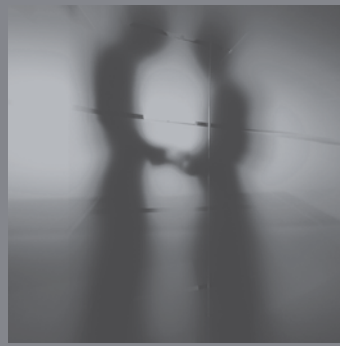


Access to Medicines: back on the agenda

reo® Research

October 2007



In this report...

- Why the issue of Access to Medicines is back on the agenda – and the industry's existential crisis
- Key elements of an Access to Medicines strategy – and when to bring in the lawyers
- Four recommendations for pharmaceutical companies

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1. Why Access to Medicines is back on the agenda

2002: the start of the public debate

Five years ago, the pharmaceutical industry was stunned by fierce criticism from a coalition of anti-poverty activists. They were intent on improving 'access to medicines' ('Access') for impoverished patients in developing countries in desperate need of treatment for life-threatening diseases. Attention focused on the availability of HIV/AIDS drugs in South Africa at a time when awareness of the ravages of the disease in Sub-Saharan Africa was reaching its peak – and the campaign drew momentum from growing public distrust and resentment of drug companies.

The industry defended itself, as it long has done, by arguing that in order to recoup the extremely high costs of discovering and developing new drugs, it needs to secure temporary monopoly status – through a patent – on each successful new drug. Once patents expire, competition from low-cost 'generics' manufacturers, who produce copies of these drugs without the legacy of heavy Research & Development (R&D) investment, can bring prices down to the 'marginal' cost of production – typically a fraction of the 'all-in' cost. Moreover, because drug prices in many developed markets are tightly capped by governments through state healthcare systems, the industry has in practice funded itself by setting prices at levels that the market can bear in markets with unregulated pricing, such as the United States, the world's single-largest market.

By contrast, developing country governments had historically tended to ignore patent protection agreements. As of 2005, however, they are now bound by new World Trade Organisation rules known as TRIPS¹ – trade-related intellectual property rights – that commit them to respecting patent rights as part of a package of global trade agreements.²

Drug companies start to engage

The South Africa dispute was resolved by the main producers, including GlaxoSmithKline, agreeing to provide HIV/AIDS drugs at reduced prices and licence 'generic' producers to manufacture the drugs. However, the dispute proved to be an industry turning point, as all the major drug companies created new 'access' programmes.

These include:

- Differential pricing in less lucrative markets
- Licensing of generic producers for targeted HIV drugs
- Refraining from registering patents in markets that could not afford the drugs

- Developing partnerships to give away large quantities of drugs to those who most need them. This includes 'Patient Assistance Programs' within the US to provide drugs to people lacking sufficient insurance.

For a time, these programmes and partnerships quelled the public controversy. However, the debate has returned with a vengeance, in response to a worldwide campaign launched by NGOs, principally Oxfam and Médecins Sans Frontières, over the availability in India of **Novartis'** ground-breaking cancer drug, Glivec. Many industry commentators believe that **Novartis** had no option but to work within the current system and apply for, and try to enforce, a patent for such a ground-breaking drug. However, the Indian courts recently ruled against **Novartis'** patent application, prompting the company to announce that its R&D investment would be moved elsewhere in Asia.

Time to call the lawyers?

In addition to **Novartis** over Glivec, two other companies have recently adopted a robust line with emerging markets governments over patent protection: **Abbott Laboratories** in Thailand and **Pfizer** in the Philippines. Within the current framework of international patent law, resorting to the courts is the most obvious way to protect a company's intellectual property when it is challenged by rivals or even a government. Such legal action is intended to help a company to protect its shareholders' interests by securing its profit margins.

