morale and recruitment, PSG concluded that companies could benefit from closer monitoring of the impact of their activities on this important value driver. This view is shared by influential commentators elsewhere. For example, a recent PricewaterhouseCoopers report concludes that there are significant gaps in monitoring around key value drivers in the industry "including most of the innovation and people measures".²⁵

Recommendations

- **Ensure that strategies for responding to the crisis are coherent, forward-looking and linked to overall business strategy, taking account of the evolution of disease burdens and patterns of political power and consumer demand over the next 10–20 years.**
- **Assess and report on the impact of company responses on value drivers, including relationships with regulators and on staff morale and recruitment.**²⁶

3.2 Leadership and governance

Company responses

All companies indicated that they wanted to be "part of the solution" and that implementing solutions required top-level commitment. Several pharmaceutical companies have emphasised that they see a positive response to the global health crisis as an integral part of their company's vision. However, it is not always clear how this vision is systematically translated into activity on the ground.

"We believe it is part of our responsibility, as one of the world's leading healthcare companies, to use our expertise to improve access to healthcare and our medicines. We are committed to finding healthcare solutions that are sustainable and have a long-term impact, particularly on the lives of those living in the Least Developed Countries and sub-Saharan Africa"

Roche website July 2004

"Our business is focused on the discovery and development of life-saving and life-enhancing medicines. Historically, the markets for these therapies have been in developed countries but as the economies of developing countries grow, new markets for our prescription medicines emerge"

Sir Tom McKillop, Chief Executive, AstraZeneca.

The global health challenge encouraged **Merck & Co., Inc.** to "Rediscover what we always knew... that the company's interests will be best served when the public is served best"

Raymond V. Gilmartin, Merck Chairman, President and Chief Executive Officer.

Several companies emphasised the fact that the lack of a conducive policy environment and healthcare infrastructure in developing countries can inhibit their ability to act. However some, such as **Merck & Co., Inc.**, **Bristol-Myers Squibb** and **GSK**, have displayed leadership by pushing boundaries in relation to public-private partnerships, which has in turn stimulated greater government action.

²⁵"A New Rx for Corporate Disclosure: Realising the Value in the Pharmaceutical and Healthcare Products Industries"; PricewaterhouseCoopers, 2004.

²⁶While PSG recognises that qualification of impacts is extremely difficult, it encourages companies to identify and communicate the business benefits of action more clearly - particularly to the investment community.

Some companies described clear governance structures for management of this issue, with defined ownership and responsibility at board level and below. This included the appointment of directors with specific responsibility for access to medicines in some cases. For example, in 2003, **AstraZeneca** appointed an Access to Medicines Director (Oncology and Infection) and **GSK** has included access to medicines among the responsibilities of a senior manager.

Several companies have channelled some or all of the ATM activity through company foundations. PSG noted, however, a lack of clarity in some cases over the role of these foundations. Matters of governance, policy and delivery were sometimes opaque and it was sometimes difficult to understand the extent to which access programmes originating with company foundations were linked to the parent company's core business.

PSG view

While company practice varies widely, PSG agrees that board level leadership and explicit high-level responsibility and accountability is critical in managing this issue effectively, as is the integration of access to medicines into core business strategy. It is particularly important to demonstrate that responsibility reaches beyond corporate affairs and is not a satellite activity and that companies are actively monitoring and forecasting key risks. Several companies are already doing this through scenario planning exercises, which is an indication of forward-thinking management.

Recommendations

- **Communicate clearly how the board views this issue in the context of core business strategy. This should go beyond high-level vision statements and articulate what the company expects to achieve.**
- **Establish clear board accountability. Options include a board member or committee with specific responsibility for the company's response to the health crisis in emerging markets.**
- **Demonstrate how this responsibility is effectively delegated and monitored.**
- **Use scenario planning or other tools to help monitor/forecast key pressures on the current business model and inform company responses.**

3.3 Mechanisms for enhancing access to products

Company responses

There are a variety of mechanisms that companies can use to enhance access to medicines including product donations, patent immunity, partnerships, differential pricing and voluntary licensing. The optimum mix of mechanisms will vary from company to company, depending on factors such as disease dynamics, product portfolio fit and geographical exposure.

All companies reported that they were using at least one of these mechanisms to enhance access to their products in these markets and all continue to strengthen their expertise. Overall, PSG noted that not all companies were able to set out a clear rationale for choosing one approach over another. Further, while some companies displayed a willingness to try several mechanisms, others were less willing to experiment with multiple approaches.

i. Patent-infringement immunity and voluntary licensing²⁷

Some companies, such as **Novartis** and **Roche**, have indicated that they will not act against infringement of patents in certain countries for certain drugs. In the case of **Roche**, a financial impact analysis concluded that not upholding patents in Least Developed Countries and Sub-Saharan Africa would have minimal impact. **Bristol-Myers Squibb** have a particularly clear policy on patent infringement immunity. However, in most companies, decisions on whether to enforce patents are taken on a case-by-case basis. In deciding on whether to allow voluntary licensing, a key consideration is the reliability for the licensee to market and/or distribute products to best effect.

