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# Public Health Must be the Leading Priority of Europe's Pharmaceutical Sector

*(Sources: An article by the European Public Health Alliance and an article by Michael Mezher for Regulatory Focus)*

In the EU, leading civil society organizations are calling for access to affordable and quality medicines in Europe while guaranteeing everyone's right to a healthy and sustainable environment. Human medicine is not an ordinary commodity. Public interest and public health should prevail as leading priorities when regulating the pharmaceutical sector. The European Commission is developing a sustainable strategy to improve transparency throughout the pharmaceutical industry – research & innovation (R&I), financing, manufacturing, authorization, and environmental risk. Currently the European Commission is looking to revamp parts of the regulatory framework for medicines in the EU to address shortages, access to medicines and innovation, according to a roadmap document released for consultation on Tuesday.

"There is a need to build a holistic, patient-centered, forward-looking EU Pharmaceutical Strategy which covers the whole life-cycle of pharmaceutical products from scientic discovery to authorization and patient access," the Commission stated in the roadmap.

Within the document, the Commission lays out six issues it aims to address with the forthcoming strategy, including medicine access and affordability; shortages of needed medicines such as antibiotics and vaccines; and environmental risks related to the manufacturing, use and disposal of medicines.

The document also raises three distinct issues related to pharmaceutical innovation to be addressed: the alignment of innovation and public health needs: the funding and capitalization of EU-based biotech research; and, barriers to innovation within the regulatory framework for medicinal products and new technologies.

"Important scientific and technological advances such as gene and personalized therapies, smart health applications, medical technologies, including AI, are transforming the landscape and becoming increasingly integrated as part of overarching therapies. However, the regulatory framework may not be keeping pace with these changes," the Commission writes.

The Commission says the strategy will explore both legislative and non-legislative actions and areas for EU investment and could include a review of orphan and pediatric medicines regulations, fees collected by the European Medicines Agency (EMA) and "could also include a targeted evaluation and subsequent review of the basic pharmaceutical legislation."

The proposal also looks at ways the EU can reduce dependence on foreign manufacturing and increase the competitiveness of European companies. The Commission notes that the strategy will be coherent with recent regulations governing clinical trials and medical devices across the EU.

The Commission has requested feedback on the initiative before moving to a public consultation on the strategy later this year, and stated it is aiming to adopt the strategy by the end of 2020.

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## In Brief...

- **McKesson Corporation** announced that it is restructuring its business into four segments beginning in the second quarter of 2021. *Brian Tyler*, McKesson's CEO, stated "We are in the midst of a dynamic healthcare environment with ongoing shifts in technology, reimbursement policy and patient centricity. This new structure positions McKesson to better meet our customers' needs by driving efficiencies, enhancing operations and delivering new solutions that are directly focused on solving the biggest challenges." The four segments include: U.S. Pharmaceutical (formerly U.S. Pharmaceutical and Specialty Solutions), Prescription Technology Solutions, International, and Medical-Surgical Solutions.
- **Walgreens Boots Alliance, Inc.** (WBA) announced financial results for the third quarter of fiscal 2020 ending May 31st. Sales increased 0.1 percent to US$34.6 billion, up 1.2 percent on a constant currency basis, led by Retail Pharmacy USA. There was an operating loss of US$1.6 billion, compared to operating income of US$1.2 billion a year ago, primarily due to non-cash impairment charges of US$2 billion in Boots UK. Adjusted operating income decreased 46.5 percent to US$919 million on a reported basis, down 46.4 percent on a constant currency basis. Separately, Walgreens expanded its partnership with **VillageMD** to open 500 to 700 full-service doctor's offices co-located at its stores. The companies are expanding the offering following a successful trial that began last year.
- **Johnson & Johnson** and Maryland-based **Emergent BioSolutions** inked a five-year work order worth at least US$480 million to help produce the New Jersey-based drugmaker's COVID-19 vaccine candidate. Emergent will provide "large-scale" drug substance manufacturing for J&J's recombinant DNA shot beginning in 2021 for the first two years of the deal.

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# IFPW Mourns the Passing of Michael Catanio of Bayer Pharmaceuticals

IFPW regrets to announce that Michael Catanio, Director of Trade Relations for Bayer Pharmaceuticals, passed away on July 3, 2020.

A native of Stockton, California, he resided in Nutley, New Jersey for the past 20 years. His career in the pharmaceutical industry spanned 55 years. For the past 15 years Michael served as Director of Trade Relations at Bayer Pharmaceutical's Whippany, New Jersey location.

Michael was a longtime supporter of IFPW and a regular participant at industry meetings. His jovial disposition and genuine smile along with his in-depth knowledge of the pharmaceutical industry will certainly be missed.

IFPW sends its heartfelt condolences to the Catanio family.

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## EU (cont.)...

The European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomed the roadmap and said in a statement that it "looks forward to working with the EU institutions and Member States to build Europe's health research ecosystem, increasing our resilience to global health threats and driving our economic recovery."

