

The Year for Pharmerging Markets

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The pharmaceutical sector will witness a shift in growth from the top seven markets to emerging markets.

In a year of transition, global pharmaceutical sales will grow 5-6 percent to over \$735 billion in 2008, compared to 6-7 percent in 2007, driven by the declining costs of drug treatment in major therapy areas, increased uncertainty over safety, pricing and market access, and intellectual property issues. There will also be a shift in growth from the top seven markets to emerging markets, and from primary care-driven to specialty care-driven drugs. Pharmaceutical players will be required to change their game plan in line with these evolving dynamics in order to stay ahead. This is according to the latest IMS Health Global Pharmaceutical Market and Therapy Forecast.

Record low growth for the US

In the US and Europe's top five markets, the expected growth in 2008 will be 4-5 percent--an all time low for the US--while Japan will see an even smaller increase of 1-2 percent. Among the factors driving this anticipated performance in these markets are a leveling-off of growth from the introduction of the Medicare Part D prescription drug benefit in the US; patent expiration of branded products, and an associated increase in the use of lower-cost generics; intensified payer pressure to control costs and limited access to certain treatments; and heightened safety scrutiny and healthcare legislation that is

slowing, and in some cases halting, the introduction of new medicines.

Increased contribution from emerging markets

By contrast, the seven "pharmerging" markets of China, Brazil, Mexico, South Korea, India, Turkey and Russia will experience growth of 12-13 percent to reach \$85-90 billion, driven by greater access to generic and innovative new medicines, as primary care improves and becomes more available in rural areas, and as more people take private health insurance.

For the first time, the seven largest markets will contribute just half of overall pharmaceutical growth, while seven emerging markets will contribute nearly 25 percent of growth worldwide.

Generics continue to grow

The growth of generic medicines, at 14-15 percent, will be a key market dynamic in 2008 as payers continue to encourage their use through various means, including requirements for pharmacists, substitution check boxes on prescriptions, no-pay and co-pay provisions and budget limits.

In Europe, greater use of generics will be driven by new government contracting initiatives in Germany, and educational programs in Spain and Italy. In the US, generics are expected to account for more than two-thirds of all prescriptions written. These factors, combined with loss of market exclusivity for leading products such as Risperdal, Fosamax, Topamax, Lamictal and Depakote, in one or more major markets around the world, will see generics grow to more than \$70 billion in 2008.

Innovative specialty products on the rise

As the impact of established pharmaceuticals losing patent protection accelerates, there will be a decline in the size of the \$370-380 billion audited market for primary care-driven drugs. Value growth will be limited to areas of unmet need, with most growth in specialist-driven classes (such as oncology and biotech), that are not as constrained by cost pressures. Overall, the specialist-driven market is forecast to register 14-15 percent growth to record \$295-305 billion in revenues. In the coming year, biopharmaceutical and generics companies will more aggressively adjust their business models to manage through these inflections, capturing new opportunities in this challenging market environment.

In 2008, up to 29 innovative new medicines will be launched, 80 percent of which will be primarily prescribed by specialists. These include new oncology drugs for treating melanoma and acute myeloid leukemia. Sales of products used in the treatment of oncology are expected to exceed \$45 billion in value in 2008, contributing nearly 17 percent of the audited market growth. IMS anticipates an increased willingness by payers and drug manufacturers in this area to enter into "payment for results" arrangements. This comes on the back of an expected rise in the use of evidence to support the value of medicines which will see pharmaceutical companies, governments and other payers implement more sophisticated economic analyses to understand the impact of pharmacotherapies on healthcare budgets worldwide.

Greater uncertainty around safety issues

Throughout 2008, IMS expects that independent bodies will conduct more meta-analyses of broadly used drugs and that risk will be assessed not only on scientific evidence, but also according to the views of legislators and juries. At this point, the FDA and the European Medicines Agency (EMA) are both focusing on glitazones, ADHD and erythropoietin. The FDA is also investigating proton pump inhibitors, bisphosphonates for osteoporosis and related disorders, and non-prescription cough and cold medicines. IMS anticipates more limited claims for newly approved medicines, the application of more "black box" warnings on labels, calls for more clinical evidence by regulators, and slower approvals. Overall, this raises the level of uncertainty that companies face in making products available to patients.

IP rights challenged on multiple fronts

Intellectual property issues under review in 2008 could potentially have significant long-term effects on patent-holders. The issue of compulsory licensing by nations, court rulings on composition of matter and process patents, granting of patents in India, enforcement of intellectual property rights in China, and the reform of patent laws in the US and Europe will all play out to some extent over the course of the following year. Each of these areas adds uncertainty to the fundamental model underpinning the R&D-based pharmaceutical industry.