

European Leadership Forum 2009

Healthcare Roundtable Summary

The global pharmaceutical industry is a \$730bn USD business. Although growth of the annual drug bill is declining by about 5% per annum, the overall cost of drugs is still increasing by \$30-35bn each year. The increasing cost of drugs is tempered to some extent by generics, but it still represents a major problem for payors and Governments, who are exerting downward pressure through a number of different measures to ensure that product value is at the core of purchasing and prescribing decisions.

Controlling cost

Measures instigated in a bid to control the growth of the drug bill include health technology assessments, such as the National Institute for Health and Clinical Excellence (NICE) in England and Wales, which aim to ensure cost-effective prescribing by rationing access use of more expensive medicines. As a result, it is now the norm in most markets for generics to be prescribed first-line, reserving more expensive branded medicines for patients who fail to respond. Because they are already cheaper, reducing the cost of generics has only a minimal effect on the drugs bill, so other cost-cutting measures such as risk-sharing and schemes that shift the cost of treatment to the patient are also being implemented.

Devolved budgets mean that physicians' prescribing is now more constrained and other non-medical personnel are involved in deciding what can be prescribed and this change has not been universally popular among physicians. It has been shown that doctors' prescribing decisions tend to become more conservative when they have budget responsibility, so this may represent an opportunity for controlling costs moving forward.

The difficulty of establishing the cost-effectiveness of many preventative medicines and treatments was acknowledged and it is likely that many potentially cost-effective solutions are not being implemented due to lack of evidence.

Articulating value

In the light of these developments, the group spent some time discussing how healthcare providers and the pharmaceutical industry should articulate value in the health debate.

Health providers need to be honest about what can be afforded. For example, in the UK, many people still believe that all their health needs will be provided by the NHS without charge. In some cases this view is so strong that there is a lack of personal responsibility for maintaining good health, as people believe that the NHS will pick up the pieces no matter how much they have abused their bodies.

It was acknowledged that it is difficult to communicate with the public on issues such as rationing of health care, especially within a public system such as the NHS as rationing involves decision-making based on what is best for society, whereas each individual will have a personal and emotional view

based on what is best for themselves and their loved ones. The recent NICE decision to improve access to medicines for end of life care was discussed as not being cost-effective, but responding to emotional arguments and media reports.

The pharmaceutical industry needs to think beyond the healthcare budget when it develops cost-effectiveness information about the value of medicines. The broader economic impact of medicines, such as reducing social care costs, or keeping people in employment and paying tax, should also be considered. Current research programmes are driven by the proposed product label, and too few companies are putting value at the core of their research programmes at early stages (e.g. Phase I, Ib) of their research programmes.

The R&D problem

Pharmaceutical companies need to change their R&D model as the current way of working is not sustainable. The combination of increased costs associated with bringing a drug to market, few products with blockbuster (>\$1bn sales) potential, downward pressure on drug pricing and the \$135bn sales of patent protected products set to lose patent in next 3-5 years, makes finding a solution to pharma's R&D conundrum a key commercial as well as scientific imperative.

The industry's response has included a growing focus on speciality products such as cancer medicines, vaccines and biotechnology products. The speciality medicine sector is likely to increase further, with companies such as Roche looking at how to integrate pharmaceuticals, biomarkers and diagnostics to provide packages of targeted therapies together with the tests to identify the patients who will respond to them. However for such highly- targeted therapies to be profitable, some participants felt that there would need to be a change in the regulatory environment to reduce the costs of bringing a treatment for a small number of patients to market, and it was felt that this would be unlikely. However an innovation in approach – for example one where medicines form part of the solution, alongside medical devices and other services – was felt to be essential.

Maintaining profitability

In the meantime, the pharmaceutical industry is taking steps to reduce its costs and maintain profitability in all its operations. Increased outsourcing, managing discounts via direct distribution, continuing consolidation and portfolio optimisation are all high on the operational agenda. Emerging markets are also a new focus for companies like GSK; others including Novartis and sanofi-aventis are entering the generic space, even though profit margins are lower, while others such as Teva, Merck Bioventures and Roche Biosimilars have a new focus on the biosimilars market.

The biosimilars debate

Biosimilars were the subject of much debate and opinion was divided on the opportunity they represent. Some delegates believed that many biosimilars could be seen as "biobetters" as they have been developed using newer technology than the originator products. Others were more cautious, highlighting the more rigorous regulatory pathway for biosimilars that exists in the EU and US compared to that for small molecule generics, because of safety concerns. The fact that biosimilars are not identical to the originator was highlighted by data showing that two biologicals targeting exactly the same receptor had different efficacy and safety profiles, as well as the case where serious adverse events were seen following a minor change to the manufacturing process for one of the EPO products.

While bulk manufacturing of biological makes a lot of sense, there is a need to regulate the price of biological products at the end of the period of marketing exclusivity. If this cannot be achieved through competition from biosimilars, it will need to be achieved through tendering for contracts, or through regulation.

Emerging markets

The top 8 pharmaceutical markets represent about 75% of global pharmaceutical sales but, with growth down to about 3%, they offer limited opportunity for expansion. The emerging markets currently account for only about 10% of the global pharmaceutical market, but their much stronger growth (about 28% per annum) makes countries like China and India increasingly attractive, although the opportunity is associated with many new challenges. In both countries, the potential middle class customer base for pharmaceuticals is expanding rapidly (approx 740m in China and over 500m in India), although returns will not be at the level in industry is used to. The key to success will be finding sustainable models in each market. For example, the Chinese government is likely to look internally rather than to the West for medicines, making strategic partnerships with local companies a potential route in. In India, although the market is set to triple in size in the next five years, there will likely be little local investment and the market is dominated by branded generics.

Thinking about the geography of a market could be an outdated view and that it might be more relevant to start thinking about the type of market, with classification according to who pays for care and the level of care provided. Categories such as national/essential medicines market, a top-up/co-payment market and 'rich' market, where a medicine does not need to demonstrate cost-efficacy, could have more relevance for the global pharmaceutical industry.