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20 Jan 2017 |

2017 Preview: Fresh Concerns And New Hopes In China

by Ying Huang

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.

As China gears up for the major Lunar New Year holidays at the end of January, industry experts in the country predict that 2017 will continue to feel largely similar to a somewhat bumpy 2016, marked by increasing tendering and hospital negotiation pricing pressures, along with shifts in commercial and distribution channels from the broader introduction of a new receipting system.

Two Receipts System

In its “Opinions on Deepening Healthcare Reform in 2016”, China's central government specified that pilots of the new the "Liangpiao" (two receipts) system will be rolled out to public hospitals in provinces adopting comprehensive healthcare reform measures. Such medical facilities will be encouraged to directly settle drug payments with drug manufacturers, which in turn will settle drug logistics fees directly with distributors.

The aim is to improve transparency and reduce the current multiple layers of invoicing and markups within the distribution chain, which are seen as contributing to rising end drug prices for patients.

The National Health and Family Planning Commission has already vowed to squeeze inflation out of drug prices, and is rolling out new healthcare reforms known as the “Sanming Model”, after the small city in Fujian province that trialed

The ‘Sanming Model’: Bad Omen Or Hope For Pharma In China?

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the two receipts system to consolidate pharma distributors and leverage payers to control large prescriptions.

The new system is currently being introduced in 11 provinces - Anhui, Jiangsu, Fujian, Qinghai, Shanghai, Zhejiang, Hunan, Chongqing, Sichuan, Shanxi and Ningxia - and depending on the results and feedback, may be introduced nationwide in the future.

By Brian Yang

25 Nov 2016

Pharma executives in China may soon get an earful of the name Sanming, as the populist healthcare reform model that began at the small city in Fujian is rolled out nationwide and impacts profoundly how drugs are tendered, priced and distributed.

Read the full article here

Healthcare analysts speculate that the new system will give rise to specialist contract sales organizations that can handle the changes. “Marketing promotion and distribution will be divided into two different business units,” predicted Yongqiang Wu, an analyst from Essence Securities. “Some multinational pharmas may be looking to acquire a good supply practice license, in order to better manage the distribution of imported drugs in China” after the changes.

Many say that the move signals that pressure is mounting in China to rein in drug prices. “Drug price monitoring is likely to become routine with overall tightening, so the pressure won't be lessening compared to the previous year,” Lin Jianning, director of the China FDA-affiliated Nanfang Institute, predicted in November.

NRDL Update

China's first national reimbursement drug list (NRDL) - containing medicines covered by the national health insurance scheme - was released back in 2009, and an expected update in 2017 will be an important watershed event this year, Helen Chen, head of China practice at L.E.K Consulting, told *Scrip*.

According to the draft of proposals for the revision of the NRDL, drugs of high clinical value and that treat critical diseases, or designed for use in children, emergency situations, and occupational diseases, are most likely to be newly added to the list.

Industry insiders are also keeping a close watch on whether Class 1.1 innovative new drugs and biologics being developed by domestic companies, as well as generics with great clinical demand, may make it onto the updated list. Products such as *Chengdu Kanghong Pharmaceuticals (Group) Co. Ltd.*'s conbercept (a VEGF-targeting drug for cancer), a recombinant human tumor necrosis factor receptor type 2 inhibitor from Hisun Pharmaceutical, and Beijing SL Pharmaceutical's lenalidomide for multiple myeloma may be included, Essence Securities' Wu noted.

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New Drug Reviews In Sharp Focus

In the regulatory arena, many eyes will be fixed on whether the China FDA delivers on its promise to eliminate the drug approvals backlog by the end of this year by speeding up IND and NDA reviews.

So far, the pace of reviews appears to be accelerating, given recent clinical trial approvals that have been granted to domestically developed biosimilars and PD-1 checkpoint inhibitors to treat cancer. Meanwhile, there have been other positive signs from multinational firms, such as *Roche* starting the recruitment of patients for local trials with its antibody-drug combination *Kadcyla* (ado-trastuzumab-emtansine) for breast cancer.

Count Me In! China To Update Drug Coverage After Long Wait

By Brian Yang

11 Oct 2016

After a long seven-year hiatus, China is finally moving to update its national reimbursement drug list, but the process will involve huge numbers of experts and the benefits of inclusion may not be as immediate or as extensive as appear at first sight.

