

BUSINESS ENVIRONMENT

AstraZeneca operates in a dynamic and rapidly changing business environment that presents both opportunities and challenges for our industry. The most successful pharmaceutical companies will be those that are able to manage effectively the risks and maximise the opportunities through timely and efficient investment, full use of intellectual property and constructive engagement with stakeholders.

The fundamentals of the world pharmaceutical market remain robust. Although industry revenue growth is slowing, mainly due to ever-greater pressure on healthcare costs, pricing and increased generic competition, the demand for healthcare that underpins the industry's future growth remains strong.

The pharmaceutical industry is arguably less exposed than other sectors to the current global economic downturn, although some impact may result from increased constraints on payers, suppliers and distributors. At the same time, there may also be opportunities, such as strategic partnerships with smaller companies seeking funding.

WORLD MARKETS

The world pharmaceutical market in 2008 was valued at \$689 billion – an increase of 5% at CER (2007: 7%). Overall growth was constrained by a significant slow-down in the US even though growth in other Established ROW was maintained and growth in Emerging ROW, in particular Emerging Asia Pacific, was strong.

Despite its slower growth, the US remains the largest pharmaceutical market in the world, representing 42% of the global sales total (2007: 46%). The order of the top ten countries ranked by market size did not change in 2008 but, Poland, Australia and Turkey moved up the overall top 20 rankings.

WORLD PHARMACEUTICAL MARKETS

	Sales \$bn	Growth %	Market value %
Emerging ROW			
2008	108	14	16
2007	87	13	14
2006	74	12	13
Established ROW			
2008	271	5	39
2007	232	4	37
2006	211	4	37
North America			
2008	310	2	45
2007	304	7	49
2006	284	7	50

Data based on world market sales using AstraZeneca market definitions as set out in the Glossary on page 199.

WORLD RANKINGS BY COUNTRY

	Rank MAT/Q3/08	Rank MAT/Q3/07	Growth MAT/Q3/08 %	Growth MAT/Q3/07 %	Market Share MAT/Q3/08 %	Sales MAT/Q3/08 \$bn
US	1	1	1	7	42	291
Japan	2	2	4	2	9	65
France	3	3	4	5	6	43
Germany	4	4	6	3	6	42
Italy	5	6	4	–	4	26
UK	6	5	2	5	3	23
Spain	7	7	8	8	3	23
Canada	8	8	6	7	3	19
China ¹	9	9	27	21	3	18
Brazil ²	10	10	12	10	2	13
Turkey ²	11	13	9	18	2	10
South Korea	12	11	11	10	1	10
Australia	13	14	11	8	1	9
Mexico ²	14	12	4	8	1	9
India ²	15	15	13	13	1	7
Poland	16	17	9	8	1	7
Netherlands	17	16	5	8	1	7
Belgium	18	18	8	4	1	6
Greece ²	19	19	12	18	1	6
Sweden	20	20	6	6	1	4

Data based on world retail and hospital pharmacy sales except:

¹Hospital pharmacy only

²Retail pharmacy only

MAT = Moving Annual Total

Source: IMS Health 2008 MIDAS Quantum

EXPANDING PATIENT POPULATIONS



DEVELOPED MARKETS

Population: 893 million
 GDP growth¹: 2.5%
 GDP/CAP²: \$38,376
 Pharma Market: \$562 billion

EMERGING MARKETS

Population: 5,638 million
 GDP growth¹: 6.8%
 GDP/CAP²: \$2,564
 Pharma Market: \$153 billion

¹ Real compound annual growth rate for years 2002-2007

² 2007 data

GDP: Gross Domestic Product

CAP: Per Capita

Source: IHS Global Insight

THE GROWTH DRIVERS

- > Increasing and ageing populations in established markets.
- > Emergence of expanded patient populations in new markets.
- > Continued unmet medical need.
- > Continued scientific and technological advance.

EXPANDING PATIENT POPULATIONS

The world population has doubled in the last 50 years from three billion to over six billion and is expected to reach nine billion by 2050.