EFPIA pushed back on some of the needs for reform, writing that it "believes that much can and should be done already now within the existing framework by recognition and efficient implementation of the lessons learned from the COVID-19 crisis."

## The Role of Pharmaceutical Distribution in Early Detection of Health Crises

*(Sources: An article by Explica)*

Cofares President, Eduardo Pastor, has pointed out that "pharmaceutical distribution" is an accurate gauge that can assist in the early detection of future health crises. Through current technology platforms, information concerning the consumption of certain medical devices as well as consumer trends can be tracked, allowing for better preparation and more informed decisions when dealing with a health crisis.

While speaking at a an industry meeting, "Spanish Companies Leading the Future", Pastor explained "from our privileged angle in the sector, in January we knew who was requesting masks along with their location, a rather unusual purchase in our country. It was the first sign that something was happening."

Additionally, he noted that technology platforms make it possible to inform the appropriate health authorities of the patient cases with suspicious symptoms through pharmacy networks.

During his participation, Pastor pointed out that protection and well-being of a population depends largely on the participants in the "health chain" where distribution is part of the connection between the industry which supports the innovation, and the pharmacy that has direct interaction with the patients.

"Even in moments of maximum stress, we have guaranteed the full supply of medicines by doubling routes and adding equipment. This [COVID] crisis has been a test of efforts from the first second and we have known how to respond." He also emphasized that, as an advanced society, it is important to support innovation in new medicines – not just vaccines, but antibiotics as well for use in future pandemics, and also provide the sector with a stable legal framework that generates certainty and security. He added that the industry does not need to make the least expensive drugs, but that it is important to provide the most efficient drugs. This is key in helping to control future outbreaks or diseases that are not yet known.

Faced with future pandemics, Pastor stressed that Spain and other countries cannot depend on outside sources to obtain strategic protection material, and must be committed to creating a contingency plan. "We have had difficulties in accessing personal protective equipment when searching for them in international markets and that cannot be repeated. We must have a well-orchestrated national contingency plan among the competent agents in the matter, starting with the company familiar with the purchasing system of international markets," he explained.

Another critical component is to maintain a strategic reserve of medicines that ensures the supply of other molecules in the event of a border closure. It is important to increase in-country production combined with the location of plants so as not to overly depend on the outside resources when it comes to these key drugs. A more localized industry means better security.

In closing, Pastor appealed to not let the health system break down. "Well, after all, when we take care of the health of others, we are preserving our own." For the system to be sustainable, governments need to increase investment in public health.

## In Brief (cont.)...

For the final three years, the partners will use a "flexible capacity deployment model" to provide annual batches as needed.

- Japanese manufacturer **Takeda** has paired with synthetic DNA services company **Twist Bioscience** to level up its biologics capacity. Under the pact, Takeda will tap the Twist's phage display libraries for the discovery, validation and optimization of antibodies in Takeda's pipeline of biologics across its four core areas: oncology, rare diseases, neuroscience and gastroenterology. Together, the companies will work to discover, validate and optimize new antibody candidates. In return, Takeda will pay Twist annual technology licensing fees as well as milestones and royalties for all compounds discovered from the Twist phage display libraries.
- The **Federation of Japan Pharmaceutical Wholesalers Association (JPWA)** issued an emergency statement making a plea against the Japanese government's plan to conduct a drug price survey for its first "off-year" re-pricing scheduled for April of 2021. The statement reiterated the all-out efforts being made by healthcare providers to tackle the COVID-19 pandemic and the adverse effects a downward re-pricing would cause.
- Two experimental COVID-19 vaccines jointly developed by U.S. pharmaceutical manufacturer **Pfizer** and German biotech firm **BioNTech** have received "fast track" designation from the **U.S. Food and Drug Administration**. The candidates, *BNT162b1* and *BNT162b2*, are the most advanced of at least four vaccines being assessed by the companies in ongoing trials in the U.S. and Germany. *BNT162b1* has shown potential against the virus and was found to be well-tolerated in early-stage human trials.
- As the COVID-19 spread continues across the world, the U.S. is likely see a shortage of generic pharmaceutical drugs, according to a new federal intelligence report prepared by the **U.S. Department of Homeland Security**. The report, distributed to law enforcement and government agencies, warned that the U.S. is already seeing shortages of more than 200 drugs and medical supplies due to strains on the supply chain caused by international shutdowns early on in the pandemic.
- Researchers at **Vanderbilt University Medical Center**, the **University of North Carolina at Chapel Hill** and **Gilead Sciences** reported that *remdesivir* potently inhibited SARS-CoV-2, the virus which causes COVID-19, in human lung cell cultures and that it improved lung function in mice infected with the virus. These pre-clinical findings help explain the clinical effect the drug has had in treating COVID-19 patients. *Remdesivir* has been given to patients hospitalized with COVID-19 on a compassionate use basis since late January and through clinical trials since February. In April, a preliminary report from the multicenter Adaptive COVID-19 Treatment Trial suggested that patients who received the drug recovered more quickly.

*(Sources: Company Press Releases, Drug Store News, FierceBiotech, FiercePharma, Pharma Japan, and Reuters)*