European Commission

Questions and answers | 26 April 2023 | Brussels

Frequently Asked Questions: Revision of the Pharmaceutical legislation

The Commission is proposing an ambitious revision of the EU pharmaceutical legislation to achieve the following main objectives:

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

The revision is the first major review of the pharmaceutical legislation since 2004. It will adapt the legislation to the needs

of the 21st century.

1. What does the package consist of?

The reform includes **two legislative proposals:** a new Directive and a new Regulation which constitute the EU regulatory framework for all medicines (including those for rare diseases and for children), simplifying and replacing the previous pharmaceuticals legislation.

Simply put, the **Directive** contains all the requirements for authorisation, monitoring, labelling and regulatory protection, placing on the market and other regulatory procedures for all medicines authorised at EU and national level.

The **Regulation** sets specific rules (on top of the ones in the Directive) for medicines authorised at EU level, in particular the most innovative ones. It sets out the rules on coordinated management of critical shortages and security of supply of critical medicines. It also sets out the rules governing the European Medicines Agency (EMA).

The reform also includes a **Council Recommendation** on antimicrobial resistance (AMR).

Finally, these legislative proposals and Council recommendation are accompanied by a Communication that explains the rationale of the changes.

2. What is new in this reform?

The reform builds on the current high standards of quality, safety, and efficacy for the authorisation of medicines and proposes new tools in the following areas:

- Move away from a “one-size-fits-all” system of incentives for pharmaceutical companies to a modulated system of incentives that rewards companies that fulfil important public health objectives, such as giving access to medicines in all Member States, developing medicines that address unmet medical needs, conducting comparative clinical trials and developing medicines that can treat other diseases as well. For medicines for rare diseases, a similar modulation for market exclusivity is proposed;

- Faster availability of generics and biosimilars and transparency of public funding;
- Addressing shortages of medicines and ensuring security of supply;
- A modern and simplified regulatory framework with faster authorisations of new medicines. For instance, for its assessment, EMA will have 180 instead of 210 days. For the authorisation, the Commission will have 46 instead of 67 days. This will help to reduce the current average of around 400 days between submission and market authorisation. For the assessment of medicines that are of major public health interest, EMA will only take 150 days regulatory sandboxes supporting the development of innovative medicines, electronic submissions and e-leaflets;
- Promotion of innovation and competitiveness;
- Better protection of the environment;
- Tackling antimicrobial resistance (AMR).

3. How will the new legislation promote innovation?

- Many measures have been proposed to support the development of innovative medicines: the authorisation process for new medicines will be sped up, thanks to **simplified procedures** and a revamped EMA structure.
- **Early scientific advice by EMA** will improve the quality of applications and tailored scientific support will be provided to SMEs. Learning from the COVID-19 experience, “rolling reviews” (i.e., a phased reviews of data as they become available), and temporary emergency marketing authorisations for health emergencies will be introduced.
- Developers of innovative products will receive **advice** on their product even years before they actually apply for a marketing authorisation which will facilitate their decisions.
- **Regulatory ‘sandboxes'**[1] allow testing new regulatory approaches for novel therapies under real world conditions. The **use of real-world evidence** and health data is also facilitated. The regulatory framework will be more agile to accommodate scientific advances,

digitalisation, artificial intelligence and cutting-edge products.

- Special provisions and incentives for **repurposing** make it easier for researchers and not-for-profits to materialise their research into authorised medicines.
- Special incentives are given for medicines delivering on **high unmet medical needs** in the case of rare diseases.
- Companies marketing innovative medicines will have a **minimum period of regulatory protection of 8 years**, which includes 6 years of data protection and 2 years of market protection. Companies may benefit of additional periods of protection, increasing the total period up to maximum 12 years, while it is maximum 11 years today. These additional periods of protection can be obtained if the companies launch the medicine in all Member States (+2 years), if the medicine addresses an unmet medical need (+6 months), or if comparative clinical trials are conducted (+6 months). A further year of data protection can be granted if the medicine can treat other disease(s) too. The additional regulatory protection of 2 years if medicines are launched in all Member States is expected to **increase access by 15%.** This means that **67 million more people** in the EU could potentially benefit from a new medicine.
- For **medicines for rare diseases**, the standard duration of market exclusivity will be 9 years. Companies can benefit from additional periods of market exclusivity if they address a high unmet medical need (1 year), launch the medicine in all Member States (+ 1 year), or develop new therapeutic indications for an already authorised orphan medicine (up to 2 extra years). The regulatory production periods can add up to maximum 13 years while today the maximum is 10 years.
- Moreover, a number of future-proofing measures will ensure that the regulatory system can keep pace with scientific and technological progress. This also comprises promoting innovative methods, including those aimed at reducing animal testing.

All these measures offer an attractive and internationally competitive regulatory protection, which is complementary to the current system of **intellectual property rights** offering businesses an additional reward for innovation.