²⁷Patent infringement immunity is the process by which companies offer countries immunity from legal challenge if they infringe certain patent rights. Voluntary licensing is the process by which companies choose to license their patents to generic producers.

GSK has issued voluntary licences for production of key antiretrovirals to Aspen and Thembalami in South Africa, which allow sale of the antiretrovirals throughout Sub-Saharan Africa. Other licences are under negotiation in South Africa and elsewhere. It also has a technology transfer, supply and license arrangement in place with the Brazilian government for the production of the measles, mumps and rubella vaccine.

In July 2001, Hetero, an Indian manufacturer, struck a deal with Aspen Pharmacare in South Africa to supply active ingredients and the technology for the manufacture of finished products of two of **Bristol-Myers Squibb's** HIV/AIDS drugs. Aspen subsequently received an undertaking from Bristol-Myers Squibb that it would not sue the company if it produced copies of its drugs for distribution in South Africa and 47 other countries in Sub-Saharan Africa.

In July 2004, **Merck & Co., Inc.** granted a non-exclusive patent license for the manufacture and sale of a generic version of efavirenz, one of its HIV/AIDS drugs, to Thembalami Pharmaceuticals Ltd, for South Africa and other countries in the Southern African Development Community. This will cover both the public and private sectors in these countries.

ii. Pricing

Prior to the South Africa court case, companies operated differential pricing in various markets on a case-by-case basis. However, since then, the sector has been called upon to extend and formalise differential pricing offers in emerging markets. Some companies have historically been reluctant to do this, contending that a concern over parallel importing restricts rollout. The degree of concern varies between companies. One company argued that the diversion issue is over-stated and re-importation problems can be negated if the drug distribution process is properly managed. Others were more tentative, but it appears that concerns are subsiding overall and many companies are now adopting differential pricing as the most sustainable solution. In most cases, these offers are made to governments in the first instance although a number of companies are also offering them to NGOs and employers.

In terms of disclosure of pricing offers, individual company practices still vary. Most companies are now transparent on pricing offers but some still cite confidentiality issues and commercial risks as obstacles to disclosure. One company stated that they had no plans to disclose pricing "as this is commercially sensitive and will lead to downward pricing pressures in other markets". Another company sought to minimise this risk and build acceptance of the need for higher prices in its mature markets by explaining the rationale and detail of its pricing strategy in advance to advocacy groups and health care officials in the EU and USA.

Accelerating Access Initiative (AAI): Established in May 2000, the AAI is a partnership among UNAIDS, the WHO, UNICEF, the UN Population Fund, the World Bank and seven pharmaceutical companies (Abbott Laboratories, Boehringer Ingelheim, **Bristol-Myers Squibb**, **GlaxoSmithKline**, Gilead Sciences, **Merck & Co., Inc.** and **Roche**). Participants in the AAI are committed to working with governments, international organisations and other stakeholders to find ways to broaden access while ensuring rational, affordable, safe and effective use of drugs for HIV/AIDS-related illnesses. While it is widely recognised that affordability is just one of the many issues to access, the companies, individually, have offered to substantially improve access to, and the availability of, a range of medicines by providing more affordable prices in developing countries.

GSK offers ARVs and anti-malarials at fixed, not-for-profit prices to public sector customers and non-profit organisations in the LDCs (as defined by the UN) and SSA, to employers in SSA which provide HIV/AIDS treatment to their staff through workplace clinics, and to fully-funded Global Fund projects. This means the not-for-profit prices are available in over 100 countries. The prices are available on their website. GSK state they set their prices at a level at which they neither make a profit nor lose money – this means the not-for-profit price can be sustained as long as patients need the product. GSK are also committed to the AAI which enables ARVs to be available at discounted prices to participating countries. For middle income countries GSK negotiates public sector prices for these treatments on a case-by-case basis both bilaterally and through the AAI.

Roche operates no profit pricing for its HIV protease inhibitor medicines, Invirase (saquinavir) and Viracept (nelfinavir) for people living in LDCs and SSA. The prices are ex-factory prices direct from Roche's headquarters in Basel, Switzerland, and are available to the public and private sectors in these countries. The prices available for direct supply from Roche headquarters mean that additional costs for freight, import, duty, taxes, distribution and inventory need to be added. The retail prices within these countries will therefore be higher and may vary substantially.

AstraZeneca has committed to consider access to medicines when defining pricing and market access strategies for new brands.

iii. Donations

Most companies argued that donations were a valuable tool in specific circumstances, such as when the disease dynamics require only one-off treatments or vaccinations. **Novartis** and the Novartis Foundation for Sustainable Development has committed to providing free treatment for all leprosy patients until the disease has been eliminated from every country, through the WHO. However, there is general agreement that donations are less commercially sustainable than other mechanisms. **Roche** said that, in principle, it does not make drug donations because of concerns about their long-term sustainability except for emergency relief or in cases meeting the WHO guidelines for drug donations. However, **Pfizer** argued that it focussed on donations rather than differential pricing because some countries cannot afford to purchase even at heavily discounted prices. Pfizer did, however, indicate it was considering differential pricing for future products including the HIV/AIDS product in its pipeline.