Read the full article here

In a newly released official video, CFDA drug reviewer Zhang Ning said the deadline to clear the backlog is akin to a sword hanging over the agency. "Our main goal is to reduce the review time and speed up access to new drugs," he declared.

In 2016, the CFDA created a procedure to prioritize the evaluation of certain categories of drugs, aiming to cut the time to market. It outlined a priority review pathway for novel products for serious diseases, products in short supply, early generics, pediatric therapies, and medicines that have either been approved in the US and EU or are undergoing review in those regions.

Priority Reviews

To date, the CFDA has released 12 priority review lists, on which cancer, rare diseases, HIV/AIDS, tuberculosis and viral hepatitis are the five most prominent areas.

The expedited review process should begin to yield results in 2017. "*Boehringer Ingelheim GMBH* will be launching their next generation EGFR tyrosine kinase inhibitor [*Giotrif* (afatinib)] for non-small cell lung cancer. We might be also getting closer to approval for *Gilead Sciences Inc.*'s sofosbuvir [*Sovaldi*]," L.E.K. Consulting's Chen said.

This January, there were other positive signs in that the CFDA announced the approvals of three first-time generics developed by domestic pharmas - gefitinib from *Qilu Pharmaceutical Co. Ltd.*, efavirenz from [Shanghai Desano Pharmaceutical Investment Co. Ltd.], and tenofovir disoproxil fumarate from Chengdu Brilliant Pharmaceutical Group.

Meanwhile, *Erbitux* (cetuximab), a cancer drug marketed by *Bristol-Myers Squibb Co.*, will lose its Chinese patent protection in the second quarter of 2017, and 13 domestic firms have already received clinical trial approvals to develop generic versions in China. The frontrunner is Shanghai Zhangjiang Biotechnology, which has started Phase II/III trials for a cetuximab/irinotecan combination to treat metastatic colorectal cancer.

More Crackdowns And Tightening?

Two events at the start of the year were seen as new worrisome signs that more compliance pressure may be coming.

A video aired on China's state broadcaster, CCTV, contained footage shot by an undercover reporter that showed streams of medical sales reps handing out envelopes of money to physicians at hospitals in Shanghai and Hunan province (Also see "*Reign In Your Distributors And Reps, Chinese Regulator Cautions*" - Pink Sheet, 10 Jan, 2017.).

Following the broadcast, many hospitals have already starting restricting and even banning sales reps, putting the chill on a sector that had just stepped out a massive anticorruption campaign three years ago.

> ***"MNCs have generally adapted to the new [compliance] environment…and should be in a good position to grow again." – Helen Chen, L.E.K. Consulting***

However, "MNCs have generally adapted to the new environment in terms of compliance requirements, competitive intensity and lower overall growth, and should be in a good position to grow again," L.E.K. Consulting's Chen observed.

On top of this, a new move to tighten foreign currency outflow from China has concerned outbound buyers, and may put a damper on Chinese healthcare companies that have in the past gone shopping overseas to snatch up attractive assets. The move, effective from January, requires stepped-up monitoring and approval of transactions from the State Administration for Foreign Exchange (SAFE) and People's Bank of China.

All purchases involving foreign currencies equivalent to $5m (around CNY35m) must reported to SAFE in Beijing as a "large transaction", and will be subject to reviews from the two bodies and

other regulators. Stricter monitoring will also be applied when the amount reaches $50m, and transactions must not be split up to avoid the reviews.

Compared to six months ago, “Payments out of China and outbound transactions are being subject to a far greater scrutiny”, noted lawyers at Hogan Lovells in a Jan.18 note to clients.

Although the move will create concerns and uncertainty to sellers to Chinese buyers, the move is only “a bump in the road”, said the lawyers, and a genuine deal that “makes business and strategic senses” can still get done, despite facing a longer timeframe, said the lawyers.

Innovation Imperative

As for other major changes expected in the Year of the Rooster, the role of innovation will become ever more vital to domestic drug companies in China, noted a top industry insider. “In 2016, innovation essentially became the core competitive advantage for China's drug-making sector,” said Helen Chui, managing director of the SDIC Fund and a former Novartis Group China president.

Whatever happens, this year will again be a dynamic one in both the commercial and regulation fields, so stay tuned to keep abreast of policy changes and emerging healthcare investment trends in China.

From the editors of PharmAsia News.