

Executive Summary

The pharmaceutical industry is a highly profitable sector, but with increasing competition and growing public and media interest in the cost of medical care, companies are finding that they must evaluate the impact of all these factors when pricing their products if they are to achieve long-term success.

The pricing of new products is crucial and cannot be left to trial and error. If the price is set too high, the product may fail to gain reimbursement or may be excluded from formularies. If the price is too low, profitability will be reduced. The price of a pharmaceutical is a reflection of its value as perceived by consumers. A more expensive product will achieve maximum profitability only if this higher price is linked to greater value. Where this additional value equals only the additional price charged there is little incentive for consumers to buy the product.

An important feature of the modern market is the greater role that patients are being asked to play in funding their own healthcare needs. In several industrialised countries the spend on pharmaceuticals as a percentage of GDP is not far off the 2% mark and this has meant that governments can no longer maintain a free national health service that offers treatments to all patients, regardless of cost. Naturally, this has led patients to take an interest in the reasons behind the high costs of new medicines that they are being asked to make contributions to.

Many US and European patient groups have been active in lobbying governments to allow newer and more effective medicines on to the market. However, they are also demanding that pharmaceutical companies make these treatments available to them at a reasonable price. Several patient groups have organised themselves into global organisations in which they can exchange information on medicines that have been made available in their countries and on how they have been priced. This makes the practice of pharmaceutical companies setting different prices for their products across the world much more difficult to defend.

The pharmaceutical industry has specified that pharmaceutical pricing is a complex process and that various special factors need to be taken into account when analysing prices. These include the types of products in question and the markets in which they are sold. The pharmaceutical industry has also conducted a number of pharmacoeconomic studies to demonstrate that the effective use of pharmaceuticals can reduce healthcare costs in the long term.

From a company perspective, future profits must eventually exceed the amount spent initially on researching, developing and commercialising the drug. Furthermore, their profits must pay for investment in drugs that might not make it to the market. To this end, companies rely on certain intellectual property rights (IPRs). The pharmaceutical industry believes that without patents many new drugs could be easily and quickly duplicated by other manufacturers, thus preventing innovative drug companies from obtaining a financial reward for their efforts. Therefore, among the various conditions it considers important to maintain a healthy research environment is the establishment of a system for effective intellectual property (IP) protection.

Patents increase the rewards for innovative products in that they give a company a temporary monopoly over the marketing of its products. However, although monopoly status rewards the company in terms of profits, consumers expect higher performance from the expensive product than competitor products and so there is no guarantee of commercial success. Although companies invest in R&D because they expect high returns from the future sales of their discoveries, the competitive nature of the pharmaceutical market means that they cannot

always predict accurately what these returns might be. Whereas some drugs have billion dollar sales, others may bring in less than US\$25m a year.

This is partly due to the fact that it is becoming more difficult to dominate the market before competition arrives. Over time there has been a shortened period between first and second products in new market segments. As many competitor products of a similar nature can eventually exist on the market, to the average consumer the high prices for a new drug appear justified. Some have complained that the industry is more interested in developing expensive 'me-too drugs' for the major therapeutic areas rather than novel drugs for areas of unmet medical need.

Governments have turned to generics in an effort to drive down spending on pharmaceuticals, as in many countries they have been shown to reduce national spending on prescription drugs. Nowhere has this view been more popular than in the US. Calculated from sales only through pharmacies, the Congressional Budget Office (CBO) estimated that by substituting generic drugs in place of brand-name products, purchasers were able to save between US\$8bn and US\$10bn in 1994. In Europe, governments have also turned to generics to reduce pharmaceutical spending. Since 1993, the European Parliament has passed several resolutions favouring greater use of generics.

Legislation in different countries has meant that generic competition appears as soon as a brand-name drug is due to come off patent. For example, in the US, before such legislation, 35% of top-selling drugs had generic competitors after their patent expired, but nowadays almost all do. For pharmaceutical companies, generic rivals represent unwelcome competition. Pharmaceutical companies have sophisticated legal defence strategies in place to fight off generic competition, because once a generic drug appears on the market the sales of the original brand-name product can fall by as much as 70% in a few weeks.

Another controversial development in the pharmaceutical sector is the acceptance of parallel trade as a cost-containment policy. Parallel trade or parallel importation is the cross-border trade in a particular product, through a route that the manufacturer may not have originally intended. By sourcing products from lower priced markets to sell to consumers in higher priced markets, parallel traders can offer significant savings to consumers, who now have an alternative to the price that the product is being sold at in their country by the original manufacturer. Parallel trade businesses have flourished as the demand for cheaper products has grown.

Parallel trade has occurred to its greatest extent within the European Union (EU). This is because the EU is considered to be a single market and so goods are generally allowed to circulate freely between individual Member States. Overall, the Europe-wide market share of parallel imports is around 2% but it is growing fast. The pharmaceutical industry has been angered by the growth in parallel trade in that this reduces its profits. Parallel trade in Europe is dominated by the legal battles between parallel traders and pharmaceutical manufacturers. There have been numerous lengthy court cases, both at national level and at European level, with both sides attempting to interpret national and European laws in their favour.

One of the key problems for pharmaceutical manufacturers is whether parallel trade might eventually occur at a global level, particularly with respect to the US. The US pharmaceutical market is the largest in the world and companies are generally free in the manner in which they price their drugs. As companies rely on the US market for much of their profits, any change in pharmaceutical policy will have a dramatic effect on their business. According to one 2002 newspaper report, between 2001 and 2002 pharmaceutical expenditure accounted for 27% of the US increase in healthcare costs. This is much higher than other industrialised countries.

Nevertheless, with pricing becoming a major election issue, certain politicians and consumer groups have called for changes in legislation to drive down drug prices in the US. Numerous surveys have illustrated the difference in price for the same medicine between the US and other countries. For example, in 1999 *USA Today* reported that the most popular drugs often cost two, three or even four times as much in the US as in other industrialised countries.

The US pharmaceutical industry does not believe in international pricing comparisons. It argues that these comparisons fail to address several issues as to why prices differ, such as differences in living standards, willingness to pay, product volume, exchange rates, patent terms, the length of time and cost of drug marketing approval, and government-imposed reimbursement and price controls. The US pharmaceutical industry is fiercely opposed to any governmental intervention and has made its views public on a number of occasions. In recent times it has intervened to prevent certain Canadian wholesalers and pharmacies selling their products to US consumers over the Internet. In letters to its customers, GlaxoSmithKline has stated specifically that its cheaper Canadian-approved products are not for export outside the country.

Outside the major markets, pharmaceutical pricing is also becoming a controversial issue, as has been highlighted by the AIDS crisis. Whilst those with AIDS in wealthy nations can gain access to effective drug treatments, they are beyond the reach of the majority of sufferers in poorer countries. The scale of the AIDS crisis in developing regions such as Africa has led to demands that treatments be supplied by the pharmaceutical industry at lower prices. However, this has been resisted by pharmaceutical companies, which argue that simply providing cheap medicines will not tackle the problem effectively. These differences have not been resolved, despite the intervention of international bodies such as the World Trade Organization. More than any other market development, this issue highlights the fact that future pharmaceutical pricing will be under greater public scrutiny than ever before.