PSG view

PSG believes that there is no 'one-size fits all' approach and the optimum mix of mechanisms will depend on company specific factors including product portfolio. However, it also believes that it is important for companies to be clear about the rationale for adopting one approach over another (e.g. donations over differential pricing) and that they should continually review the suitability of their approaches. It is also important for companies to routinely integrate access issues into the planning of future product launches and marketing so they are prepared to respond to increasing demand for a wider range of products in the future.

PSG also concluded that companies that are developing expertise in a range of approaches (e.g. voluntary licensing, differential pricing, donations) will be better prepared to respond to changing expectations and regulatory environments. Conversely and also looking to the future, companies that focus exclusively on one approach can expect to have to provide fuller justifications for their approach.

With regard to pricing disclosure, the fact that several companies have disclosed their prices indicates that concerns about commercial sensitivity are not shared across the industry. Transparency over pricing offers is an important tool for enhancing trust in the industry and demonstrating its contribution to addressing the public health crisis. While PSG understands that there may be concerns about downward pricing pressures in traditional markets, it believes that lack of disclosure is not the best way to manage this risk. Indeed, this approach could exacerbate mistrust and actually fuel discontent with pricing policies in mature markets. Some companies are beginning to use transparency and better relationships with governments, investors and others to engage in a debate about the importance of differential pricing, with regulators and legislators in all regions playing their part. PSG considers this strategy to be much more likely to be effective. Having an objective, standards-based strategy for defining pricing would also allow companies to raise prices as countries become more developed and GDP increases.

Recommendations

- **Establish and communicate a clear rationale for the choice and scope of access mechanisms and the rationale for the geographical boundaries of pricing offers. Provide evidence that the pros and cons of alternative options have been considered carefully, as have factors such as commercial sustainability, proportionality, effectiveness and risks of diversion.**
- **Integrate access issues into key stages of product life cycle including product launch and marketing.**
- **Demonstrate flexibility and breadth by using a range of options where appropriate.**
- **Consider disclosing pricing offers wherever possible.**

3.4 Scope of access initiatives (geographical and product range)

Company responses

In developing their response to public health needs in LDCs such as Africa, companies indicated that the business case for action did not really relate to the likelihood of viable markets developing even in the medium term, but rather was more indirect and related to risks to their social contract, reputation and relations with regulators and governments. Hence, their responses were more in the area of philanthropy and or 'non-profit making' activity (e.g. 'at cost' pricing). For others countries like Brazil, India and China – and to a lesser extent those in Central and Eastern Europe – companies appeared convinced of the value of securing and developing significant market opportunities. However, they reported few projects designed to deliver drugs to poorer communities in these countries. Some companies, including **Merck & Co., Inc.** and **Roche**, do have programmes with greater geographical and more systematic reach.

Merck & Co., Inc. has developed an innovative approach for determining country eligibility for three tiers of pricing discounts for CRIXIVAN™ and STOCRIN™ based on the United Nations' Development programme Human Development Index (HDI) and adult HIV/AIDS prevalence rates as reported by UNAIDS. Under this scheme, all low HDI countries and all medium HDI countries with an adult HIV prevalence rate of 1% or greater qualify for the lowest prices where Merck makes no profit. This group includes all countries in SSA, as well as countries in Asia, Latin America and Eastern Europe (e.g. Thailand, Cambodia, Haiti, Guatemala, Honduras, Panama). Countries in the medium HDI category with an adult HIV prevalence of less than 1% (e.g. Brazil, Egypt, Malaysia) also qualify for significant discounts. Once a country's eligibility is established, any customer within that country has access to the drug at that one price.²⁸

Roche includes countries categorised as low and lower middle income countries (e.g. India and Brazil) in its differential pricing programme.²⁹

In general, companies did not give examples of how learning from well-developed access programmes (e.g. in Sub-Saharan Africa) was being shared across geographical boundaries, although **Novartis** made a strong reference to the transferability of core principles and some practices.

PSG view

Given the fundamental dynamics at work (e.g. the growing power of BRIC countries in trade discussions and the enormous impact of AIDS in these countries), it is clear that the public health crisis in emerging markets is going to become a bigger challenge year on year. This is an issue that is certainly not going to go away. Indeed, whilst the current focus is on infectious diseases, the growing prevalence of First World diseases in Third World countries means the range of drugs that will come under scrutiny will increase. We did not hear a convincing story that the sector is ready for this – i.e. that it has a proactive strategy for adapting to these new realities.

Exactly why this is the case is something that PSG cannot make a definitive conclusion about. Like all well-run companies, pharmaceutical companies are highly proficient at spotting new market opportunities so it may simply be that the sector is not ready to communicate its strategy on emerging markets and how questions of access relate to core business strategy. Alternatively, it may be that companies are coming to conclusions about limited commercial viability in certain markets as a result of applying the prevailing business model approach used in mature markets (e.g. high price, low volume) to such countries.

