

The European Union's Newly Adopted Pharmaceutical Strategy

Sources: (A Press Release by the European Commission)

Innovation and the implementation of digital technology present new possibilities in how medicines are developed and used. However, innovative therapies do not reach all patients across Europe quickly and patients might not have access to medicines they need due to shortages. The unprecedented coronavirus pandemic further demonstrates how important it is to have a crisis-resistant system and ensure availability of medicines, no matter the circumstances.

At the same time, Europe's population is aging and faces a rising burden of diseases and emerging health threats such as COVID-19. Equally concerning is the challenge health systems and patients have when bearing the cost of necessary medicines. The EU is also becoming increasingly dependent on outside countries for importation of medicines and active ingredients needed to manufacture important drugs. Complications and issues such as anti-microbial resistance and environmental sustainability of medicines is also a major concern.

The Pharmaceutical Strategy for Europe, which was recently introduced by the Commissioner for Health and Food Safety Stella Kyriakides, was adopted as an important component of the new EU Health Union. The strategy aims to address these issues by creating a regulatory framework and support the industry in promoting research and technologies that reach patients and fulfill their therapeutic needs while addressing existing and potential market failures. It will also account for weaknesses exposed by the coronavirus pandemic and factor-in appropriate actions to strengthen the system.

It will be based on 4 specific pillars, which include legislative and non-legislative action:

- Ensuring access to affordable medicines for patients and addressing unmet medical needs.
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and more environmentally "green" medicines.
- Enhancing crisis preparedness and response mechanisms, diversified and secure supply chains and address drug shortages.
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

The Commission Communication on a Pharmaceutical Strategy for Europe includes a set of actions. Work in some areas, which are more mature, is already well under way, and includes the revision of the legislation on rare diseases (including those currently without a cure), combatting cancer, pediatric diseases, antimicrobial resistance, transparency in the supply chains of medicines, joint EU procurement, public-private partnerships, and finalising the health technology assessment legislation. Other important issues to be addressed were raised, including the development of medicines for

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♦ US wholesaler and distributor **Cardinal Health** has been chosen by its home state to support efforts in the distribution of the COVID-19 vaccine. The **Ohio Department of Health** has selected Cardinal's **OptiFreight Logistics** to provide same-day delivery services of any vaccine doses received by the state for distribution at Ohio's 350 vaccine locations throughout 88 counties. The first doses are expected sometime between December 18 and December 20, 2020.

♦ **ColdJet**, the worldwide leader in the manufacturing of dry ice production and blasting equipment — has announced that it is now helping industry and governments to safely distribution billions of vaccines across the globe. "Dosing dry ice directly into temperature-controlled thermal shippers is the only way to maintain that temperature level during transit and storage," said **Wim Eeckelaers**, Managing Director, EMEA, Cold Jet. "At all points in the vaccine transportation and distribution cold chain, dry ice is needed to maintain temperature." ColdJet's Dry Ice Production Hub will help solve the issue of a lack of dry ice, particularly in developing countries where millions of doses could be lost due to cold chain failures.

♦ Pharma manufacturer **AstraZeneca (AZN)** has reached a final agreement with Japan to supply 120 million doses of the COVID-19 vaccine once approved. According to a statement on December 11th by the **Ministry of Health, Labor and Welfare**, the vaccine supply to Japan will start early next year, with 30 million doses to be received by March. Separately, AZN announced that it will acquire pharma manufacturer **Alexion** for a stock and cash offer valued at US\$39 billion. The acquisition further strengthens AZN's long-term pipeline.

♦ **Sanofi** and **GlaxoSmithKline** announced a delay in their COVID-19 vaccine candidate after disappointingly low immune response in Phase I/II trials. The companies are combining Sanofi's recombinant protein-based vaccine with GSK's adjuvant technology. The companies had hoped to move into Phase III trials by the end of 2020 but believe these trials will start in the second quarter of 2021.

♦ **Viatis**, the newly minted merger between **Pfizer's Upjohn**

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The IFPW Staff wishes its members, colleagues and constituents a **safe** and **healthy** holiday season, and a successful New Year!

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many rare diseases. The implementation of the strategy will span the mandate of this Commission and incorporates a proposal for revision of pharmaceutical legislation in 2022.

Since the publication of the Strategy Roadmap in June 2020, the Commission has conducted a series of consultations and meetings to inform the public, and a period for public comment (through an online forum) on the Pharmaceutical Strategy for Europe closed on September 15, 2020.

The Commission has taken into account the positions and priorities raised by stakeholders and the public and has been working closely with Member State authorities in the context of its consultative committees.

