A Pharmaceutical Strategy for Europe: Questions and Answers

Brussels, 25 November 2020

1. Why is the Commission presenting this strategy now?

The new pharmaceutical strategy for Europe is a key pillar of the **European Health Union**, which President **von der Leyen** called for in her 2020 State of the Union speech.

To help building a true European Health Union, the strategy aims to the **tackle long-standing weaknesses** in the area of medicines, weaknesses that have been further exacerbated and thrown into sharp focus by the current COVID-19 pandemic. The main challenges concern the affordability, access and shortages of medicines as well as the need to support the EU pharmaceutical industry to innovate, tackle its economic and environmental sustainability challenges and be a world leader in a fast changing global environment.

To address these challenges, the pharmaceutical strategy covers the **full lifecycle of a medicine**. This includes a broad scope of areas such as research and development of medicines, laboratory testing, clinical trials, marketing authorisation, manufacturing, health technology assessment, pricing and reimbursement, access, intellectual property (IP) protection, and the entry of medicines, including generics and biosimilars in the market.

The Strategy will also ensure that the latest scientific trends and digital technologies such as advances in biotechnology and the use of artificial intelligence (AI) are taken into account.

Finally, the strategy will build synergies with various other policy areas, such as research & innovation, industrial policy, competition, trade and environmental policies.

2. Is the strategy taking into account lessons from the COVID-19 pandemic?

The COVID-19 pandemic has demonstrated that existing flaws in the health systems can have grave consequences in a crisis. The Pharmaceutical Strategy will address both the short-term challenges linked to COVID-19, and the longer-term challenges linked to unmet medical needs, open strategic autonomy and sustainable health systems.

One of the early lessons from the pandemic is that the EU needs to **reinforce its governance tools** and further develop the mechanisms that have been put in place in the context of COVID-19.

The EU capacity to deal with such events and the lessons from this pandemic have already been largely addressed in the **European Health Union Package** adopted by the Commission on 11 November. In the area of medicines, the Commission proposed to **strengthen the role of the European Medicines Agency (EMA)**. The Agency is to serve as a central hub for scientific excellence and coordination to help monitor, quantify and mitigate shortages of crucial medicines during a crisis, to be more efficient and avoid duplication at different levels in the EU.

The Pharmaceutical Strategy for Europe will complement the Health Union Package and will assess what **further improvements** are needed **in the medium to longer term** to address such threats in a more comprehensive and coordinated manner.

3. What is the importance of the pharmaceutical sector for the EU's economy?

The pharmaceutical industry is of key importance for the EU's economy.

In 2019 it invested more than €37 billion in Research and Development (R&D), it is responsible for 800.000 direct jobs and almost 110 billion € in trade surplus.

At the same time the EU is the second largest market in the world for pharmaceuticals. The EU's total pharmaceutical spending was around €190 billion in 2018. The overall pharmaceutical sales

is even greater when including the medicines used in hospitals.

4. Is the strategy linked to other recent initiatives by the Commission?

The strategy will have strong synergies with other major policy initiatives of the Commission, such as the **European Green Deal**, including the **Chemicals Strategy** as building block of the upcoming Zero Pollution Action Plan, as well as with the new **Industrial Strategy for Europe**, the Action Plan to implement the **European Pillar of Social Rights** and the strategy on **Europe's Digital Future**. Several actions proposed in the Pharmaceutical Strategy make the link with these different policies.

Another example is the creation of a **European Health Data Space**. An interlinked system giving access to comparable and interoperable health data from across the EU is an important asset for research and regulatory work.

5. How will the pharmaceuticals sector become more sustainable?

To respond to the objectives of the **Green Deal,** a more sustainable pharmaceuticals sector is necessary. Action is required throughout the lifecycle of medicines to reduce resource use, emissions and levels of pharmaceutical residues in the environment, including those from antibiotics. This will be done by building and complementing the existing EU Strategic approach of pharmaceuticals in the environment, and by introducing changes in the legislation where necessary and reviewing the provisions on environmental risk assessment.

6. How is the Strategy interacting with the European Health Union Package and the upcoming Europe's Beating Cancer Plan?

The availability of safe, effective and affordable medicines is necessary both in times of crisis and in normal times.