However, this traditional model has important variations even in the USA (e.g. long-standing discount cards for elderly and more recently the un-insured; plus discounted payments via Medicaid). It is plausible, therefore, that the sector may benefit from developing more integrated strategies that make flexible use of other business models (e.g. sector collaboration to support infrastructure development³⁰, voluntary licensing for high volume, low premium sales, etc.). How pharmaceutical companies choose to respond to this challenge is a management decision but what investors would like to better understand is the range of strategic options they are considering, the choices they are making and the reasons for these decisions. We believe this will be an important window on quality of management – one of the most important factors when choosing between companies in a given sector – in an increasingly globalised world.

²⁸Merck & Co., Inc., Pricing Policy for CRIXIVAN™ and STOCRIN™ in Developing Countries, April 2004.

²⁹<http://www.roche.com/med-cor-2004-06-08>

³⁰Some positive examples in this regard are the Initiative on Public-Private Partnerships for Health, Medicines for Malaria Venture and the Global Alliance for TB Drug Development. Even here, however, not all the companies that could be involved are fully engaged. Even less well-developed are projects to co-ordinate resources within emerging market countries. The absence of such co-ordination can seriously over-stretch local capacity and undermine impact - see the forthcoming report from UNAIDS (Aids in Africa: Scenarios for the Future).

Recommendation

- **Demonstrate the extent to which companies are assessing future opportunities in emerging markets and what assumptions they are making in terms of future business models for these markets.**

3.5 Research and development

Company responses

Most companies indicated that their most important contribution to addressing the global health crisis is through their investment in R&D, particularly for 'developing country' diseases. This includes both diseases that are global (e.g. HIV/AIDS) and those that are largely restricted to the developing world (e.g. malaria, TB, sleeping sickness). Despite the uncertainty about their profitability, a number of companies continue to invest significant amounts in these disease areas. In some cases, this has involved establishing specialist units or research centres (see box below).

AstraZeneca: In 2001, **AstraZeneca** announced that it would invest US\$10m in capital for a new R&D facility in Bangalore, India, which would focus wholly on finding a new treatment for tuberculosis (TB). More specifically the centre will look at developing improved diagnostic tests and more effective therapies. The facility was completed and opened in June 2003. The company has committed to an additional US\$10m on equipment and a further minimum US\$5m a year from 2001–2005 to support research programmes.

Novartis: The Novartis Institute for Tropical Diseases (NITD) in Singapore is dedicated to research on tropical diseases. It was established in 2001 and aims to address diseases, initially TB and dengue fever, that Novartis feels do not attract sufficient research funding in our market driven world.

GSK has an extensive portfolio of products and R&D projects for diseases of the developing world and is undertaking R&D into the prevention and treatment of all three of the WHO's priority diseases in LDCs: HIV/AIDS, tuberculosis and malaria. It has over 20 R&D projects and programmes of relevance to LDCs, ten of which are aimed at producing vaccines and medicines for diseases that disproportionately affect LDCs. In addition to R&D on AIDS, it created an R&D Group at its Tres Cantos laboratory which is dedicated to 'Diseases of the Developing World'. Projects are prioritised primarily on socio-economic and public health benefits rather than on their commercial returns with the current focus on malaria and TB.

PSG view

PSG wholeheartedly agrees that R&D is a critical component of the sector's contribution to addressing the global health crisis. Without continued R&D, there will be no cure or vaccination for HIV/AIDS and other life-threatening diseases and the efficacy of existing treatments will be eroded as resistance levels increase. Moreover, PSG thinks that the sector does not communicate its contribution through R&D as effectively as it might. Enhancing public understanding of the sector's vital role in this area could help manage perceived negative factors such as those relating to pricing strategies.

It is also important to acknowledge the major barriers to R&D into diseases that are relevant to developing countries.³¹ One is that marketing imperatives can tend to dominate R&D decisions early on. As the pay-off is unlikely to be anywhere near as high as for R&D into developed world drugs, health needs in developing countries can be neglected. There are also various risks associated with R&D into developing world diseases which can also reduce corporate commitment to undertake such investment. These include the complexity and relative lack of understanding of the science of these less researched diseases and the lack of information about and access to patients in some countries. What is required to stimulate R&D in these circumstances are mechanisms that provide incentives for research (e.g. R&D tax credits) or help create secure markets which ensure returns on investments.

³¹Less than 10% of global spending on health research is said to be devoted to diseases or conditions that account for 90% of the global disease burden - see Global Forum for Health 10/90 Report on Health Research 2001–2002 www.globalforumhealth.org

PSG believes that companies have been wrongly criticised for not investing in so-called neglected diseases where the commercial incentives are weak. It is government's role to create the context where necessary research happens. This may happen through the Global Health Fund, although its capacity to perform this role has been seriously hampered by low levels of funding from most EU countries combined with little support from the USA. Of the \$15bn that President Bush announced in 2003 would be spent on AIDS, only \$15m has been allocated to the Fund.³² The UK Government has committed to scaling up its own financial and analytical support for R&D and has made clear its intent to see the Fund succeed, not least by announcing that it would double its own contribution to more than £150m.³³ The critical issue, however, is whether it will be able to use its presidency of the G8 and EU in 2005 to ensure a more effective and co-ordinated international response since, without this, new incentives for relevant R&D are likely to be, at best, sub-optimal.

