# European Health Union: Towards a reform of EU's pharmaceutical legislation

Brussels, 28 September 2021

Today, as part of its work to create a future-proof and crisis-resilient regulatory framework for the pharmaceutical sector, the Commission has published a public consultation on the revision of the EU's pharmaceutical legislation. This is the latest step towards an ambitious reform as announced in the Pharmaceutical Strategy for Europe, adopted in November 2020.

**Stella Kyriakides**, Commissioner for Health and Food Safety, said: "*Today we take an important step for the reform of EU's pharmaceutical legislation by the end of next year. A regulatory framework for pharmaceuticals, which is modernised and fit for purpose, is a key element of a strong European Health Union and crucial to addressing the many challenges this sector is facing. I call on all interested citizens and stakeholders to help us shape EU rules for the future, responding to patients' needs and keeping our industry innovative and globally competitive.*"

The consultation, which will run for twelve weeks, until 21 December, will gather the views from both the general public and stakeholders to support the evaluation of and the impact assessment for the revision of the EU's pharmaceutical legislation. Today's development follows on from the public consultation conducted for the preparation of the Strategy itself.

Since the adoption of the Strategy, the Commission has been working on a number of actions in close cooperation with Member States' authorities, the European Medicines Agency and with stakeholders' organisations. A major flagship action is the **revision of the general pharmaceutical legislation,** foreseen for end 2022, which is also being supported by an ongoing study. Other flagship actions of the Strategy focus on Health Technology Assessment, EU Health Data Space, legislation on rare diseases and medicines for children and strengthening the continuity and security of supply of medicines in the EU.

This public consultation launched today notably addresses:

- The performance of the EU's pharmaceutical legislation;
- Unmet medical needs;
- Incentives for innovation;
- Antimicrobial resistance;
- Future-proofing the regulatory framework for novel products;
- Improved access to medicines;
- Competitiveness of the European markets to ensure affordable medicines;
- Repurposing of medicines;
- Security of supply of medicines;
- Quality and manufacturing of medicines;
- Environmental challenges.

**Background**

The last comprehensive review of the general pharmaceutical legislation was tabled almost 20 years ago. Since then. societal and scientific changes, as well as new areas of concern such as antimicrobial resistance, environmental challenges and shortages of medicines, have emerged. In that context, the Pharmaceutical Strategy adopted in November 2020 includes an **ambitious agenda of legislative and non-legislative actions** to be launched over the coming years and has four main objectives:

- Ensuring **access to affordable medicines** for patients, and addressing unmet medical needs (e.g. in the areas of antimicrobial resistance, cancer, 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, and addressing security of supply;
- Ensuring a **strong EU voice in the world**, by promoting a high level of quality, efficacy and safety standards.

**For More Information**

Consultation

A Pharmaceutical Strategy for Europe

European Health Union

IP/21/4882

Press contacts:

Stefan DE KEERSMAECKER (+32 2 298 46 80)
Darragh CASSIDY (+32 2 298 39 78)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email