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Tatsuya Kimura: Japan is a steadily growing market

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The Asian business strategy of multinational pharmaceutical companies in terms of resource reallocation and investment will become a key issue for future growth and success. In the world pharmaceutical market, Asia is the most rapidly growing region.

The total world pharmaceutical market in 2011 was $955.5 billion and it recorded a compound annual growth rate (CAGR) of 6.1 percent from 2007-11. IMS Health estimated the growth rate of Asia, Africa and Australia in 2011 at 13.1 percent with a market size $163.1 billion. Although the growth of the global pharma market has been largely supported by emerging countries, the huge impact of major markets like Japan on total market growth cannot be underestimated.

The Japanese pharma market in 2011 was $114.7 billion and is still the second largest following the US market at $346.2, according to IMS Health. The topline market data by IMS Health, projected that the CAGR from 2012-16 for the Japanese pharma market would be in the range of one-to-four percent, which is the same as the US market and better than the European market growth of zero-to-three percent.

Some believe that the growth of the pharmaceutical market in Japan is slowing and it has become less attractive for investment. Moreover, expensive development costs have led multinational companies to reconsider investment in Japan and made them to reallocate to emerging markets in Asia.

However, market data clearly shows that the Japanese market has grown steadily and will continue to do so into the future. Because of the stable growth potential and it nature of addressing challenges in productivity in development, not only in industry but also at the regulatory authority level efforts, major multinational companies have begun to put resources in Japan again, identifying it as a strategically important country for business growth.

In terms of productivity in drug development, the Japanese pharma industry has expended much effort to improve the drug development process. Multi-regional clinical trials (MRCTs), being conducted in Asian countries, have increased in number, which has further resulted in a reduction in drug development duration and cost efficiencies since the number of Japanese

patients in clinical trials has decreased.

The Pharmaceuticals & Medical Devices Agency (PMDA) has also reduced the time for review process of a new drug. Data shows that the 'drug lag' in 2010 has decreased by 2.3 years on average from 2007 mainly due to a decrease in review time by PMDA, which is closing in on the US review timeline. Reducing the 'drug lag' results in earlier patient accessibility to new drugs. The PMDA is also investigating the possibility of accepting clinical data in Asian countries with the evaluation of ethnic differences.

Another attractive point of the Japanese market is its speed-to-market access. In Japan, regulations state that 60 days after a new drug application (NDA) is approved by the regulatory authority, a new drug price is decided and listed and this is 100 percent reimbursable. Accordingly, Japan would be the fastest country in terms of the speed of patient access, which measures the aggregation of time from review to approval, and the time taken to determine drug price and get reimbursement. This enables pharma companies to quickly market a new drug for patients with sure predictability unlike in other Asian countries.

The Japanese regulatory agency has also made a concerted effort to improve time to approval by accepting MRCTs data, as well as by increasing the number of reviewers and adopting efficient review processes. With continued efforts to resolve complicated issues, the Japanese pharmaceutical market will provide greater value to patients, as well as stakeholders in medical related industries worldwide.