There are an increasing number of people who can access the highest standards of healthcare, especially among the elderly, who represent a rising proportion of developed nations' populations. In addition, the fast-developing economies, such as China and Brazil, continue to offer new opportunities for the industry to gain access to an expanding number of patients who can benefit from medicines.

Emerging markets currently represent 85% of the world population and 20% of the total pharmaceutical market. Fuelled by faster GDP growth than in developed nations, pharmaceutical industry growth in emerging markets was in 2008 double the rate of that in established markets (World Pharmaceutical Market Values table on page 9).

UNMET MEDICAL NEED

In most established markets, ageing populations, more sedentary lifestyles and the availability of improved detection

techniques are leading to an increased incidence and diagnosis of chronic diseases, such as cancer and diabetes, which require long-term management. Chronic disease is on the increase in middle-income countries too, and is also beginning to have an impact in the least developed countries.

Many diseases remain under-diagnosed, sub-optimally treated or do not have effective therapies. Projections indicate that global mortality and the burden of disease will continue to increase over the next 20 years, mainly in non-communicable disease areas³. The leading causes of death globally in 2030 are predicted to include ischaemic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease (COPD), lower respiratory infections, lung cancer and diabetes.

At AstraZeneca, we are focused on six therapy areas: Cardiovascular, Gastrointestinal, Infection, Neuroscience, Oncology, and Respiratory and Inflammation, which together represent a significant proportion of the worldwide burden of disease. Details about the therapy environment in each of our areas of interest are provided in the Therapy Area Review (page 53).

SCIENCE AND TECHNOLOGY ADVANCES

The demand for healthcare will be met not only by existing therapies, but also by innovation resulting from advances in both the understanding of disease and the application of new technologies. Small molecule R&D remains a significant aspect of the pharmaceutical business, although the importance of large molecules or biologics is increasing. Advances in science are paying back in increased understanding of the key

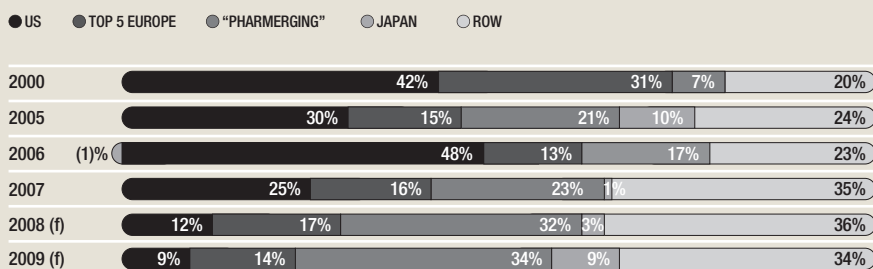
processes involved in the initiation and progression of disease. Together with advances in the technologies for the design and testing of novel compounds, this is enabling new opportunities for the delivery of innovative small molecules as therapeutic agents.

It has been predicted that within the world's top 100 products, 44% of sales will come from products produced using biotechnology, based on forecasts for 2012. This compares to only 25% in 2007 and 11% in 2000. The rate of growth for biologics has been faster than the small molecule segment in recent years and this trend is forecast to continue in the immediate future.

Biotechnology techniques are used to modify an organism's genetic material at the cellular or molecular level to produce biotechnology-derived products, which include monoclonal antibodies and vaccines, and are often referred to as large molecules in comparison to chemical compounds that are referenced as small molecules. Biologics are often more complex to manufacture than small molecule therapies because they are made by generating biological material from cells. The regulatory regimes for 'biosimilars' (similar versions of existing biological products or vaccines) are less well established than those for generic pharmaceuticals, although regulatory authorities in Europe and the US are currently reviewing approval processes. Difficulties producing an identical copy of a biological drug mean that, for biologics, generic competition has been less prevalent. These factors can help to deliver longer product life-cycles for biologics compared to traditional pharmaceuticals.

³ Source: WHO statistics 2008.

