

SALES AND MARKETING

Active in over 100 countries, we have an extensive worldwide sales and marketing network. In the majority of key markets, we sell through wholly-owned local marketing companies. Elsewhere, we sell through distributors or local representative offices. Our products are marketed primarily to physicians (both primary care and specialist) as well as to other healthcare professionals. Marketing efforts are also directed towards explaining the economic as well as the therapeutic benefits of our products to governments and healthcare buying groups.

Our Global Marketing (GM) function is responsible for developing and leading our global brand strategy, to ensure strong customer focus and commercial direction in the management of our R&D and brand development activity, across the full range of pipeline and marketed products. As part of this, GM works in partnership with our largest marketing companies to create a consistent platform upon which all our local marketing companies can build according to individual market needs.

We define at an early stage of the drug discovery process what we believe the profile of a medicine needs to be to work most effectively in combating a particular disease. These disease target product profiles (TPPs) are based on the insight GM provides into the needs of patients and others for whom the medicine must add value, including regulators, prescribers and those who pay for healthcare. The attitudes and needs of these groups are key drivers of the development of the TPPs which are used throughout the life cycle of a medicine to guide our R&D activity and help shape the therapy area and marketing strategies.

We view the need to understand and demonstrate the value of our medicines to payers as key to creating access to medicines. Early in the development of new products, we share our approach with payers and elicit their views to help ensure the value proposition for the products is reflected in the clinical programme. Specific value teams are created to drive the formation of payer value propositions that are relevant to the major national payers. We are also investing at the marketing company level to ensure we are able to tailor the value proposition to increasingly important regional budget holders.

GM is also responsible for developing the global communications strategy for each brand, working closely with the major marketing companies to ensure that we

have clear, consistent brand communications that are integrated across all our channels of communication.

In the highly competitive environment in which we work, driving top performance of our products in key markets is critical to our success. As well as building on our leading positions in existing key markets such as the US, Japan and Europe, we continue to increase our strength through strategic investment in the fast-growing markets of the future, such as China.

Face-to-face contact is still the single most effective marketing method, but increasingly the efforts of our sales forces are being complemented by our use of the internet to facilitate and enhance our commercial activities. For a few products we also use direct-to-consumer television advertising campaigns in the US, where it is an approved and accepted practice.

The way in which biological products are marketed and sold is an intensive, personal approach that is more targeted compared with traditional pharmaceuticals, with extensive use of specialty pharmaceutical distributors and little direct-to-consumer advertising.

A specific focus on sales and marketing innovation is driving us to explore new ideas, including implementation of learning from other industries, to ensure AstraZeneca is at the forefront in responding to the rapidly changing external environment.

As part of our ongoing dialogue with patients and their physicians to understand what they need and want, we also work to understand what more we can do to help them manage the healthcare challenges, beyond the provision of effective medicines.

For example, to help patients keep up with their treatment, we have been looking at ways in which mobile phone technology and text messaging can be used to remind them when their medication is due. This is particularly appropriate for conditions, such as schizophrenia, where outcomes are critically affected when patients do not follow a regular regime.

We also look at ways in which we can help to build awareness of health conditions and encourage early diagnosis. For example, in the UK, working with the Airedale Primary Care Trust, we piloted a new approach to identifying patients with Type 2 diabetes, which is on the increase in the area. In particular,

the programme focused on the South Asian community where there was low awareness of the disease and the associated risks. The Diabetic Awareness and Screening programme included holding awareness-raising events and screenings in familiar settings such as community centres, managed by a health worker who speaks South Asian languages and a team of nurses. The project resulted in over 500 people being diagnosed with diabetes as well as the community becoming more aware of the need for screening.

During 2007, we also brought together clinicians, patients, carers and advocacy group representatives from the US and Europe in a first of its kind event designed to facilitate the sharing of experience and insight regarding the treatment of mental health disorders. The participants welcomed the opportunity for dialogue and discussion, and the insights gained from this workshop will help shape future programmes.

