



Pharma CEOs Meet with President Trump

(Sources: Drug Store News and an article prepared by Dan Mangan and published by Biotech and Pharmaceuticals)

Executives from several pharmaceutical companies (Amgen, Johnson & Johnson, Merck & Novartis) and the Pharmaceutical Research and Manufacturers of America (PhRMA) convened at the White House for a meeting with President Donald Trump, Vice President Mike Pence and House Energy and Commerce Committee chairman, Rep. Greg Walden. The president started the meeting by mentioning the price of drugs and the need for competition in the market place.

"You folks have done a terrific job over the years, but we have to get prices down for a lot of reasons. We have no choice," Trump said. "I'll oppose anything that makes it harder for smaller, younger companies to take the risk of bringing a product to a vibrantly competitive market. That includes price fixing by the biggest dog in the market, Medicare [the US program for the elderly]. But we can increase competition and bidding wars - we have to, big time - in that program [Medicare]."

PhRMA CEO, Stephen Ubi, said the meeting was "positive and productive" and said they "discussed many areas of common ground including: advancing stronger trade agreements to level the playing field with countries around the world; reforming our tax code to spur investment and job creation here in the United States; and removing outdated regulations that drive up costs and slow innovation." He noted that some policies, if enacted, could bring as many as 350,000 new jobs over the next 10 years due to biopharmaceutical industry growth. "Our industry takes seriously the concerns raised about the affordability and accessibility of prescription medicines, and we have expressed our commitment to working with the administration to advance market based reforms," Ubi said. "The current system needs to evolve to enable the private sector to lead the move to a value-driven health care system. To do this, we need to reform existing laws and regulations that are currently preventing private companies from negotiating better deals and paying for medicines based on the value they provide to patients and our health care system."

President Trump said that his administration is "focused on accelerating FDA approval - we're going to make the process much faster," with an emphasis on "streamlining the process so that, from your standpoint, when you have a drug you can actually get it approved if it works instead of waiting for many, many years."

Ubi said, "We look forward to working with the administration and Congress to advance solutions that promote economic growth and job creation and create a more competitive health care marketplace." The President called on the CEOs to produce their pharmaceuticals in the United States and said that he wanted to control "astronomical" drug prices. He was critical of foreign countries, which he said have been "freeloading" on the United States with price controls that limit what their citizen can be charged for medications.

Separately, many members of Japan's Central Social Insurance

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◆ **AmerisourceBergen Corporation** (ABC) announced increased revenues of US\$38.2 billion, an increase of 4%, for the first quarter of FY2017. ABC's pharmaceutical distribution segment (including AmerisourceBergen Drug Corporation and AmerisourceBergen Specialty Group) rose 3.9% to US\$36.6 billion. ABSG revenues surged 10.3% year over year, and total revenues for AmerisourceBergen Consulting Services, World Courier and MWI Veterinary Supply were up 5.4% to US\$1.7 billion. Separately, *MailMyPrescriptions.com* (America's only wholesale pharmacy service) announced a strategic pharmaceutical distribution agreement with AmerisourceBergen. Through this agreement, MailMyPrescriptions.com will be able to offer its members the same generic prescription drugs offered by Publix and Walgreens (both also supplied by AmerisourceBergen) at the same price.

◆ **McKesson Corporation** reported revenues for its third quarter ended December 31 of US\$50.1 billion. The results included pre-tax charges of US\$3 million related to the company's cost alignment plan previously announced in March of 2016. Distributions Solutions GAAP operating profit was US\$813 million and GAAP operating margin was 1.64%. Third quarter adjusted operating profit was US\$809 million on a constant currency basis, down 24% year over year. Also, on January 24, 2017, McKesson entered into an agreement to purchase **CoverMyMeds** for approximately US\$1.1 billion. CoverMyMeds, a privately-owned company, provides electronic prior authorization solutions to pharmacies, providers, payers and pharmaceutical manufacturers.

◆ **Walgreens Boots Alliance** has partnered with **WPP** (and selected a team of WPP agencies aka "Team WBA") to assist with the operation and development of multiple marketing and communications channels for its retail and wholesale businesses as well as its health and beauty product brands. "We are very pleased to confirm this new partnership and WPP and the creation of Team WBA," stated WBA Executive Vice Chairman and CEO *Stefano Pessina*. "We have grown so rapidly, so too
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Medical Council, or Chuikyo, raised concerns over the possibility that U.S. President Trump could ratchet up pressure on the Japanese pricing system with respect to his "America first" pledge.

Chuikyo's drug pricing subcommittee reached a consensus that US prices should be removed from what is called the foreign price adjustment rule, which is currently used to tweak prices of newly approved drugs based on the average of prices in four major countries overseas (US, UK, Germany, and France).

Regarding this proposed exclusion, Shoji Kono, director of the National Federation of Health Insurance Societies (Kenporen) who sits on the panel representing bill payers, worried that it might have an impact on distributions as there are a myriad of US-originated drugs. "We should carefully consider it [the exclusion] given his 'America first' slogan," he added.

Counterfeit *Harvoni* Discovered in Japan's Supply Chain

(Source: *Pharma Japan*)

The counterfeit issue, a rarity in Japan, sprang up earlier in January, when Japan's Ministry of Health, Labor and Welfare (MHLW) and *Harvoni*'s maker, Gilead Sciences, announced that five bottles containing fake *Harvoni* tablets were found at a pharmacy chain in Nara Prefecture. In response to the issue, the MHLW has been working with prefectural governments to retrace distribution channels based on records of lot numbers specified in these bottles; licensed wholesalers are required by law to keep logs of products upon their purchases and sales.