CONTRIBUTION TO GLOBAL GROWTH BY KEY REGIONS



"Pharmerging" markets include: China, Brazil, India, South Korea, Mexico, Turkey and Russia.
 (f) = forecast – complete 2008 data unavailable at the date of publication of this Report.
 Source: IMS Health, Market Prognosis, September 2008.

THE CHALLENGES

- > Continued pressure on the price of medicines.
- > Higher regulatory hurdles for new medicines and new indications.
- > Competition from research-based and, increasingly, generic pharmaceutical companies.

PRICING PRESSURE

The growing demand for healthcare means ever-increasing pressure on healthcare budgets and, whilst payers recognise the need to reward innovation, they have a duty to spend their limited financial resources wisely. Cost-containment, including pharmaceutical spending, therefore continues to be a fundamental consideration. The current global economic downturn is likely to further constrain healthcare providers and those patients who pay directly for their medicines, and additional challenges may arise if suppliers and distributors face credit-related difficulties.

The research-based pharmaceutical industry's challenge is to manage the associated downward pressure on the price of its products, whilst continuing to invest in the discovery, development, manufacturing and marketing of new medicines.

Most of our sales are generated in highly regulated markets where governments exert various levels of control on price and reimbursement. The network of pricing systems creates a complex matrix that must be managed to optimise revenues. This may be further complicated by currency fluctuations within regions. The principal aspects of price regulation in the major markets are described more in the Geographical Review from page 48.

Payers also increasingly require demonstration of the economic as well as therapeutic value of medicines. Meeting these needs across a diverse range of national and local reimbursement systems requires significant additional resources.

REGULATORY REQUIREMENTS

The pharmaceutical industry is one of the most regulated of all industries and, whilst efforts to harmonise regulations globally are increasing, the number and impact of these regulations continue to grow. Regulatory drug review and approval is a complex and time consuming process, typically taking between six months and two years. In recent years, regulatory processes have become subject to more conditions including patient risk management plans, patient registries, post-marketing requirements, and conditional and limited approvals.

Traditional clinical trials designed to establish safety and efficacy remain a core component of drug development programmes but regulators are increasingly requiring that programmes also clearly demonstrate the benefits and risks of new medicine in the context of other available therapies, as well as demonstrating long-term medical outcomes, such as survival and quality of life improvements.

In addition to safety and efficacy, pre-approval regulation covers every aspect of the product including the chemical composition, manufacturing, quality controls, handling, packaging, labelling, distribution, promotion and marketing. Post approval and launch, all aspects relating to a product's safety, efficacy and quality must continue to meet regulatory requirements. See also Ensuring Product Quality (page 27).

COMPETITION

Our main competitors are other international, research-based pharmaceutical companies that sell innovative, patent-protected, prescription medicines. Following patent expiry, our products also compete with generic pharmaceuticals. Since generic manufacturers do not bear the same high costs of R&D, nor do they typically invest as significantly in safety monitoring or marketing, they typically adopt lower prices for their products.

The generic industry is increasingly challenging innovators' patents and in the US, the world's largest pharmaceutical market, many leading medicines 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. It is increasingly complex to enforce patent rights and other intellectual property in certain markets, especially those where practices are in place to encourage broad access to medicines. While there are few established regulatory systems for biosimilars of biological products, several markets, including the US, are considering regulatory structures that might allow for an abbreviated marketing approval mechanism akin to that for generic pharmaceuticals. Further information about the risk of the early loss and expiry of patents is explained in the Intellectual Property section on page 26.

Competition also comes from collaborations and partnerships between traditional pharmaceutical companies and smaller biotechnology and vaccine companies. Increasingly, as pharmaceutical companies seek to expand their pipeline, they are able to gain access to promising new product candidates by partnering with these smaller companies that may lack some of the infrastructure for growth that a larger company can provide. Competition for high quality collaborations is increasingly fierce as the major pharmaceutical companies frequently focus on the same opportunities to enhance their in-house capabilities.

Further information about the principal risks and uncertainties we face can be found in the Risk section from page 74.