Japanese Pharmaceutical Market
Japan is a mixed bag of fortunes for pharmaceutical companies

Pharmaceutical companies face many challenges in Japan in terms of its complex regulatory and pricing process and the regular price cuts which pose hurdles for the introduction of new innovative drugs. These have kept the overall market size stagnant, growing by only 1% in 2012, according to Datamonitor Healthcare’s Company Analysis. One of the most significant challenges faced by pharmaceutical companies in the Japanese market is the practice of biennial price cuts, which mean that the price of a drug can typically only decrease following launch. A further compounding factor is increasing generics uptake, following a raft of pro-generics measures introduced since 2007.

Despite these challenges, the world’s second largest pharmaceutical market presents a number of opportunities, including an aging population, together with a relatively low barrier to reimbursement compared to many EU markets. Indeed, the Japanese reimbursement system is streamlined compared to the complicated processes companies need to go through in other countries, with pharmacoeconomics rarely used to make listing decisions. In addition, measures taken by the drug regulatory authorities to reduce the lag period in terms of new drug approvals compared to the US and the EU are beginning to yield results, with the number of new drugs approved in Japan on the rise over the past few years.

Measures taken by Japan to reduce the drug lag period are showing results

Until 2008, the Japanese regulatory system was criticized for lagging behind in terms of new drug approvals compared to the US and EU. One of the key factors leading to the delay in approvals was the limited number of reviewers at the Pharmaceuticals and Medical Devices Agency (PMDA), which increased the overall time taken from the filing of an application to marketing approval compared with the US and EU. However, this scenario changed in 2009 following a staff expansion at the PMDA. Consequently, in recent years the number of new drugs approved in Japan has been on the rise. Furthermore, with Japanese sites now routinely being included in many multinationals’ global clinical trial programs, the availability of data for new drugs in the Japanese population is no longer considered a major obstacle for approval.

Price premiums awarded at launch are difficult to get

One of the major challenges encountered by pharmaceutical companies when launching a new drug is the difficulty in obtaining any price premiums over comparators. This poses limitations on the prices that can be achieved in the market. For example, Roche/Chugai’s Perjeta (pertuzumab) achieved only a 5% premium, while Kadcyla’s (ado-trastuzumab emtansine) launch has been delayed due to difficulties in pricing negotiations. Furthermore, the number and size of premiums awarded have been declining: in 2013, only 15% of drugs priced through comparison-based pricing were awarded a premium, versus 50%
in 2009. Furthermore, receiving a pricing premium for innovativeness (equal to a premium of 70–120%) is rare in Japan, with no drugs awarded the most coveted premium during 2009–12.

Against this backdrop of difficult pricing conditions at launch, Japan’s Ministry of Health, Labour and Welfare (MHLW) implements various cost-containment measures, of which the biennial price cuts are the major tool. The practice of biennial price cuts is one of the most significant challenges faced by pharmaceutical companies in the Japanese market as it means that the price of a drug can typically only decrease following launch. However, the new premium for the development of unapproved drugs, launched as a pilot program in 2010 by Japan’s Central Social Insurance Medical Council (Chuikyo), protects the prices of innovative drugs against the biennial price cuts until patent expiry if certain conditions are met. The program has represented one of the key silver linings for the pharma industry; however, it is speculated that it may have impacted the rate and number of new drugs receiving price premiums.

**Market expansion re-pricing rule bites strong performers**

In addition to the price cuts aimed at aligning reimbursement prices with market prices, there are additional rules that can result in price revisions. Market expansion-based price re-setting is one such category where the prices of drugs are cut if the drug achieves greater sales than initially forecast due to changes in usage or target population. In all, 48 products had their prices cut due to the market expansion re-pricing rule in the last round of cuts in April 2012. Moreover, following the amendment to the market expansion re-pricing rule in April 2012, it is likely that more medicines will be affected during the next biennial price revision, which is due in April 2014.

**The ministry is making further efforts to increase the uptake of generic drugs, which may harm branded manufacturers**

Once considered one of the most immature generics markets, a series of reforms launched since 2007 resulted in generics reaching 26% volume share by the end of 2012 in Japan, up from 18.7% in 2007.

Despite missing the target of 30% volume share by the end of 2012, Japan’s MHLW has continued pushing its pro-generics agenda with its generics roadmap of April 2013 aiming to increase the total volume share of generics to around 34% by 2018. The new initiative includes measures such as the encouragement of generic drug prescribing and dispensing, the provision of information for patients at pharmacies with regard to generic alternatives for prescribed drugs, the promotion of generic name prescribing by physicians, and the modification of prescription forms to create provision for generic drug substitution to increase generic drug uptake. While the initiative will benefit generics manufacturers, it is expected to lead to further erosion of branded drugs, with many original drugs being newly opened up to generic competition.

**Few reimbursement obstacles exist, providing price negotiation has been successful**

One of the key advantages of the Japanese market is that unlike in many EU countries, drugs that get approved are typically included in the reimbursement list within three months, conditional on successful price negotiation. Moreover, the Japanese reimbursement system is straightforward relative to most EU
countries and the US, which often have complex health technology assessment (HTA) requirements and fragmented healthcare systems. Japan operates a single payer system, and while the HTA requirements are expected to evolve going forward, pharmacoeconomic assessment currently does not play a major role in pricing and reimbursement decisions.