However, taking a government to court also has serious commercial implications, particularly in India – recently forecast to be the world's fifth-largest drugs market by 2020³. Gaining entry to such markets requires building trust and confidence with the government in addition to establishing legal rights – as **Novo Nordisk** has done in China. The danger is that legal action or sabre-rattling may protect near-term margins, but do a company's long-term interests more harm than good.

What is a good Access to Medicines strategy?

A consensus is emerging among companies and NGOs on the essential elements of an Access strategy – based on eight components proposed by the Dutch-based Access to Medicines Foundation⁴, and a ninth on 'partnership' added by the industry itself⁵. These cover areas ranging from governance and management systems, to R&D into neglected diseases, equitable pricing, drug donations and ethical marketing. However, companies still hotly debate which components are most important and whether pursuing all nine is necessary to have an effective strategy. NGOs stress the importance of giving away drugs, while

¹ Trade-Related Intellectual Property Rights

² TRIPS came into force in 2005; Least Developed Countries, principally in Africa, have until 2016 to enforce TRIPS.

³ Source: Goldman Sachs.

⁴ <http://www.atmindex.org/foundation>

⁵ Led by the trade body International Federation of Pharmaceutical Manufacturers and Associations

each company emphasises the elements that fit its business model – for example, a specialist in cancer drugs would be naturally reluctant to expand into researching infectious diseases in the tropics.

Despite some examples of best practice, and **GlaxoSmithKline** is widely cited, the industry has not been able to head off renewed criticism – to its obvious puzzlement, despite good faith efforts to address the Access issue. **AstraZeneca** has created a TB research institute in India, costing \$11 million to set up, purely from philanthropy. **Novartis** alone gave away drugs valued at US \$755 million to 33 million patients in 2006, and has provided extensive access to Glivec in India, so that over 99% of Glivec users do not pay for the drug. Critics claim

We said...

“**Most sectors in which I invest view emerging markets as an opportunity, whereas the pharma sector seems to view them as a threat.**”

Niall Kirk, Director of US Equities, F&C Management Limited

that companies are mostly reactive and ad-hoc in their Access approaches – which are better adapted to the challenge of HIV/AIDS in Africa than the conundrum of the emerging middle-income countries, such as India and China, where some can afford to pay but many cannot.

2. An industry in existential crisis

Glivec’s revival of the Access debate has revealed deep fault lines within the industry - also highlighted by Pharma Futures II⁶, a recent project convening drug companies – **AstraZeneca, Bayer, GlaxoSmithKline, Johnson & Johnson, Novartis, Novo Nordisk** and **Pfizer** - and their investors, including F&C, to analyse the future shape of the industry. Three issues of long-term concern for investors are:

- pharmaceutical companies’ difficulties in exploiting the potential of emerging markets - despite the commercial necessity of doing so
- the decline in R&D pipelines and the industry’s reliance on producing huge sales from blockbuster drugs, with the related need for an inflexible – and potentially obsolete – global patent regime
- the conflict between the need to recoup R&D costs from those individuals and governments that can afford to pay, and the strong resistance of cost-constrained national health and insurance payors.

What is also clear is that although the Glivec case happened in India, and it is emerging markets governments that are threatening the international patent regime, the industry’s pricing woes will affect it in developed home markets as well.

The UK’s National Health Service (NHS) recently caught drug companies off-guard by announcing it would unilaterally slash £500 million from its annual drugs bill. A Democratic victory in the next US presidential election could cause further turmoil in the world’s most lucrative market. **Johnson & Johnson** meanwhile sprang a surprise in the UK market by announcing it would refund the cost of Velcade, an expensive cancer drug, in cases where the treatment was not effective – a step-change innovation that won the drug approval for use in the NHS.

We said...

