Europe Set to Tackle its New Pharmaceutical Strategy from 2021

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PRICENTRIC BRIEF

- In November 2020 the European Commission (EC) adopted a new Pharmaceutical Strategy for Europe, covering everything from access and affordability to competition support and frameworks for innovation
- The plan is primarily a crisis response outline, building on lessons learned from COVID-19, in order to better prepare for future potential pandemics and other crisis
- Another primary feature of the plan is to support the competitiveness and innovative capacity of Europe's pharma industry, as well as revising the EU's pharma legislation in order to simplify and ultimately streamline regulatory frameworks

THE DETAILS

BELGIUM, Brussels – In November 2020 the European Commission (EC) adopted a new Pharmaceutical Strategy for Europe, covering everything from access and affordability to competition support and frameworks for innovation. The project will be proposed by the end of 2021 according to the EC, and will be based on four specific pillars, which include legislative and non-legislative action:

- Ensuring access to affordable medicines for patients, and addressing unmet medical needs (e.g. in the areas of antimicrobial resistance, rare diseases);
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines;
- Enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages;
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

The plan is primarily a crisis response outline, building on lessons learned from COVID-19, in order to better prepare for future potential pandemics and other crisis.

The agenda will be implemented over the coming years, and tackle issues such as cooperation between national authorities on pricing, payment and procurement policies in order to help improve affordability and cost-effectiveness of drugs.

Another primary feature of the plan is to support the competitiveness and innovative capacity of Europe's pharma industry, as well as revising the EU's pharma legislation in order to simplify and ultimately streamline regulatory frameworks.

Before she officially announced the outline of the plan, President of the European Commission, Ursula von der Leyen explained: "We are changing the way we address cross-border health threats. Today, we start building a European Health Union, to protect citizens with high quality care in a crisis and equip the Union and its Member States to prevent and manage health emergencies that affect the whole of Europe."

Feedback

The European Federation of Pharmaceutical Industries and Associations (EFPIA) "welcomed" the Strategy, but simultaneously expressed that it believes "the approach to addressing access and affordability outlined in the Strategy is the wrong one."

A number of the detailed points in the plan are in a similar vain to EFPIA's own 'Regulatory Road to Innovation', which focuses on strengthening regulatory assessment, working on use of RWE in decision making and streamlining pathways for regulation of devices with drugs.

EFPIA Director General, Nathalie Moll specifically noted that "In tackling AMR, the Strategy recognizes the importance of incentives in driving research into unmet medical need. However, at the same time,

the Strategy suggests destabilising and weakening incentives designed to support innovation in multiple areas including for medicines for rare diseases and children, as a way of addressing issues of access and affordability of medicines."

EVERSANA Insight

On the release of the plan, EVERSANA's Europe and Asia-Pacific Vice-President, Mike Ryan, reminded that "patient access and health data collection has been hindered by increasing drug development costs and, subsequently, pricing, as well as inconsistent drug availability across the EU. The onset of COVID-19 further emphasized the need to improve patient access, drug affordability, competitive pricing, and overall crisis preparedness and response in the EU healthcare system.

"In particular, the EU will encourage greater incorporation of health technology assessment (HTA) requirements in the design of clinical trials and subsequent closer collaboration between HTA authorities. The EU is advocating greater consistency in the data requirements for HTA approvals in all member states.

"This urgent push for affordable pricing will, the EU believes, contribute to increased competition among pharmaceutical companies in the EU healthcare system. As competition escalates, especially between generic and biosimilar drugs, pharma companies will need to meet heightened standards in HTAs and efficacy as well as supply chain demands."

Putting the Strategy into Action

Consultations with member states at the political level began in December 2020, and implementation of the various aspects is expected to occur as imminently as possible.

Going forward, the Commission has outlined a number of priority "flagship" actions, including a revision of the basic pharmaceutical legislation with a proposed target date of 2022.

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The strategy outlines a proposal for an EU Health Emergency Response Authority, dubbed HERA, which has been planned for the second half of 2021.

The long-term project also wants to initiate a structured dialogue with and between all actors in the pharmaceutical manufacturing and public authorities to "identify vulnerabilities in the global supply chain of critical medicines and shape policy options to strengthen the continuity and security of supply in the EU."

Some aspects of the strategy have been met with almost unanimous approval, such as pan-European HTA, accelerated marketing authorization, parallel scientific advice on trial design, optimized SPCs, European Health Data Space, and support for innovative trial designs, according to Neil Grubert, founder of Future of Pharmaceutical Market Access group.

Grubert noted, however, when speaking at the 3rd Annual Pharma Pricing, Reimbursement & Market Access 2020, that other aspects of the plan are somewhat uncertain in terms of impact on industry.

These parts of the framework include research on the root cause of market access delays, improving the competitive functioning of markets, developing framework for repurposing off-patent medicines, and the use of digital technology to tailor incentives for innovation.