The Pharmaceutical Strategy for Europe covers the whole domain of pharmaceuticals, as well as some aspects of medical devices. It creates synergies with the European Green Deal and the EU Strategic Approach to Pharmaceuticals in the Environment. This initiative also aligns with the new Industrial Strategy for Europe, Europe's Beating Cancer Plan, and the European Digital Strategy. It is also linked to the action plan on Intellectual Property.

The strategy marks the beginning of a process involving several legislative and non-legislative actions, which will be launched and agreed upon by Parliament in the coming years.

Earlier this month, Parliament adopted its position on the EU4Health Programme after securing a significant increase in the budget to €5.1 billion (US\$6.2 billion) in the compromise on the EU's long-term budget.

Pharmacies Accelerate Use of Technology During Pandemic

(Source: An article by Tom Skelton for Surescripts)

Pharmacists have always been on the front lines, more so now than possibly at any other point in time. Every moment counts, and time spent on hold or waiting for a fax to resolve administrative issues related to drug therapy problems creates inefficiencies. While pharmacies have been using electronic prescribing for nearly the past 20 years, the opportunity for improvement on efficiency exists and is necessary now more than ever.

An example of this is the RxChange transaction, a technology solution developed by SureScripts that saves time and replaces manual processes, including alerting prescribers when a therapeutic interchange might be beneficial, a prescription needs clarification, or a medication is out of stock, in shortage, or no longer available. RxChange is helpful in resolving issues in a fraction of the time and with an added level of safety. This allows pharmacists to focus on more important aspects, such as patient care.

One of the biggest threats to medication adherence is cost, a challenge that is getting progressively worse. But medication affordability can be a problematic issue for pharmacies due to manual processes that impede availability of cost information when it is needed.

Fortunately, pharmacies are turning to benefits-based prescription price transparency tools that enable quick access to therapeutic alternatives, real-time prescription costs and coverage details – all within the ease of an electronic workflow.

Another immediate challenge is dealing with patients who have chronic conditions, requiring quick dispensing of their needed medications. Oftentimes obtaining these medications in a timely manner is not easy. According to a survey by Surescripts,

specialty prescriptions can take as many as four days to fill, and delays of up to seven days are not uncommon. The survey also revealed that administrative tasks were an obstacle to efficient and effective patient care. The leading cause of administrative delays was prior authorizations.

Despite inefficiencies and other barriers, specialty pharmacies are working overtime to ensure that important therapies are not interrupted due to COVID-19. The solution lies in replacing manual processes with a more streamlined electronic workflow. These specialty pharmacies can now initiate a patient search of clinical information and prior authorization yielding faster treatment and drug therapy dispensing.

Accelerating health IT use in pharmacies will assist pharmacy staff. Increasingly, these healthcare professionals are recognized as essential patient resources and critical members of the overall healthcare team, particularly during the COVID-19 pandemic. By leveraging these new technologies, pharmacies can exponentially improve workflow, giving pharmacists the opportunity to provide expanded patient services and optimal patient care.

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unit and **Mylan**, has detailed plans for a corporate restructuring that involves the closing of up to 15 facilities and a downsizing of its workforce, resulting in a cost savings of at least US\$1 billion from its cost base. The restructuring is slated to be complete by no later than 2024 and will include the closing of facilities in West Virginia (U.S.), Ireland and Puerto Rico, plus its active ingredient plants in India.

- ♦ Japan's **Ministry of Health, Labor and Welfare (MHLW)** announced that wholesalers who have the appropriate criteria will be selected to distribute COVID-19 vaccines in Japan. While fair competition needs to be ensured, distributors with certain capabilities and track records will be preferred during the selection process. **The Federation of the Japan Pharmaceutical Wholesalers Association (JPWA)** will pick wholesalers that meet the requirements and ask them about their intentions regarding vaccine distribution. JPWA will then report the result to the MHLW, who will then compile a list of candidates for each region and oversee the selection process.

- ♦ A new variant of the coronavirus has been found in parts of England, according to Britain's Health Secretary, *Matt Hancock*. The BBC reported at least 60 different local authorities have recorded cases of the virus caused by the variant. Hancock said that there is nothing to suggest it caused worse cases of the virus or that vaccines will be ineffective in treating the new variant.

- ♦ Korean pharmaceutical companies are speeding up clinical trials to develop COVID-19 treatments using drug repositioning, in keeping with the government's schedule to introduce COVID-19 therapies by January of 2021. Drug repositioning is a method of developing new drugs by identifying new indications for already commercialized medicines or those in the clinical stage. Companies can quickly develop new drugs at a relatively lower cost using this method compared with existing new drug development strategies.

(Sources: Drug Store News, Economic Times, FiercePharma, Korea Biomedical Review, Pharma Japan, Scrip Intelligence, and Seeking Alpha)