Price regulation

Our sales and marketing effort also has to take account of the fact that prescription medicines are subject to government controls on price in most of our markets. The main aspects of price regulation in our major markets are described below:

US

Currently, there is no direct government control of prices for non-government drug sales in the US. However, an increasing volume of pharmaceuticals are reimbursed through the Medicare federal healthcare system for the elderly and the disabled and through the state Medicaid programmes for indigent populations. Participation in these programmes imposes certain price controls on pharmaceutical products that are reimbursed through those systems. State Medicaid programmes are, for example, entitled to a mandatory discount or the best commercial price available, whichever is better, and may also require additional 'supplemental rebates'. Since the US government, through these programmes, may often be a large or, in some cases, the largest payer for certain products, these price controls can also have an effect on reimbursement rates established by private payers. US public and private payers are also increasingly implementing limits on the amount and frequency of reimbursement for pharmaceutical and biotechnology products, rather than relying on direct price regulation. This often means that the need for particular medicines has to be justified with more rigour than in the past.

OUR RESOURCES, SKILLS AND CAPABILITIES CONTINUED

Europe

Most governments in Europe control the price and reimbursement of medicines after taking into account the clinical, economic and social impact of a product. This budget-based approach reflects increasing constraints in overall healthcare spending and in some markets budget caps can have a serious impact on the uptake and availability of innovative medicines. Governments increasingly require more assurance of the cost-effectiveness of medicines as well as some assurance on predicted sales volumes. This has led to an increasing interest in new pricing and market access models within the industry as well as among health authorities and insurers.

In several European countries, the pricing, reimbursement and budgetary systems are continually reviewed, with the aim of controlling and limiting the growth in drug expenditure. This is an ongoing cost-containment process that puts a downward pressure on prices and reimbursement, as well as limiting the uptake of new medicines. One example of this is the increasing focus on using generic versions of branded drugs, as seen in a number of countries such as France and Spain. This impacts the volume uptake of innovative medicines, which in many therapy areas are now positioned as second-line agents for smaller patient populations. Recent changes in legislation have also accelerated regulatory approval for generic medicines.

In Germany, therapy area reference pricing was introduced in support of a general aim to reduce spending on drugs, by calculating new and lower reimbursement price levels. These therapy area groupings are formed around broad drug classes such as statins and proton pump inhibitors, which include branded as well as generic products; this has driven significant price reductions or volume reductions for some patented drugs. Increasingly, payers are driving the substitution of generic medicines for innovative medicines in the same therapy area.

Overall, the introduction of new cost-containment measures in Europe is increasing in frequency and intensity. This escalating pressure on price and market access is increasingly targeted at recently introduced innovative medicines, which can delay the availability of such medicines for several months and, in some cases, over a year. This pressure typically manifests itself as higher price cuts on faster-growing products, by therapy area reference pricing or by restricting formulary access to fewer patients than have been shown to benefit from treatment.

Japan

There is formal central government control of prices by the Ministry of Health, Labour and Welfare in Japan. New product prices are determined primarily by comparison with existing product classes. Regulations include an overseas price referencing system, under which prices can be adjusted according to the average price of four major countries (the US, the UK, Germany and France). The price system was last reviewed in April 2006, when measures were put in place that reduce the occurrence of upward price adjustment. To qualify, the product must now be available in at least two of the above markets. Premium prices will be more readily available for innovative products and are newly established for products registered for children under the age of 15. This is dependent on satisfying all three defined criteria for innovativeness: useful new mechanism of action; efficacy or safety superior to similar drugs; and improvement in therapeutic methods. All existing products are subject to a price review based on the market price at least every two years, and the next review of the pricing rule is expected in April 2008. The new system may include an expansion of the pricing premiums or an opportunity to raise prices based on evidence of usefulness proven in post-launch studies. Although Japanese pharmaceutical industry groups have been working to eliminate the price revision of drugs under patent and to have the ability to determine pricing themselves, these changes are not considered likely in the near future. The long-term ambition of the Japanese government is to raise generic volume share from 17% to 30% by 2012. Further reforms aimed at increasing generic use may be determined in April 2008.