This is exactly what the strategy intends to ensure. It is therefore a key component of the work to build a strong European Health Union as proposed by the Commission. The first package of measures adopted by the Commission on 11 November intends to make the EU more resilient to crises, by ensuring it acts in a coordinated manner to **cross border health threats** and has the tools to find solutions. The proposed revision of the mandates of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) mandates are part of this response. In particular, the Commission proposed to reinforce the role of EMA in the areas of monitoring, anticipating and mitigating supply shortages in times of crisis. The proposal also reinforces EMA's capacity to provide sound scientific input for the timely development of required therapies and vaccines.

The EU Health Emergency Response Authority (HERA) to be proposed next year, will also focus on horizon scanning and a robust foresight capacity that will help us anticipate threats but also identify promising and innovative countermeasures.

The pharmaceutical strategy also supports the goal of sustainable **cancer** prevention by introducing the right incentives to boost innovation to address for unmet needs. These include vaccination against treatable infections that cause cancer. With its focus on ensuring accessible, affordable and available medicines, the strategy also supports the rights to access high standard diagnosis and treatment. All this will directly contribute to the objectives of prevention and treatment under the upcoming **Europe's Beating cancer plan'.**

7. Will the strategy tackle the issue of shortages of medicines?

The Commission acknowledges that shortages of medicines is a **long standing problem with serious consequences for public health**.

In most cases, shortages become more frequent for products that have been on the market for many years and are widely used. In other cases, shortages are the result of fragile supply chains, an insufficient number of suppliers, or the lack of commercial incentives to develop cheap and low-volume medicines. This is particularly problematic for smaller and less wealthy markets.

Several elements explain this situation, such as marketing strategies, parallel trade, weak public service obligations, supply quotas and pricing and reimbursement policies.

The Commission will therefore **revise the basic pharmaceutical legislation to enhance**

security of supply and address shortages. Minimising the impact of medicines shortages on patient care will require both preventive and mitigating measure.

Moreover, and as a direct response to the COVID-19 crisis, the **European Health Union Package** adopted by the Commission on 11 November 2020, proposed to monitor and mitigate shortages of medicines during a health crises and to reinforce the capacity of EMA.

The mandate of the upcoming European Emergency Response Authority will support the development and deployment of advanced medical goods as well as other key technologies.

Finally, public authorities need to **reinforce their oversight** of the supply chain and the quality of medicines and raw materials to identify vulnerabilities and strategic dependencies, without compromising the benefits of global trade and integrated value chains.

8. Will the strategy lead to a reshoring of the production of medicinal products to the EU?

Achieving strategic autonomy while preserving an open economy is a key objective of the Union.

As requested by the European Council, the Commission will identify strategic dependencies and propose measures to reduce them. These may include diversifying production and supply chains, ensuring strategic stockpiling, and fostering production and investment in Europe.

This is, however, a very complex issue which requires the collection of **additional data and further evaluation**. The Commission will therefore ensure a **"structured dialogue"** with actors in the pharmaceuticals manufacturing value chain and public authorities to identify vulnerabilities in the global supply chain and help formulating policy options to strengthen the continuity and security of supply in the EU.

9. Will the strategy address affordability concerns and the problem of increasingly high prices for certain products?

The current EU system is based on the principle that innovative medicines should be rewarded through a patent system that limits competition and the entry of generics. Upon expiry of a period of exclusivity, competition is restored and generics may enter the market at a lower price and allow to increase the availability of treatment options.

This approach is however increasingly put under pressure.

For instance, new expensive medicines **increase pharmaceutical expenditures**, and put a financial burden on our health systems. For more than 50% of households in the EU the cost of medicines represents a financial or heavy financial burden. Member States increasingly face **uncertainties over the real-life effectiveness and related overall costs of new medicines**. Moreover, competition, which should in principle drive down prices and thereby increase affordability, is becoming less straightforward over time as new types of products make up a growing shares of budgets.

The EU Pharmaceutical Strategy therefore proposes actions at EU level to promote the affordability of medicines and the sustainability of our health systems.

The Commission will support **cooperation between national authorities on pricing, payment and procurement policies**, to improve the affordability, cost-effectiveness of medicines and health system's sustainability. The Commission will also help improving transparency on methods used for establishing the R&D costs of medicines.

