

## India Plans API Production Push

(Source: An article by Kyle Blankenship for FiercePharma)

The novel coronavirus pandemic has caused a host of problems in the global pharmaceutical supply chain, particularly in China, a major producer of active pharmaceutical ingredients (APIs). India is reportedly working on a plan to focus on this opportunity to elevate and grow its own ingredient manufacturing to combat Chinese dominance in the market.

The Indian government is planning to escalate domestic production of pharmaceutical ingredients to counteract a perceived over-reliance on Chinese imports now hampered by COVID-19 shutdowns. The country has identified and prioritized production of 53 raw materials and APIs as part of its "China-plus-one" policy to fill in supply gaps of affordable medicines. The plan includes investing US\$1.3 billion in domestic pharmaceutical producers and potentially reviving state-run companies to ramp up cheap generic production.

According to the news outlet, Bloomberg, 70% of India's imports of APIs come from China, totaling US\$2.4 billion of India's US\$3.56 billion in import spending for those products each year.

In early March, India ceased exports of 26 APIs and drugs that range from paracetamol—the ingredient in *Tylenol*—to antivirals like acyclovir for treating shingles and antibiotic neomycin. India is reportedly upping production of paracetamol and antibiotics penicillin and ciprofloxacin.

India's reported move to challenge Chinese dominance as a producer of pharmaceutical ingredients comes as the novel coronavirus pandemic has trained a spotlight on the state of the global supply chain.

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## IFPW's 2020 General Membership Meeting Postponed Until 2021

With the continuing COVID-19 pandemic creating critical situations regarding the health and well-being of IFPW members and the public at large, and the uncertainty involving worldwide travel, IFPW's board of directors and staff have made the difficult decision to postpone the IFPW 2020 General Membership Meeting to October 6-8, 2021.

This was a decision that was not arrived at easily, but IFPW believes it is in the best interest of our members' safety to avoid travel and participation in such a large group function during the originally scheduled dates. Additionally, IFPW member organizations are extremely busy in responding to the extra demands and challenges of their respective markets at this time which would make supporting the event's programming particularly challenging.

IFPW looks forward to welcoming you to Tokyo in 2021! If you have any questions, please contact Christina Tucker at [c.tucker@ifpw.com](mailto:c.tucker@ifpw.com)

## In Brief...

- ♦ **United Health** President, *Sir Andrew Witty* announced a leave of absence to co-lead the **World Health Organization's** effort to speed up development of a COVID-19 vaccine. Witty previously served as chief executive and a director of **GlaxoSmithKline** from 2008 to 2017.

- ♦ U.S. generics manufacturer **Mylan** is bringing back *Robert J. Coury*, its current chairman of the board and former CEO, to the role of executive chairman as the drugmaker navigates its way through the final stages of a generics megamerger with **Pfizer's Upjohn** unit, the company said Wednesday. Coury, who stepped away from the CEO role in 2012 in favor of *Heather Bresch*, previously held the executive chairman's job from 2012 to 2016.

- ♦ Twelve of the 13 largest pharmaceutical companies have reported first quarter declines, ten of which suffered double-digit declines. **Eli Lilly**, the only outlier, saw its valuation increase by almost 5%, closing out March 31. **Bayer AG** had the most substantial decline, seeing its share value fall more than 28%. **Roche** has been the least affected by the coronavirus outbreak with a valuation decrease of 1%. Despite these declines, all companies but Bayer AG saw a better first quarter than the S&P 500.

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## GIRP Welcomes EC Guidelines on Optimal and Rational Supply of Essential Medicines for COVID-19

(Source: GIRP Press Release)

GIRP welcomes the publication of the European Commission (EC) guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak. The guidance document focuses on the rational allocation of essential medicines (medicines used strictly in the context of COVID-19) in order to prevent their shortages during the ongoing COVID-19 pandemic.

We applaud "these EC guidelines as a strong statement of support to the ultimate goal of protecting public health while preserving the integrity of the EU Single Market" – Bernd Grabner, President, GIRP said.

GIRP, the voice of full-service healthcare distributors (with pharmaceutical full-line wholesaling as core function) highly appreciates and fully supports the EC's calls to EU Member States for supply chain optimization which asks them to:

- Ensure necessary support to the full-service healthcare distribution sector. The guidelines recognize that full-service healthcare distributors are responsible for distributing medicines within the EU/EEA and must be allowed to continue operating at full capacity and supply medicinal products to hospitals and pharmacies.

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## India (cont.)...

In the U.S., which relies on Indian APIs for a range of medications, the federal government has sparred with its South Asian supplier to keep supplies open, particularly the antimalarial hydroxychloroquine. The longtime generic med has received a raft of interest as a possible treatment for COVID-19 and is currently involved in several trials. It is also being used off-brand to treat COVID-19 patients.

