

## China's "4 + 7" Scheme - What's at Stake

(Source: An Article by Brian Young for Scrip)

China's expanded centralized "4+7" procurement scheme is being rolled out nationwide, including some of the largest provincial markets and involving massive volumes of products. The pilot program was announced last November with the release of the "4+7 Centralized Pharmaceutical Document". The initial round covered the four mega-cities of Beijing, Shanghai, Tianjin and Chongqing, plus seven regional hubs that include Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an.

The Shanghai Procurement Administration posted a notice on its website stating that the general coordinator of the original "4+7" pilot scheme, announced the kick-off of the new round of the program designed mainly to control drug costs. The core of the 4+7 scheme lies in offering large and pooled promised volumes in exchange for price cuts that ensure selection in the bidding process. Related price reductions were made through a bidding negotiation process, and manufacturers must ensure quality and delivery while hospitals must guarantee payment.

After 10 months of the initial pilot being in place, the Chinese government is ready to roll out the program on a larger platform.

## In Brief...

- ◆ **Pfizer's** Board of Directors unanimously elected current CEO *Albert Bourla* to the position of chairman effective Jan. 1, 2020. He succeeds current Chairman, *Ian Read*, who will retire effective December 31, 2019. Bourla began his career with the company in 1993 in the animal healthcare unit and most recently served as the company's COO until being named CEO on January 1, 2019. Bourla said, "I am honored to have been chosen to succeed Ian as the chairman of the board of this wonderful company...I want to thank Ian for his unwavering dedication to Pfizer over the past four decades and during this leadership transition."

- ◆ **Dr. Reddy's** and **Novartis AG's Sandoz** have recently decided to halt distribution of their generic OTC versions of *Zantac (ranitidine)* due to discoveries of the drug being tainted with *N-nitroso dimethylamine (NDMA)* during its manufacturing. With the risk of stopping medication being higher than the risk of taking the drug, the FDA urged patients to continue to take their medication while they work towards a solution. Canada, and other regulators, decided to stop distribution of the drug until there was further knowledge of the risks. **Sanofi**, maker of *Zantac*, has decided to continue with distribution of the drug except in Canada, while **CVS** has halted sales of the drug at its stores across the U.S. **GlaxoSmithKline's** Japan unit initiated a voluntary recall of the drug on September 26th.

- ◆ *Emma Walmsley*, CEO of **GlaxoSmithKline** since 2017, was nominated as a **Microsoft** Board Member. Walmsley currently holds two other appointments; Co-chair of the Consumer, Retail and Life Sciences Council and Honorary Fellow of the Royal Society of Chemistry. The decision, to be made at the annual shareholders meeting Dec. 4, would

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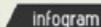
## "4+7" Nationwide Rollout

Centralized procurement gets rolled out to 25 Provinces in China



0.0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1.0

Out of total 31 provinces, only two are excluded: Hebei, Fujian

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## What We Know and Don't Know About Drug Pricing

(Source: An Article by Allison Gatlin for Investor's Business Daily)

It is well established that drug prices are at record-level highs and under a great deal of regulatory scrutiny as both the executive and legislative branches criticize pharmaceutical companies such as Pfizer, Novartis and Amgen. The first half of 2019 saw increases of 10.5% on 3,400 medicines, according to Rx Savings Solutions, a consulting firm for health insurance plans and employers. That was five times the rate of inflation.

Drugmakers are placing the responsibility for increases with pharmacy benefit managers (PBMs), many of which are controlled by health insurers. These PBMs negotiate discounts called rebates on prescription prices. Critics are quick to point out that PBMs are padding their profits by keep keeping the majority of the savings.

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## China (cont.) ...

The expanded area now covers 25 provinces, forming its own block and including: Shanxi, Inner Mongolia, Liaoning, Jilin, Heilongjiang, Jiangsu, Zhejiang, Anhui, Jiangxi, Shandong, Henan, Hubei, Hunan, Guingdong, Guangxi, Hainan, Sichuan, Guizhou, Tynnan, Tibet, Shaanxi, Gansu, Qinghai, Ningxia and Xinjiang. The new round of procurement will cover mainly public hospitals in the provinces within the block. Operational bidding will once again be overseen by the Shanghai Pharmaceutical Centralized Procurement Office.

Twenty-five products have been selected for the new round of bidding, including widely used statins such as *Lipitor* (*atrovastatin*), *rosuvastatin*, *losartan*, and the anti-platelet agent *Plavix* (*clopidogrel*). Also included are *Norvasc* (*amlodipine*), *Paxil* (*paroxetine*), *Viread* (*tenofovir*) *Risperdal* (*risperidone*), *Fosinoprl*, *Iressa* (*gefitinib*), *Gleevec* (*imatinib*) and *Alimta* (*pemetrexed*).