Recommendations

- **Communicate more effectively the sector's contribution through R&D.**
- **Encourage governments to create the right incentives for further investment in related R&D.**

3.6 Collaboration and sharing good practice

Company responses

Some companies recognised that there can be sound commercial reasons for working together to find innovative solutions and to enhance the reputation of the industry as a whole since all companies suffer if public trust in the sector remains at a low ebb. Although speaking about another issue, one executive reported a conversation where the analyst said "I love your house but I hate your neighbourhood" to indicate how individual companies can be hampered by the performance and perception of the sector as a whole. Some examples of collaboration to find innovative solutions are set in the box below.

Accelerating Access Initiative (AAI) – See Box p.18.

In May 2004, **Merck & Co., Inc.**, Gilead Sciences and **Bristol-Myers Squibb** announced a collaboration that is considered the first of its kind in the field of HIV/AIDS. They are developing a once-daily, fixed-dose combination of three HIV/AIDS drugs (tenofovir disoproxil fumarate, emtricitabine and efavirenz), as well as exploring certain co-packaging options for the components of the combination. The companies agree on the importance of the task—to support the need for simplified treatment regimes, particularly in resource-constrained settings such as in the developing world.

In May 2004, **GlaxoSmithKline** and Boehringer Ingelheim also announced an agreement to assess the development of co-packaging of HIV/AIDS drugs for the developing world. The belief is that treatment simplification can help to optimise therapy.

In addition to sharing learning externally, it is important for the development of access policies and strategy that learning is shared within the company. **Novartis** is notable in stating that its efforts are informed by a 'learning by doing' approach. A key lesson for it was the need to apply "more flexibility and innovation for more complex treatments"³⁴ and in its meeting with PSG, it mentioned the need to transfer learning between programmes in mature and developing countries.

PSG view

PSG agrees that there can be a business case for collaboration with peer companies in certain cases. In most cases, the incentive is to enhance the reputation of the industry as a whole. PSG recognises that there may be a tension between this objective and that of gaining leadership advantage from superior performance on access issues. Companies will need to balance these two objectives in identifying potential areas for collaboration in the short term. Over time, they could better educate their stakeholders to recognise the leadership importance of collaboration, so that the rules of the game are changed and all parties could compete at collaborating.

In situations where the argument against entering a developing market is one of cost or lack of opportunity, it may make commercial sense for companies to share the burden. For example, sharing costs for infrastructure, distribution and marketing between companies with complementary portfolios, would lower the barriers to entry and reduce the hurdle rate for obtaining a satisfactory return.

³² 'Who should lead the war on Aids?', Pete Engardio, *BUSINESS WEEK*, 15 July 2003

³³ <http://www.number-10.gov.uk/output/Page6141.asp>

³⁴ *Novartis Partnership Programmes presentation at INSEAD July 2003.*

PSG also feels that sharing learning and good practice will ensure that future initiatives are effective and sustainable and reduce the potential for the kind of pitfalls experienced by some companies in the past.

Recommendations

- **Identify areas where collaboration can generate commercial benefits.**
- **Communicate good practice and share learning in the industry to maximise success.**

3.7 Public policy influence

Company responses

Most companies we spoke with accepted that there is growing concern about the relationship between a company's policies on access to medicines and the appropriate use of their influence on governments at the local, national and international levels.

All companies stated that they have a right to lobby assertively to protect the industry's interests and make political donations. However, no company seemed to have in place a clear process for ensuring consistency between lobbying activities and access strategies. A few companies seemed more alert to the risks from a public perception perspective than the sector as a whole. The Corporate Responsibility Committee of **GSK**, for example, had recently considered the wider implications of the issue including the impact on the company's and the industry's reputation.

Some companies have committed to using their influence positively to address this issue. Many have publicly encouraged other stakeholders to take involved, and some, such as **Bristol-Myers Squibb** and **Pfizer**, have been vocal in their support of initiatives such as the USA HIV/AIDS bill. (See box below).

Some companies highlighted the importance of encouraging emerging market governments to invest in health care infrastructure and put in place the right policy prerequisites for drug availability programmes to be effective. Others were less clear about their boundaries with regard to whether it was legitimate for them to attempt to influence developing country government expenditure in developing countries.

Roche said it is not the duty of companies to tell a developing country government to spend more on health care. However, it was using its influence in appropriate spheres such as the Global Fund and NGOs to raise such issues.

In May 2003, President Bush enacted an international HIV/AIDS bill that would authorise US\$15bn over five years to fight the disease in Africa and the Caribbean (US\$3bn a year for five years to international programmes, with up to US\$1bn in 2004 going to the Global Fund to Fight AIDS, Tuberculosis and Malaria). The bill is said to have received significant public support from some pharmaceutical companies, including **Bristol-Myers Squibb** and **Pfizer**, and some investors first heard of the President's initiative from the IR department of one company.

