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2017 Preview: Give And Take Marks Mixed Japan, Korea Outlook

by Jung Won Shin

As much of Asia celebrates the Lunar New Year holidays, the pharma sector in Japan and South Korea is looking ahead to the Year of the Rooster with a mixture of uncertainty and hope, providing the industry with much to crow about either in support or opposition.

JAPAN

While 2017 will be an "off year" for the existing system of regular price cuts imposed every other April, this year is starting off on an uncertain footing for the research-based pharma industry in Japan, following the fundamental drug pricing reform process rushed through by the government at the end of 2016.

While much remains to be discussed and negotiated with stakeholders, including the pharma industry, what is fairly certain at this stage is that there will be a planned shift to annual (rather than biennial) general reimbursement price cuts, probably from April 2018.

Discussions are also ongoing about limiting the use of foreign reference prices used to set drug reimbursement prices in Japan, and it is looking likely that US prices (which in turn could come under more pressure from the Trump administration) will be removed from the calculation methodology.

Whatever happens, it was clear that the rapid policy review, ordered by Prime Minister Shinzo Abe, was a rushed response to the political and public concern last year over the rising cost to the national healthcare insurance system of high-priced new drugs for cancer and hepatitis C.

This has already led to a 50% price cut for *Ono Pharmaceutical Co. Ltd.*/*Bristol-Myers Squibb Co.*'s *Opdivo* (nivolumab), but also put drug pricing firmly on the political and policy agenda. By the middle of this year, following expected recommendations from the Central Social Insurance Medical Council, we should know better what the future holds.

If past policy changes are anything to go by, stakeholders are likely to be given multiple opportunities to make their voices heard, and the pharma industry will be hoping its views will be reflected in the final scheme.

More broadly, the already confirmed death of the hard-won Trans Pacific Partnership regional free trade deal at the hands of Donald Trump raises the possibility of potential new pricing or regulatory initiatives under Japan's participation in a proposed new bilateral trade deal with the US.

From past experience, this could be used by the US research-based industry as a forum to push for such changes, but realistically any final deal remains probably years away, although negotiations may feasibly get under way sometime this year.

2017 Preview: Fresh Concerns And New Hopes In China

By Ying Huang and Brian Yang

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If 2016's Year of the Monkey was a period of ups and downs in China, filled with a series of rapid changes in regulations and plans for overseas expansion by domestic pharma companies, 2017's Year of the Rooster is likely to be even more uncertain, industry insiders say.

Read the full article here

Commercial Outlook

On the commercial front, the big news in the first quarter will be the expected completion of *Takeda Pharmaceutical Co. Ltd.*'s $5.2bn acquisition of *Ariad Pharmaceuticals Inc.* by the end of February, which will further bolster the top Japanese firm's presence both in oncology and the US.

A US NDA for Ariad's ALK inhibitor brigatinib - a major attraction in the deal - is expected in non-small cell lung cancer in the first half.

More broadly, it seems a sure bet that Japan Pharma's strategic focus on oncology will continue unabated, with *Sumitomo Dainippon Pharma Co. Ltd.* the latest to join the bandwagon. The company's now completed acquisition of small specialist US venture *Tolero Pharmaceuticals Inc.* for up to $780m is a signal that we can expect other deals during the course of the year targeting assets, technology, or entire companies.

India Pharma 2017: 3Cs And D (Disruption)?

By Anju Ghangurde

12 Jan 2017

2017 is predicted to be action-packed for the Indian pharmaceutical industry. Compliance-

In the meantime, some of the major approvals and launches in Japan this year will include Takeda's oral proteasome inhibitor ixazomib for relapsed or refractory multiple myeloma, whille *Merck & Co. Inc.*'s *Keytruda* (pembrolizumab) should be priced and launched for non-small cell lung cancer (including first line) in the first quarter, going head-to-head with Opdivo.

In other disease areas, there should be approvals for *Sanofi*'s interleukin-6-targeting antibody sarilumab for rheumatoid arthritis (filed last October), and potentially its IL-4 receptor-targeting antibody dupilumab for atopic dermatitis. *Amgen Astellas BioPharma KK*'s anti-sclerostin antibody romosozumab should be cleared for osteoporosis following a filing in late 2016.

related issues, consolidation, a potential pick-up in collaborations between innovator and local firms, and activity around Indian biosimilars on the global stage, are just some of the things to keep an eye out for. Meanwhile, India's demonetization move and the Trump presidency will be reminders to expect the unexpected...

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Planned 2017 product approval filings in Japan in the oncology field include *Eisai Co. Ltd.*'s oral multikinase-inhibiting molecule lenvatinib in the major new indication of hepatocellular carcinoma, with submissions also planned in the US, EU and China.

These launches, combined with a lack of a price cut in April and barring further one-off individual price cuts, should contribute to stronger overall growth for the Japanese market this year.

SOUTH KOREA

Across in South Korea, pharma firms and bioventures are hoping to benefit this year from an improving operating environment and a range of new policy support measures.

The government has already expanded tax benefits for clinical trials and other R&D incentives, eased drug pricing controls, and simplified stock listing regulations for biotech firms. Despite ongoing political scandals and uncertainties, the government has made it clear it is seeking to continue expanding policy and administrative support, as it looks to build a technology and business ecosystem that can help turn the country into a true international pharma player.

The health ministry for instance is planning to increase its budget over 2016 to assist healthcare projects, including R&D into novel cancer drugs, and will establish new clinical trial centers to verify the utility of novel compounds and prototype medical devices.

The finance ministry's proposed R&D spending for the biotech industry and medicine industry

meanwhile is set to rise 8% and 14% respectively over last year, according to Dongbu Securities. A new $257m public-private fund unveiled just recently will be ploughed into R&D and other policy support for health biotech and 11 other "growth engine industries".

There have already been positive signs that venture capital and other investors are increasing their interest in the pharma/bioventure sector as a result of these moves and as more companies begin to show substantial R&D progress.

We can expect companies with attractive clinical pipelines or assets close to the commercialization stage to continue to hog the spotlight.

Biosimilar Prospects

The domestic medicine market in South Korea has been stagnant for several years due to an official policy of lowering drug prices through regular price cuts under the national health insurance system that is akin to that in Japan.

But, besides the new policy support, one bright spot is that drug exports are set to increase sharply this year with the commercial launch last November in the US - the world's biggest biosimilar market - of *Celltrion Inc.*/*Pfizer Inc.*'s biosimilar infliximab, *Inflectra*.

All eyes will be on this sector as the race to develop and commercialize internationally a range of biosimilars developed by South Korean firms becomes ever fiercer. Celltrion, for one, has already secured the South Korean approval of its biosimilar rituximab *Truxima*, and is seen to be in a favorable position to become the first mover elsewhere.

South Korea's official memberships of the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Co-operation Scheme (PIC/S) - which relates to good manufacturing practices - and the International Conference on Harmonisation (ICH) are also expected to make it easier for the country's novel drugs to enter more pharmerging markets such as South America and Southeast Asia.

From the editors of PharmAsia News.