The new round of block purchases increase volume by approximately 12-fold compared to the first round, as noted by analysts. The largest purchase jump is expected to come from *gefitinib* at the 250 mg dosage, estimated to be a volume purchase of 5.74 million tablets. Among other major products, *amlodipine*, *atorvastatin*, *clopidogrel* and *rosuvastatin* will see increases between 268% and 432%.

The management of the new round of centralized procurement is requiring interested bidders to submit proposed prices for their products from 24 September. Prices should not be higher than the winning prices in the previous 4+7 bidding rounds and should not exceed the winning prices in the provincial bidding rounds that have taken place up to July 2019 in the “block” provinces. This means that winning prices of the newly expanded 4+7 round will potentially be equal or even lower than the previous round, putting even more pricing pressure on pharma firms.

Another aspect to keep in mind is that there is no longer a “winner takes all” situation in play. Under the expanded scheme, there will be no limits on the number of suppliers for a particular drug. However, in the case that there is only one winning bid, the order volume from block provinces will be cut to half of the promised volume. In the case of two winning bids, the volume will be 60% rising to 70% if there are three winning bids.

To ensure adequate supplies, producers will now be required to fulfill the promised volumes with the contract time of one year before submitting any bid.

## Drug Pricing (cont.) ...

But PBMs are pushing back, contending that the price increases are the fault of the drug manufacturers. They also point out that US\$9 out of every US\$10 in rebates are passed back to the health insurance plan or employer to lower insurance premiums for all.

No one disputes that the drug pricing system is complex and lacking in transparency. Furthermore, the U.S. is not willing to walk away from drugs that are too expensive – unlike other countries. Also, according to research, new drugs are launching at much higher price points, even as the costs of some old drugs rise. An example is the prescription prices of oncology drugs, which have doubled in the U.S. from 2013-2017 (as shown in a report by

Informa Pharma Intelligence dated 2018.) In fact, in 2017, every new cancer drug launched at more than US\$100,000, senior editor Jessica Merrill stated in the report.

With the rise in popularity of high-deductible insurance plans, so has the exposure of patients to increasing drug prices. However, some drugs qualify for rebates; unfortunately, these discounts are not applied at the pharmacy counter, meaning that the savings are never realized by the patients directly.

Nearly all countries (except the U.S.) have a government agency that determines if the drug price is appropriate. This explains why drug prices tend to be higher in the U.S. than in other countries. In the U.K., the National Institute for health and Care Excellence, or NICE, is responsible for determining if a prescription price is justifiable. If it is not, the agency is willing to deny access to that drug.

Pharmacy benefit managers also play a key role in the drug-pricing conversation. Through competition among drug makers, they negotiate rebates on prescription prices. In exchange, an insurer agrees to cover a specific drug. It’s important to realize that Medicare Part D operates similarly to employer insurance. Patients must pay a monthly premium and reach a deductible. Once the deductible is met, the patient pays a portion of the cost of the drug. In the case of Medicare Part D, the entire rebate goes back to the insurance company sponsoring the plan. Critics say that PBMs are keeping an increasing portion of those rebates. But because negotiations over rebates are secretive, it is difficult to know how much PBMs stand to benefit from these rebates.

It is this lack of transparency that has both consumer advocates and politicians saying that pharmaceutical companies are getting rich on the backs of the patients.

## In Brief (cont.)...

benefit both companies as GSK delves deeper into digital transformation and Microsoft wades further into healthcare.

- ◆ *Doug Long*, IQVIA’s Vice President of Industry Relations, presented at NACDS’ *Total Store Expo* in August 2019 with a rundown of pharmaceutical trends for the year. U.S. market dollar sales are up 6%, prescriptions are down 1%, 90-day prescriptions grew 3%. The 2019 flu season was less severe than 2018, but vaccine sales were good. Regarding prescriptions in stores, a U.S. retail store fills greater than 22,000 adjusted prescriptions per quarter, chains average 30,756 scripts, and independent average 12,233 scripts. Reimbursement issues will continue to worsen as they have in the past 10 years. Generic sales have decreased, despite the number of approvals in 2019, less products are making it to market. This has led to mergers and alliances like Bristol-Myers and Celgene, AbbVie and Allergan, and Upjohn and Mylan in an effort to consolidate the sector.

- ◆ *Eisai’s* Indian subsidiary entered a license agreement with the *Mylan’s* business unit in India, giving them the right to distribute and promote Eisai’s anticancer drug *Halaven* (*eribulin*) under the brand name *Teceris* in India. Eisai’s market is mainly urban areas with a tiered-pricing plan that ranges from full price to free, based on patient income.

(Sources: *FiercePharma*, *CBS News*, *Pharma Japan*, and *Scrip*)