Merck & Co., Inc. state that "Corporations must be willing to help build the capacity to get those medicines to the people who need them".

PSG view

PSG is aware that the sector, and its trade associations, has been heavily criticised for allegedly misusing their influence and failing to ensure that their lobbying positions were consistent with their corporate responsibility activity and that this criticism is now common even in mainstream business-friendly settings.³⁵

We are concerned that this poses a reputational risk to the sector. Lobbying can play a critical role in promoting a company or a sector's commercial and political interests but can become distorted or over-simplified, particularly when carried out by trade bodies. It may also directly conflict with other company objectives, such as those on access to medicines. This poses a reputation risk to the sector as a whole.

³⁵See, for example, *Drug Makers' Paths of Influence Need to Be Less Hidden*, 11 November 2003 and *Drug-Importation Vote Is Cue For Industry to Change Its Ways*, 29 July 2003 by Alan Murray, *Wall Street Journal* and the June 2004 letter from ICCR to PhRMA.

From a long-term investment risk perspective, well-diversified investors have an interest in seeing that markets work efficiently and that public policy is not captured by special interests groups – in this regard, investors have a duty to be “pro-market and not pro-business.”³⁶ As explained earlier (see section 2.1), investors also have an interest in ensuring that governments do much more than they are currently doing to better manage the public health crisis in emerging markets.

For these reasons, PSG considers that the industry as a whole needs to significantly enhance its performance on this issue. Whilst there are no magic solutions, we do consider the essential step forward to be greater disclosure on lobbying activities and exploring ways to provide assurance of consistency in public and private policy positions, including the positions taken by trade associations and management in different countries. This should help prevent questions about the industry’s integrity and limit damage to companies’ reputations.

PSG also believes that companies are in a unique position to lobby developing country governments to ensure that the necessary policy pre-requisites are in place for effective access programmes including the adequate healthcare infrastructures. This will not only help to ensure the effectiveness of company programmes but, in the long-term, could help to develop new markets for the pharmaceutical industry.

Recommendations

- **Establish internal procedures to ensure private lobbying activity is consistent with public positions and that any major discrepancies in any region are reported to the board.**
- **Report on the policy challenges that the company faces with regard to emerging markets and the lobbying positions that have an impact on public health in emerging markets, and indicate how these contribute to long-term value. These should include positions on international trade and patent protection (whether as a company or through trade and industry bodies).**
- **Use influence with emerging market governments to encourage a policy environment and investment in health care infrastructure that is conducive to meeting the needs that exist.**
- **Use influence with mature market governments to encourage proactive responses to the public health crisis in emerging markets as needed.**

3.8 Transparency and performance measurement

Company responses

Companies expressed concern that the industry’s performance on this issue is highly dependent on factors outside its control such as government action to establish health care infrastructure and to create the right incentives for investment in R&D. It is therefore difficult to set targets when their achievement is only partially under company control.

Despite this, some companies have introduced measures of performance in this area. These include numbers of supply arrangements, number of countries supplied with certain drugs, value of projects and, in some cases, project objectives and goals. These companies were, however, the exceptions.

In terms of external metrics, some companies are reporting using Global Reporting Initiative guidelines and have expressed an interest in the development of sector-specific GRI guidelines for the pharmaceutical sector. Both **Novartis** and **AstraZeneca** already report using the GRI guidelines for general corporate responsibility and **Novartis** expressed the greatest interest in the further development of industry-specific guidelines. Others felt that, as companies’ programmes and approaches were so diverse and newly-developed, sector-specific guidelines covering access issues would be premature. Some companies indicated that there was a degree of scepticism in the industry towards the introduction of additional reporting frameworks as the industry was already too heavily regulated and already very responsive.

³⁶The Economist, ‘Pro-market, not pro-business’, 26 June 2003

In reporting on performance, many companies have focused on output data.

Bristol-Myers Squibb reports on the total value of funds allocated for grants, the number of programmes in operation and the number of people recruited/trained.

GSK reports on the progressive reduction in price offers, the number of agreements it has to supply drugs and the number of countries this relates to, as well as the total volume of drugs supplied.

Merck & Co., Inc. reports on the number of drugs donated through its programmes.

Novartis, in its Annual Report, summarises in tabular form its projects, objectives, focus regions and costs, as well as the number of new patients reached in a particular year and the total number so far.

All companies report on new agreements and partnerships as they develop, as well as progress in their R&D pipelines.

PSG view

The nature and level of disclosure on this issue has improved significantly. However, it still lags behind the industry's disclosure on other corporate responsibility issues and is largely confined to qualitative descriptions. There is some mention of specific policies and systems, but few performance indicators and little discussion of performance against policy. Furthermore, there is a general lack of consistency in terms of reporting content, making it difficult for investors to benchmark management and performance. While the volume of information from companies on access continues to increase significantly, it is generally not related to value creation or core business strategy issues.

