European Commission - Press release

# European Health Union: Commission proposes pharmaceuticals reform for more accessible, affordable and innovative medicines

Brussels, 26 April 2023

Today, the Commission is proposing to revise the EU's pharmaceutical legislation - the largest reform in over 20 years - to make it more agile, flexible, and adapted to the needs of citizens and businesses across the EU. The revision will make **medicines more available, accessible and affordable**. It will support innovation and boost the **competitiveness** and attractiveness of **the EU pharmaceutical industry**, while promoting higher environmental standards. In addition to this reform, the Commission proposes a Council Recommendation to step up the **fight against antimicrobial resistance** (AMR).

The **challenges** this reform addresses are fundamental. Medicines authorised in the EU are still **not reaching patients quickly enough** and are not equally accessible in all Member States. There are significant gaps in addressing **unmet medical needs**, rare diseases and antimicrobial resistance (AMR). **High prices** for innovative treatments and **shortages** of medicines remain an important concern for patients and healthcare systems. In addition, to ensure that the EU remains an attractive place for investment and a world leader in the development of medicines, it needs to adapt its rules to the **digital transformation** and **new technologies**, whilst cutting red tape and simplifying procedures. Finally, the new rules need to address the **environmental impact** of medicine production in line with the objectives of the European Green Deal.

The revision includes proposals for a new Directive and a new Regulation, which revise and replace the existing pharmaceutical legislation, including the legislation on medicines for children and for rare diseases. It aims to achieve the following main **objectives**:

- Create a **Single Market for medicines** ensuring that all patients across the EU have **timely and equitable access to safe, effective, and affordable** medicines;
- Continue to offer an attractive and **innovation-friendly framework** for research, development, and production of medicines in Europe;
- Reduce drastically the **administrative burden** by speeding up procedures significantly, reducing authorisation times for medicines, so they reach patients faster;
- Enhance **availability** and ensure medicines can always be supplied to patients, regardless of where they live in the EU;
- Address **antimicrobial resistance** (AMR) and the presence of pharmaceuticals in the environment through a One Health approach;
- Make medicines more **environmentally sustainable.**

To achieve these objectives, the reform addresses the **entire lifecycle of medicines.**

**Key elements of the proposal:**

- **Better access to innovative and affordable medicines for patients and national health systems:** new incentives will encourage companies to make their medicines available to patients in all EU countries and develop products that address unmet medical needs. Furthermore, earlier availability of generic and biosimilar medicines will be facilitated, and market authorisation procedures simplified. Measures for greater transparency of public funding of medicines development will be introduced and the generation of comparative clinical data will be incentivised.
- **Promoting innovation and competitiveness through an efficient and simplified regulatory framework:** the reform will create an innovation-friendly regulatory environment for the development of new medicines and the repurposing of existing ones. The European Medicines Agency (EMA) will provide better early regulatory and scientific support for developers of promising medicines to facilitate the fast approval and help SMEs and non-profit developers. The scientific evaluation and authorisation of medicines will be sped up (e.g., EMA authorisation procedures will take 180 days, helping reduce the current average of around 400

days) and the regulatory burden will be reduced through simplified procedures (e.g., by abolishing in most cases marketing authorisation renewal and introducing simpler procedures for generic medicines) and digitisation (e.g., electronic submissions of applications and electronic product information). **The highest quality, safety, and efficacy standards** for the authorisation of medicines will be maintained.

- **Effective incentives for innovation:** regulatory protection of up to a maximum of 12 years for innovative medicines, combined with the existing intellectual property rights, will ensure Europe remains an attractive hub for investment and innovation. To create a single market for medicines, the reform will move the current system away from its 'one-size-fits-all' regulatory protection towards a **more effective incentives framework for innovation that also promotes public health interests**. To achieve this, it proposes a minimum period of regulatory protection of 8 years that can be extended in the following cases: if medicines are launched in all Member States, if they address unmet medical needs, if comparative clinical trials are conducted, or if a new therapeutic indication is developed. The combination of the existing intellectual property rights and the new regulatory protection periods will also safeguard the EU's competitive edge in pharmaceutical development, one of the most protective world-wide. The reform will drive efforts so that research and development will focus on the patients' greatest needs and there is more timely and equitable patient access to medicines across the EU.
- **Addressing shortages of medicines and ensuring security of supply:** the reform introduces new requirements for monitoring of shortages of medicines by national authorities and EMA and a stronger coordination role for EMA. Obligations on companies will be strengthened, including earlier reporting of shortages and withdrawals of medicines and development and maintenance of shortage prevention plans. An EU-wide list of critical medicines will be established, and supply chain vulnerabilities of these medicines will be assessed, with specific recommendations on measures to be taken by companies and other supply chain stakeholders. In addition, the Commission can adopt legally binding measures to strengthen security of supply of specific critical medicines.
- **Stronger protection of the environment:** better enforcement of current environmental requirements will limit the potential negative consequences of medicines on the environment and public health.
- **Tackling antimicrobial resistance (AMR):** AMR is considered one of the top three health threats in the EU. The reform offers incentives through transferable vouchers to companies that invest in novel antimicrobials that can treat resistant pathogens, addressing the current market failure. Measures and targets for prudent use of antimicrobials, including adapted packaging and prescription requirement, will also be introduced to keep the antimicrobials effective.