Sales and marketing ethics

We are committed to ethical sales and marketing practices worldwide that, as a minimum, meet or exceed the standards set by external regulations and codes of practice. To that end, we require all our national companies to have national codes of practice in place that are in line with our own global Code of Sales and Marketing Practice and are at least as restrictive as all relevant external codes.

Over the past 24 months, AstraZeneca and all our affiliate companies outside North America have introduced a new, strengthened code of sales and marketing practice, supported by extensive training of all staff in all countries. Each local code provides details about what is permissible and what is not and the financial limits, in local currency, for the hospitality associated with meetings and

scientific congresses. In the US, we have continued to refine our extensive set of sales and marketing policies to provide greater clarity to staff on our expectations for ethical business conduct in the evolving external environment. We have also continued to reinforce new and existing policy through communications and training of all employees.

Line managers throughout our marketing companies monitor compliance within their teams, supported by dedicated compliance professionals, who also work to ensure that appropriate training in sales and marketing practice is provided to all relevant staff. Each Marketing Company President chairs a local Compliance Committee and most local management team members are included. In the US, the Executive Director, North America, has delegated compliance oversight to the Business Integrity and Assurance Team (BIAT), which is headed by the VP Business Operations and includes senior representatives from across the business.

We also have a nominated signatory network that focuses specifically on approving promotional materials for release, to ensure that these meet all applicable internal and external code requirements. At a global level, our Group Internal Audit teams conduct local compliance audits within our Marketing Companies and Regional Offices. Marketing Companies outside North America conduct their own local audits under the control of the Local Compliance Officer, reporting to the Regional Compliance Officer.

Information concerning instances where our practices are not up to the standards required is collected through our continuous compliance reporting process and reviewed by senior management. As appropriate, serious breaches of the code are reviewed by the AstraZeneca Board and the AstraZeneca Audit Committee, led by Non-Executive Director, John Buchanan.

The different national external frameworks for regulation of sales and marketing practices create a challenge in interpreting the key performance indicator (KPI) that we introduced in 2005 (the number of cases of confirmed breaches of codes or regulations ruled by external bodies). Nevertheless, the KPI provides a benchmark against which to measure our performance over time. In 2007, we identified a total of 32 such cases (44 in 2006), based on information gathered from 59 countries in which we have AstraZeneca marketing companies or branch offices where we have significant subsidiary operations.

We believe this decrease reflects our continuing commitment in this area, and arises primarily from our strengthened internal procedures where our strict code of practice requires that medically qualified individuals authenticate all promotional or scientific material in advance. The decrease should also be seen in the context of the continuing rise in strict standards from national and international codes. Our 2007 figure includes cases where our promotional materials were challenged by competitor companies. In addition there were some cases where, while not confirmed breaches, regulatory authorities raised concerns with us.

We take all breaches very seriously and take appropriate action to prevent repeat occurrences. This may include re-training, discipline, or other corrective action up to and including dismissal, depending on the circumstances.

Accusations of inappropriate sales and marketing activities sometimes reach the press and this is a part of the appropriate scrutiny that the pharmaceutical industry undergoes. When these incidents are examined by external code of practice or regulatory bodies, they may or may not conclude that the criticism was well founded and constituted a breach. Only confirmed breaches are included in our KPI. Internally, all such incidents are fully investigated and appropriate action taken, irrespective of whether a breach has been confirmed.

We can also gain useful information by examining the number of breaches relative to other companies' performance where such data are made public by the authorities. AstraZeneca accounted for approximately 1% of all international breaches (3% in 2006), and while our number of breaches has fallen, the number of breaches for the industry as a whole has increased.