“**The sector is facing a series of ESG challenges that will play out over the next ten years and will have an inevitable effect on company valuations - the expansion of emerging markets, patent expiries, and declining R&D productivity - over and above the more immediate issues of clinical trial design and quality, challenges to commercialising products that are not genuinely innovative, pricing pressure and ethical marketing. The Access to Medicines debate comes on top of this, and the response of a company to the Access debate gives analysts an indication of who is best equipped to tackle the wider strategic challenges faced by the industry.**”

Susie Jana, Associate Director, Equity Research, F&C Management Limited

3. F&C's assessment

F&C has been in dialogue with the major pharmaceutical companies – including **Abbott Laboratories**, **AstraZeneca**, **GlaxoSmithKline**, **Johnson & Johnson**, **Merck**, **Novartis**, **Novo Nordisk**, **Pfizer** and **Roche** and – as well as Oxfam, other NGOs active in Access campaigning and the Brookings Institution. F&C also plans to engage other companies in the debate, such as generics producers and healthcare providers.

F&C's assessment is that the attack on pharmaceutical companies over Access will continue until their responses are better adapted to the specific challenges of doing business outside the traditional lucrative markets of the US, Europe and Japan. Poor healthcare in emerging markets is not the fault of the pharmaceutical companies, but for better or for worse they are getting much of the blame, and risk compromising their long-term prospects in those markets unless they can shake this perception of guilt by association.

The BRICs countries (Brazil, Russia, India, and China) and others are increasingly important markets in the global economy and India, in particular, has a fast-developing pharmaceutical sector with increasing R&D spend. In general, drug companies have been slow off the blocks to find a way to sell to the BRICs countries, while still generating sufficient income for R&D – although **Novo Nordisk** stands out as a leader. Critics claim that the pharmaceutical business model of blockbusters and patents is fundamentally ill-suited to the changing world. While no viable alternative system has yet emerged to take its place, the Access debate may be an early-warning signal that the industry's core business model will need a radical re-think over the long term.

4. Where next for the industry?

There is a lively debate about whether the current structure of the industry will allow any Access strategy to be successful on the scale required to meet the public health need, or whether companies and the industry require a fundamental change in business model if Access becomes a widely-accepted social priority. F&C has identified four areas for consideration by drug companies relevant to Access to Medicines:

- **Becoming healthcare partners:** to establish a licence to operate in new markets, companies need to demonstrate they are partners in healthcare – operating within systems and cultures that are profoundly different from their traditional markets. This may mean being more willing to take responsibility for filling the healthcare gap in countries where systems are poor, rather than insisting on the current boundaries between what a company does and what a government does. For now, they can contribute their market experience and intellectual capital to related initiatives – for example by participating in DFID's Medicines Transparency Alliance.
- **Implementing a comprehensive Access strategy:** at minimum, drug companies need to show that they have actively considered all nine components of an effective Access strategy discussed above – and should be able to explain the rationale for not implementing those they consider inappropriate. Above all, companies need a strategy, not simply an ad-hoc reaction to events.

- **Going to the courts:** while legal action is a natural remedy to defend a company's interests, and shareholders should strongly support the protection of the intellectual property that they have paid for in R&D investment, companies must also consider the long-term fallout from antagonising the public and regulators, and should therefore weigh carefully the short-term benefits against the long-term implications of such action. A company taking legal action should be able to demonstrate to its shareholders that this is more likely to provide a net positive benefit than other possible remedies.
- **Articulating a long-term strategy:** to date, the industry has steadfastly denied that the traditional patent-protected blockbuster model is under threat – but failed to convince that it is able to adapt to the looming demands of a fast-changing world. It needs to seize the initiative, and shape the debate through creative solutions, rather than staying on the back foot.

The industry stands at a crossroads where a new set of unfamiliar drivers will determine its success or failure over the next twenty years. It may be the case that innovation is a better protection than patents – a business model for which **Novo Nordisk** has been praised. Finding the solution to Access to Medicines will not solve all the industry's structural dilemmas: but it is a good start. If drug delivery is more efficient, there will be a healthier society and wealthier economy that can afford more drugs. Pharmaceutical companies need to find a way to produce this win-win scenario.

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F&C/5465-10/07



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