PSG appreciates the challenges of identifying meaningful performance indicators and targets in this area particularly when performance is often dependent on factors outside the sector's direct control. That said, we believe that an absence of performance data makes it difficult for investors to make meaningful comparisons and for the sector as a whole to tell a credible story. Investors would benefit from consistent reporting across companies. We would also welcome more information on outcomes (drug success rates) as opposed to outputs (e.g. numbers of drugs delivered). Much of this work could usefully be done collaboratively and there are various initiatives which could be used, such as the GRI and the Enhanced Business Reporting Initiative³⁷.

In terms of enhancing public understanding and trust, it is advisable to establish targets and indicators and to explain that their achievement is partly dependent on outside factors. Not only does this help manage external expectations; it also highlights the very real challenges involved in delivering positive outcomes.

Recommendations

- **Consider the extent to which existing data monitoring processes capture the full scope of access initiatives, and review as necessary and appropriate.**
- **Set objectives and identify KPIs and performance targets where possible and monitor performance against these targets.**
- **Consider the development of an industry-wide common reporting framework.**

³⁷<http://www.ebrconsortium.org/>

Table 2: Summary of recommendations

	Recommendations
<i>Business rationale</i>	<ul style="list-style-type: none"> • Ensure that strategies for responding to the crisis are coherent, forward-looking and linked to overall business strategy, taking account of the evolution of disease burdens and patterns of political power and consumer demand over the next 10–20 years. • Assess and report on the impact of company responses on value drivers, including on relationships with regulators and on staff morale and recruitment
<i>Leadership & governance</i>	<ul style="list-style-type: none"> • Communicate clearly how the board views this issue in the context of core business strategy. This should go beyond high-level vision statements and articulate what the company expects to achieve. • Establish clear board accountability. Options include a board member or committee with specific responsibility for the company’s response to the health crisis in emerging markets. • Demonstrate how this responsibility is effectively delegated and monitored. • Use scenario planning or other tools to help monitor/forecast key pressures on the current business model and inform company responses.
<i>Mechanisms for enhancing access to products</i>	<ul style="list-style-type: none"> • Establish and communicate a clear rationale for the choice and scope of access mechanisms and the rationale for the geographical boundaries of pricing offers. Provide evidence that the pros and cons of alternative options have been considered carefully, as have factors such as commercial sustainability, proportionality, effectiveness and risks of diversion. • Integrate access issues into key stages of product life cycle including product launch and marketing. • Demonstrate flexibility and breadth by using a range of options where appropriate. • Consider disclosing pricing offers wherever possible.
<i>Scope of access initiatives</i>	<ul style="list-style-type: none"> • Demonstrate the extent to which companies are assessing future opportunities in emerging markets and what assumptions they are making in terms of future business models for these markets.
<i>Research & development</i>	<ul style="list-style-type: none"> • Communicate more effectively the sector’s contribution through R&D. • Encourage governments to create the right incentives for further investment in related R&D.
<i>Collaboration & sharing best practice</i>	<ul style="list-style-type: none"> • Identify areas where collaboration can generate commercial benefits. • Communicate good practice and share learning in the industry to maximise success.
<i>Public policy influence</i>	<ul style="list-style-type: none"> • Establish internal procedures to ensure private lobbying activity is consistent with public positions and that any major discrepancies in any region are reported to the board. • Report on the policy challenges that the company faces with regard to emerging markets and the lobbying positions that have an impact on public health in emerging markets, and indicate how these contribute to long-term value. These should include positions on international trade and patent protection (whether as a company or through trade and industry bodies). • Use influence with emerging market governments to encourage a conducive policy environment and investment in health care infrastructure as is needed. • Use influence with mature market governments to encourage proactive responses to the public health crisis in emerging markets as is needed.
<i>Transparency (performance measurement)</i>	<ul style="list-style-type: none"> • Consider the extent to which existing data monitoring processes capture the full scope of access initiatives, and review as necessary and appropriate. • Set objectives and identify KPIs and performance targets where possible and monitor performance against these targets. • Consider the development of an industry-wide common reporting framework.

SECTION 4: CONCLUSION

As a group of institutional investors with actual and potential exposure to the pharmaceutical industry, PSG has a legitimate interest in protecting long-term shareholder value by ensuring the industry addresses significant risks and opportunities. Early on, PSG felt that the public health crisis in emerging markets was likely to have profound implications for the pharmaceutical industry, both in terms of risks and opportunities. However, the exact nature and significance of these risks and opportunities was difficult to determine. To address this, PSG initiated a process to better understand the issue, evaluate the industry's response to date and draw out some conclusions on what additional action could be required to protect and enhance shareholder value.

Dialogue with senior management of leading companies using the framework developed by PSG was a key element of this. Having completed our programme of engagement activities, PSG has gained valuable insights which we believe can inform the ongoing debate and, more specifically, help to guide companies' management of the issue in an effective manner.