**Stepping up EU actions to combat AMR in a One Health approach**

Antimicrobials are crucial medicines. However, over the years, their overuse and misuse have led to increasing antimicrobial resistance (AMR), meaning that antimicrobials lose their effectiveness, and it becomes more difficult, if not impossible, to treat infections. Therefore, today's package also includes a **proposal for a Council Recommendation** containing complementary measures to combat AMR in the fields of human health, animal health and the environment, through the so-called One Health approach.

The proposal **supports the prudent use** of antimicrobials, recommending concrete and measurable targets to reduce their use and promote high levels of infection prevention, notably in hospitals, and control in the area of human health. The proposal also improves public awareness, education and training of relevant professionals and fosters cooperation between stakeholders from all relevant sectors.

**Recommended targets** were designed with the support of the European Centre for Disease Prevention and Control (ECDC) and take into account national situations (different levels of antimicrobial consumption, spread of key resistant pathogens across the Member States). They also allow better monitoring of progress in the coming years.

In addition, the proposal will boost national **One Health action plans** on AMR, foster research and innovation, reinforce surveillance and monitoring of AMR and antimicrobial consumption, enhance global actions, contribute to the design of an EU multi-country financial incentive to improve access to antimicrobials and incentivise the development of other AMR medical countermeasures such as vaccines and rapid diagnostics.

**Background**

In November 2020, the Commission presented a Pharmaceutical Strategy for Europe which aims to create a future-proof and patient-centred pharmaceutical environment in which the EU industry can innovate, flourish, and continue to be a global leader.

An EU pharmaceutical ecosystem that is crisis-resilient and fit for today's landscape and tomorrow's challenges is one of the central pillars of a strong European Health Union and will complement other key initiatives, including the reinforcement of the EU health security framework with the new legislation on cross-border threats to health and stronger mandates for EU health agencies, the establishment of the Health Emergency Preparedness and Response Authority (HERA) as well as Europe's Beating Cancer Plan and the European Health Data Space.

The Strategy kick-started an ambitious revision of the current pharmaceutical legislation, a comprehensive response to the current challenges faced in the EU pharmaceutical sector.

**Next steps**

The legislative proposals will now be submitted to the European Parliament and the Council.

**For More Information**

EU's pharmaceutical legislation

Questions and Answers on the pharmaceutical legislation

Questions and Answers on the Recommendation on AMR

Factsheet on putting patients in the centre

Factsheet on driving innovation for pharmaceutical industry

Factsheet on tackling antimicrobial resistance

Pharmaceutical Strategy for Europe

EU Action on Antimicrobial Resistance

Video on the revision of the pharmaceutical legislation

IP/23/1843

Quotes:

This proposal is a once-in-a generation occasion to overhaul a legislation which is crucial for patients and for the strengthening and development of one of the EU's key industrial sectors. Our proposals aim at striking the right balance between promoting innovation and ensuring patient access to affordable medicines across the EU. They also take heed of the lessons learned from the COVID-19 crisis, showing once again that the EU can adapt itself to new global realities. Our EU Health Union is emerging as a one of the most tangible achievements of this Commission.
Margaritis Schinas, Vice-President for Promoting our European Way of Life - 26/04/2023

Today we add another central pillar to our European Health Union. We are putting forward proposals to ensure that medicines reach patients everywhere in Europe, in a timely and equitable fashion. It is a reform which ensures that Europe remains attractive for business, and our pharmaceutical industry a global innovation powerhouse. Building a single market for medicines is a necessity both for our citizens and our companies.
Stella Kyriakides, Commissioner for Health and Food Safety - 26/04/2023

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