Earlier this month, India walked away from a full-scale export lockdown on hydroxychloroquine after intervention by the United States. India, which produces around 47% of the U.S. supply of hydroxychloroquine, agreed to license its stock of hydroxychloroquine to "badly affected" countries and others that rely on its supply of the drug.

The combination of hydroxychloroquine and antibiotic azithromycin is viewed as a potential game changer in the race for a COVID-19 therapeutic as the pharmaceutical industry cycles a number of older medications through clinical trials to determine their efficacy in treating the disease. The U.S. Food and Drug Administration previously posted shortages of chloroquine and hydroxychloroquine due to increased demand partly tied to President Trump's explicit and public endorsement.

Meanwhile, China has also been closely watched for its response to the crisis. But thus far, the government there hasn't directly affected American supply, despite its ongoing trade dispute with the Trump White House, U.S. FDA Commissioner Stephen Hahn stated earlier this month.

However, Hahn did highlight the need for U.S. drug makers to build "redundancy" into their supply chains, potentially obviating the country's dependence on drugs made abroad.

## GIRP (cont.)...

- Their employees should have access to the necessary PPE. In order to ensure deliveries, vehicle drivers should also receive permits to travel without restriction and access hospitals, pharmacies and other dispensing sites (especially in quarantined areas).

- Lift export bans and export restrictions within the EU which can have detrimental impact on the availability of medicines on the EU market. Such restrictions can lead to shortages in other EU Member States.

- The guidelines remind that many of the current export bans are illegal. Fully implement 'green lanes' as production and distribution are multinational and border delays affect them.

- Avoid national stockpiling. Ensure fair distribution of supply within Member States and ensure that wholesale distributors, community pharmacies and hospitals receive their usual stocks of medicines.

- The possible extension of expiry dates of essential medicines by the Marketing Authorization Holder (MAH), based on their stability data.

GIRP also welcomes the proposal for the optimization of the retail sales to introduce limits on the amounts of essential medicines that patients can purchase via their retail pharmacies. Early in the crisis GIRP published a statement calling on EU institutions and national authorities to support the full-service healthcare distribution sector by calling for:

- National authorities to support stock optimization measures by full-service healthcare distributors or their customers.
- 'Green Lanes' for vehicles carrying medicines and medical supplies across all EU/EEA territories.
- Export bans on medicines to be lifted where they have been applied.

Monika Derecque-Pois, Director General, GIRP stated: "We are very pleased to see that most of our early thinking and calls have been reflected in the EC guidelines and believe the rapid adoption of national measures to apply the guidelines should be a top priority for all national authorities in their fight against the COVID-19."

## In Brief (cont.)...

- ◆ Pharmaceutical manufacturers, **GlaxoSmithKline (GSK)** and **Sanofi**, have partnered to produce a COVID-19 vaccine. The companies plan to bring GSK's vaccine adjuvant technology together with Sanofi's 'S-protein' candidate. The two companies have already partnered with other companies to combat the virus, however, the companies' large scale manufacturing capacity and R&D experience may prove to be an important factor in determining the product that will make the most impact. The companies aim to have an available vaccine to develop by the second half of 2021. Separately, Sanofi, in collaboration with California-based **Luminostics**, is developing a mass-scale testing solution. Luminostics has developed a technology that fits onto a smartphone to allow for COVID-19 self-testing.

- ◆ Japan's **Ministry of Health, Labor and Welfare (MHLW)** issued a notification to the **Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ)**, the **Pharmaceutical Research and Manufacturers of America (PhRMA)**, the **European Federation of Pharmaceutical Industries and Associations (EFPIA)**, as well as the **Federation of Japan Pharmaceutical Wholesalers Associations (JPWA)** and other drug distributors. The notification asked to closely monitor and plan for shortages due to manufacturing or import stoppages, and keep tabs on product-by-product supply outlooks. Meanwhile MHLW also asked industry organizations to reduce workforces by 70-80% by having non-essential employees work from home in order to end the state of emergency brought on by COVID-19 in a month. MHLW also requested that companies stagger work hours in order to maintain proper social distancing.

- ◆ U.S. based **National Association of Chain Drug Stores** has named **Walgreens** president *Richard Ashworth* to the chairman's position of the NACDS board of directors. He will succeed *Chris Lane*, executive vice president of Wakefarm Food/ShopRite. Lane will remain on the board of directors. Additionally, NACDS named four new executive committee members, and re-elected three board members. Three new board members were also elected.

(Sources: *Drug Store News, Endpoint News, FierceBiotech, FiercePharma, Pharma Japan, Pharma Times, and Scrip*)