INTELLECTUAL PROPERTY

Patents are important incentives for the continued innovation that drives society's progress. As described elsewhere in this report, the discovery and development of a new medicine demands a huge investment of time, resource and money by research-based pharmaceutical companies over a period of 10 or more years. For this investment to be a viable commitment for a company to make, the results of the investment – new medicines – must be safeguarded from copying for a reasonable period of time with a reasonable amount of certainty. The principal safeguard in our industry is a well-functioning patent system that recognises our effort

and rewards our innovation with appropriate protection that allows the time for generating the revenue needed for continued pharmaceutical innovation.

The first level of protection in our industry is typically the patent to the new molecular entity (NME), either a new chemical entity (NCE) or a biological drug. However, because we continue to explore all the ways in which our medicines can bring benefit, further innovations are often made during the R&D process and beyond; for example, new formulations to provide different ways of taking the treatment, new medical uses and combination products. Each of these developments also requires significant resource investment to obtain marketing approval from regulatory authorities around the world. Our policy is to protect all the innovations that result from the investment we make in leading-edge science to deliver new and improved medicines.

We apply for patent protection relatively early in the R&D process to safeguard our increasing investment. We pursue these patents through patent offices around the world, responding to questions and challenges from patent office examiners. In some countries, our competitors can challenge our patents in the patent offices, and in all countries competitors can challenge our patents in the courts. We can face challenges early in the patent process and throughout the life of the patent, until the patent expires some 20 to 25 years later (patent expiry is typically 10 to 15 years after the first marketing approval is granted). These challenges can be to the validity of a patent and/or to the effective scope of a patent and are based on ever-evolving legal precedents. There can be no guarantee of success for either party in patent proceedings taking place in patent offices or the courts.

Worldwide experience of biotechnology patent procurement and enforcement is, like the technology itself, relatively young and still developing. As a result, there can be significant uncertainty about the validity and effective scope of patent claims in the biotechnology arena, compared with the small molecule pharmaceutical industry. The investment in bringing biotechnology innovations to the market is huge and a well-functioning, predictable patent system is vital.

The generic industry is increasingly challenging innovators' patents and almost all leading pharmaceutical products in the US have faced or are facing patent challenges from generic

manufacturers. The research-based industry is also experiencing increased challenges elsewhere in the world, for example in Europe, Canada, Asia and Latin America. We are confident of the value of our innovations and, through close collaboration between our intellectual property experts and R&D scientists, we will continue to seek to obtain effective patent protection for our intellectual property, and vigorously defend our patents if they are challenged. Further information about the risk of the early loss and expiry of patents is contained on pages 193 to 194.

Compulsory licensing (the substantial elimination of patent rights to allow patented medicines to be manufactured by other parties) is increasingly being included in the access to medicines debate. We support the appropriate use of compulsory licensing as implemented by the World Trade Organization (WTO) in December 2005 following the agreement reached in August 2003. This enables developing countries with no domestic manufacturing capability to import copies of patented medicines to treat diseases such as HIV/AIDS, malaria and tuberculosis in a public health emergency. We believe that this should apply only when other ways of meeting the emergency needs have been considered and where healthcare frameworks and safeguards to prevent diversion are in place to ensure that the medicines reach those that need them.

SUPPLY AND MANUFACTURING

We have some 12,200 people at 25 manufacturing sites in 19 countries, dedicated to delivering a secure, high quality, cost-effective supply of our small molecule product range worldwide. Of these 12,200 people, around 1,100 are employed in active pharmaceutical ingredient supply and 10,500 in formulation and packaging. We operate a small number of sites for the manufacture of active ingredients in the UK, Sweden and France, complemented by efficient use of outsourcing. Our principal tablet and capsule formulation sites are in the UK, Sweden, Puerto Rico, France and the US, and we also have major formulation sites for the global supply of parenteral and/or inhalation products in Sweden, France, Italy and the UK. Packaging is undertaken at a large number of locations, both at our sites and at contractors' facilities, which are located close to our marketing companies to ensure rapid and responsive product supply. Our biologics and vaccines business has some 600 people working at four principal commercial manufacturing and distribution facilities in the US and Europe.