PSG's overall conclusion was that, while much progress has been made in recent years, further improvement is nevertheless needed. Our learning has led us to draw a number of recommendations (contained in the previous section) which are intended to guide companies on what they should do to manage the issue. These have in turn led to PSG distilling eight key elements on how companies can develop an effective strategy with regards to the opportunities and challenges posed by the public health crisis in emerging markets. These are as follows:

- **Articulate the business case:** While recognising that companies may have philanthropic reasons for their activities, a clear articulation of the business case for action and its potential impact on long-term value/risk is the essential underpinning of a good practice strategy.
- **Promote leadership at board level:** A board member or committee with specific responsibility for this area of corporate activity is critical because various aspects of corporate strategy will need to adapt to allow progress in this area.
- **Take a forward-looking approach:** A good practice strategy needs to be forward-looking and take account of evolving disease burdens and patterns of consumer demand over the next 10–20 years.
- **Objectively assess alternative options:** This should take into account factors such as such commercial sustainability, proportionality, effectiveness and risks of diversion.
- **Show flexibility and breadth:** Companies that have expertise in a range of approaches (e.g. voluntary licensing, differential pricing, donations) will be better prepared to respond to changing expectations and regulatory environments.
- **Collaborate and share best practice:** Collaborating with peers in order to deliver innovative solutions, contain the problem of 'free-riders' within the sector and generally rebuild public trust is another important criterion.
- **Demonstrate responsible use of influence in public policy:** It will become increasingly important to provide evidence that a company's public policy positions and lobbying efforts are aligned with its access targets and strategy.
- **Track performance and be transparent:** Systematic reporting of goals, objectives and activities, ideally with relevant KPIs and performance targets, and discussion of how these activities relate to core business strategy and value creation will allow for continuous improvement.

PSG recognises that responding to the public health crisis in emerging markets is a dynamic issue. Through addressing the above elements as part of an overall strategy, this will help companies better articulate their approach to investors and other stakeholders, which in turn will help investors understand and support sound management decisions. PSG welcome dialogue and feedback with companies and other stakeholders on the usefulness of the observations and suggestions set out in this report.

Appendix 1: March 2003 investor statement & framework of best practice and current recommendations

As mentioned in the introduction of this report, the initial focus of PSG was to consider how the sector was addressing the challenges related to the public health crisis in emerging markets.

The Pharmaceutical Shareowners Group (PSG) was established following the launch of an investor statement and framework outlining good practice on pharmaceutical companies and the public health crisis in emerging markets³⁸ in March 2003 by ISIS Asset Management and the Universities Superannuation Scheme Ltd and supported by a group of global financial institutions representing some £600 billion in funds under management. Following the announcement of the March 2003 framework, the (then) 12 institutional investors supporting the guidelines decided undertake collaborative engagement based on the framework with selected pharmaceutical companies. In order to do this effectively, they formed PSG as a group, with a Steering Committee, Chair and Secretariat.

PSG believe that the March 2003 framework reflected best practice at the time. However, we recognise that the management of this emerging issue is a dynamic process. Specific examples of noteworthy practice will change over time, reflecting greater understanding, experience and other external factors.

The areas addressed by the March 2003 Framework of Good Practice are:

- Risk management & internal controls: companies to disclose whether the Board had identified and assessed the significant risks or opportunities to the company's short- and long-term value arising from this issue, whether the company had in place effective systems for managing these and, where relevant, incorporate this into performance management systems and appropriate remuneration incentives;
- Good practice management: in developing policies and systems, companies to consider examples of good practice as outlined by PSG. In particular, investors were keen to understand the rationale for companies adopting specific policies or approaches as this would give them a better indication of the risks and rewards involved. Examples of good practice were suggested on the following issues:
 - Research & Development (R&D)
 - Pricing & patents
 - Diversion
 - Public-Private Partnerships (PPPs)
 - Product donation programmes
 - Measuring impact and effectiveness of programmes
 - Product research and marketing
 - Leadership and use of influencing (public policy lobbying)
 - Transparency & openness

As the report has demonstrated, the March 2003 framework provided an extremely useful starting point for company discussions. It helped to ensure a common basis on which PSG could explore the issue with all companies, and so facilitate broad benchmarking of approaches and performance. The framework enabled PSG to test out whether the topics and approaches identified were indeed significant components of companies' responses to risks and opportunities, and to what extent. It also allowed the Group to identify gaps in its knowledge and develop our understanding of the issues, so as to inform our further questions and future activities.

The framework allowed us to identify companies' responses on particular issues, such as pricing and R&D – but was not able to convey companies' overall response on the broader issue of access strategies in emerging markets. In other words, it focused on specific approaches and initiatives, rather than on generic principles and companies' overall strategies on issues surrounding access.

In this report, PSG highlights key elements of a corporate strategy for addressing access issues in emerging markets which complement the March 2003 framework of best practice. The report is intended to aid companies by indicating areas they should consider in developing a corporate strategy on issues relating to access in emerging markets, whilst the framework provides a set of options for mechanisms for implementing them.

³⁸ Available at www.pharmashareownersgroup.org

With thanks to CIS for the design, printing and distribution of this report.