So far, onsite inspections of pharmacies and wholesalers have been carried out in Nara, Kyoto, and Osaka Prefectures as well as Tokyo, finding that nine operators (eight in Tokyo and one in Osaka) appear to have been involved in their distribution.

The MHLW said that the probe has identified an exact supply route for one of the five bottles, saying that it was distributed through 1) "an unlicensed seller," 2) "a wholesaler in Tokyo," 3) "another wholesaler in Tokyo," and 4) "a wholesaler in Osaka," and then reached the Nara pharmacy chain operator. The ministry did not disclose the name of these distributors, but revealed the name of the Nara pharmacy operator as Kansai Medico, and that the five counterfeits were discovered at three stores of Sun Pharma, a pharmacy it runs.

During the investigation, nine additional bottles containing counterfeit *Harvoni* tablets were discovered from inventories owned by two wholesalers in Tokyo, bringing the total number of counterfeits found in Japan to 14. All 14 bottles of counterfeit *Harvoni* were in the supply chain without box packaging or package inserts.

The MHLW said on February 1 that it has most likely confirmed the distribution routes of *Harvoni* counterfeits found in Japan in January. Most likely that a "genkin donya" dealer in Tokyo is responsible for placing the fake versions into the ethical drug supply chain. The "genkin donya" dealers typically purchase unsold inventories from medical institutions and sell them cheaper than drug wholesalers procuring products from the official source, or drug makers. Nevertheless, these dealers have a drug wholesaling licenses and, therefore, it is legal for pharmacies to buy their products from them.

The MHLW also revealed the results of investigations into the composition of fake pills contained in the five bottles found at Kansai Medico, and one bottle found in Tokyo. The five Kansai Medico bottles contained 1) pills containing multiple types of vitamins, 2) Kampo used for rhinitis and colds, 3) *Sovaldi* (sofosbuvir), and 4) *Harvoni*. One bottle found at a genkin donya dealer in Tokyo contained multiple types of vitamins.

China's New Monitoring Rules to Prevent Drug Shortages

(Source: An article by Wang Xiaodong and published by China Daily)

China will improve the monitoring of drugs that are prone to short supply to ensure they can be replenished quickly, according to a new national guideline. The guideline's drug regulations are aimed at addressing irregularities in the production and circulation of drugs and improving the quality and efficiency of drugs, Wang Hesheng, Vice Minister of the National Health and Family Planning Commission, said recently.

The guideline was drafted by the State Council's Health

Reform Office and the China Food and Drug Administration. Wang said the guideline has been approved and will be released soon. He further stated that under the guideline, authorities will take various steps, such as improving oversight of the production of drugs and expediting approval of new drugs, to improve the quality of drugs available for use.

The guideline also emphasizes streamlining the circulation of drugs between pharmaceutical companies and hospitals to reduce the price of drugs and control the increase of drug expenditures, Wang said. Periodic reports of short supplies of commonly used drugs, including essential drugs, in many parts of China have stirred public attention in recent years.

Protamine sulfate, an injection necessary for some operations including heart surgeries, was reported by media in April to be in short supply in many areas of China, forcing many hospitals to temporarily suspend heart surgeries. The National Health and Family Planning Commission responded in May that pharmaceutical companies in China had suspended production of the drug at the end of 2015 due to new standards released by health authorities, causing a shortage. It took measures to encourage production of the drug so it could be quickly supplied to the market again, the commission said in its May statement.

Wu Zhen, head of the China Food and Drug Administration, said that many drugs in short supply are especially for children. Guo Xiang, deputy director of consumer goods at the Ministry of Industry and Information Technology, said the ministry has selected seven kinds of drugs for children's use and has authorized pharmaceutical companies, since last year, to produce them to ensure the needed supply. The ministry invested 80 million yuan (US\$11.6 million) last year to help increase the supply of drugs for children's use, he said.

Fu Mingzhong, executive president of the China Association of Pharmaceutical Commerce [and a member of IFPW], said a national data platform on the monitoring of drugs should be established to address the shortage of drugs in China.

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have our marketing and communications needs, and this multi-dimensional model and new way of working will better support our vision for the company and future growth plans." Team WBA will provide a variety of services, including traditional and digital advertising, media investment management, promotion and relationship marketing, public affairs and media relations/communication for the enterprise.

- ◆ **Merck & Co.** announced that it will offer more detail regarding its U.S. pricing practices in an effort to provide more transparency. The company figures will be released on its website on February 3rd, and will show an average increase of 9.6% and an average net price increase of 5.5%.

- ◆ **Walgreens Boots Alliance** and **Rite Aid** extended their merger agreement in which Walgreens Boots Alliance will acquire all outstanding shares of Rite Aid. A new deal was also restructured that would value Rite Aid at approximately US\$6.8 billion to US\$7.4 billion (down from the initial acquisition cost of US\$9.4 billion.) WBA will be required to divest up to 1,200 Rite Aid stores and certain additional related assets for regulatory approval. The companies agreed to extend the end date under the previously announced agreement from January 27 to July 31.

(Company Press Releases, Drug Store News, MarketWatch & Wall Street Journal)