Over the next three years, and beyond, this will help national public authorities to improve their capacities and take better decisions. But it will also help the producers of high valued products to better make their case, and the EU patients to access cost-effective medicines in a timely, equitable and affordable way.

10. How important is innovation in the context of the strategy?

Innovation is a key element of the Strategy.

Since the current pharmaceutical legislation was designed and adopted, the so-called "fourth industrial revolution" has showed us that science evolves and new technologies and digitalisation

provide new opportunities. For example, we have seen an increasing number of products that integrate medicines with medical devices and/or artificial intelligence (AI) components.

Developments in genomics, personalised medicine and others need to be taken into account to shape future pharmaceutical policies. For example, vaccines developed for COVID-19 relying on new techniques (e.g. mRNA) show how innovative trends can transform traditional development approaches, and reduce timelines. Advance therapy medicinal products are another example.

In that context, the **current pharmaceutical legislation may need to be revisited to avoid bottlenecks or regulatory gaps and to encourage innovation, new breakthroughs and EU competitiveness.**

The Commission will work to ensure that the new framework supports innovative trial designs. Moreover, in coordination with the European regulators, patient groups and stakeholders, it will support more patient-oriented design, planning and conduct of clinical trials. This can be done by harmonised international guidance and by taking into account the experience acquired from the conduct of clinical trials for COVID-19 vaccines and treatments.

11. What is the link between the pharmaceutical strategy and the Intellectual Property action plan?

Intellectual property rights, in particular patents and supplementary protection certificates (SPC), offer protection to innovative medicinal products and regulate when competitive products may come on the market. Incentivising innovation whilst ensuring access, availability and affordability of medicines are key considerations of the pharmaceutical strategy.

The EU's IP system works in tandem with the EU system of pharmaceutical incentives (e.g. market protection, data protection), both contributing to these objectives.

Some initiatives currently considered by the Commission, such as a modernisation of the (SPC) system, relate to both intellectual property and pharmaceutical policies. Any revisions of the rules on IP and pharmaceutical incentives will recognise the complementarity of their effects on the need to foster innovation and make medicines accessible and available to all patients at an affordable price.

12. When will the Commission propose the creation of an EU Health Emergency Response Authority? What will it look like?

The creation of this Agency was announced by President Von der Leyen in her State of the Union speech in September 2020 and is part of the European Health Union Package adopted on 11 November.

The Commission is now working on a proposal with a view to present it to the Member States and the European Parliament in the second half of 2021.

The overall objective of the Agency will be the coordination of operations across the whole value chain and strategic investments for research, development, manufacturing, deployment, distribution and use of medical countermeasures. It will support the EU's capacity and readiness to respond to cross-border threats and emergencies with a focus on chemical, biological, radiological and nuclear threats, epidemics, emerging diseases and pandemic influenza.

The Commission is currently **exploring the functions and possible structure for this Authority**. The Commission will launch an impact assessment and consultation on the establishment of this EU authority, with a view to proposing in 2021 a structure with an appropriate mandate and resources to start operations in 2023.

13. What are the next steps for the Strategy? When will the Commission table a revision of the pharmaceutical legislation?

The Strategy will be discussed at political level at the EPSCO meeting of 2 December 2020.

The implementation will start immediately after adoption, with the actions, pilot projects and studies announced in the Communication, including the process for the evaluation of the basic pharmaceutical acts.

It will include legislative and non-legislative actions which will follow the usual better regulation

principles (including evaluation and impact assessment).

The **actions will be rolled out gradually** starting with the first proposals in the coming months, including the revision of the EMA fees legislation and the revision of the legislation on children and rare diseases (Orphans and Paediatric Regulations).

Moreover, **actions will also take place in non-pharmaceutical areas** which are important to reach the objectives of the strategy (e.g. development of the European data strategy, or a further development of the European system of intellectual property rights, such as patents).

Depending on the evaluation process, the strategy plans a **proposal for revision of the basic pharmaceutical acts* in late 2022.**

* Directive 2001/83/EC and Regulation (EC) No 726/2004.

For More Information

A Pharmaceutical Strategy for Europe – Communication

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QANDA/20/2174

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