

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.