4. Will the proposed reform have an impact on the Intellectual Property (IP) protection covering medicinal products?

No. The reform does not affect the EU system of intellectual property protection (IP) (patents, trademarks, copyrights, supplementary protection certificates). That means Europe will continue to offer a globally **competitive system of IP incentives**.

5. What is the AMR "vouchers" system about?

The development of novel antimicrobials is hindered by a **market failure**: to avoid the development of resistant bacteria, the use of antimicrobials should be restricted. But with limited sales prospects for innovative products, many investors are no longer interested in this area. Therefore, and without public intervention, we may find ourselves in a situation where there are very few or no new medicines capable of fighting multi-dug resistant pathogens in the future.

This is where the voucher system comes in. It will provide **'transferable data exclusivity vouchers'** to developers of 'game changing' novel antimicrobials, which they can either use themselves or sell. The voucher will offer to the developer an additional year of data protection from competition for the medicine that the voucher applies to.

The system will **generate revenues** for businesses that successfully develop such revolutionary medicines, without direct financial contributions from Member States. Indirectly, and as a result of the longer protection period for the medicines to which it is transferred, the voucher is financed by the national health systems, but this cost will be largely counterbalanced by the prevented deaths and illnesses thanks to the novel antimicrobials.

The vouchers will be granted and used under **strict conditions**. They will be provided in limited numbers over a limited period (no more than 10 vouchers in 15 years) thus capping the potential burden on health systems.

6. How will the new rules give patients access to more and innovative medicines?

A central objective of the reform is to ensure that **all patients across the EU have timely and equitable access to safe and effective medicines**. Today, this is not always the case, especially for innovative medicines, as patient access varies between Member State.

The reform addresses this concern by making two years of data protection conditional on launching a medicine in all Member States.

A **reduction of the standard regulatory protection** period by 2 years (compared to today) and measures that encourage **early market access of generic and biosimilar** entry will also provide more affordable options to patients and contain health systems' pharmaceutical expenditure.

Incentives for **repurposing existing medicines** and for using comparative trial data will give patients quicker access to new therapies that deliver on their needs. Using comparative trial data will help national authorities to better assess the cost effectiveness of a new medicine.

A simplified decision-making system **reduces authorisation times for new medicines**.

Incentives will be offered for the development of innovative medicines addressing unmet medical needs.

In addition to the existing paper leaflets, **electronic product information** will ensure accurate information to patients in their own language through electronic leaflets and help address shortages through the easier redirection of stocks to countries that need them.

7. Will the new rules impact the way medicines and vaccines are authorised in the EU?

Yes. The proposed reform cuts down the regulatory burden, with a **leaner EMA structure.** It **simplifies procedures** to ensure efficient assessments, boost the scientific capacity of the EU regulatory network and reduce the time for authorisation of medicines.

The reform also **strengthens the voice of patients** in the EMA by adding patient representatives to the main scientific committee.

8. How will changes to EMA's work speed up the authorisation of medicines?

For the authorisation of the most innovative products, the European Medicines Agency (EMA) coordinates the work of national experts, through several committees.

The legal proposal therefore **simplifies EMA's structure** to two main scientific committees for human medicines: the Committee for Human medicinal products and the Safety Committee (PRAC). The orphan, paediatric and ATMP committees would be discontinued.

The new, leaner structure is complemented by a stronger support for the two remaining committees (through working parties and expert pools). This will reduce the assessment time and free up scientific resources to strengthen pre-authorisation support to developers and gain efficiency.

The mandate of the EMA and its Executive Steering Group on Shortages and Safety of Medicinal Products will be extended with respect to the management of critical shortages and the security of supply of critical medicines

An inspectorate will be established within EMA to reinforce Member States' capacities, in particular for inspections in third countries to build efficiency in surveillance and support marketing authorisation procedures.

9. Will there be more transparency on the development of medicines?

Yes. Currently, there is a lack of transparency on research and development (R&D) costs or public contributions to these costs. While R&D costs are not relevant for the assessment

of a medicine's benefit-risk balance, **more transparency on public support** for the development of medicines may **strengthen the negotiating position** of authorities responsible for pricing and reimbursement of medicines when negotiating prices with the pharmaceutical companies. This could **help reduce prices** and thereby improve access to medicines.

Pharmaceutical companies will therefore be required to **publish information on all direct financial support** for the research and development of medicines received from public authorities or publicly funded bodies. This information will be easily accessible to the public on a dedicated webpage of the company and through the database of medicinal products for human use authorised in the Union.

10. Will the reform tackle shortages of medicines?

Shortages of medicines have been a **serious concern** in the EU for several years. The COVID-19 pandemic in particular highlighted shortcomings of the current legal framework, negatively impacting patients, health systems and healthcare professionals.

The **extension of EMA's mandate** as part of the European Health Union, allowed improving coordination and management of the supply of medicines shortages **during crises**.

Today's reform, however, goes beyond crisis preparedness and response and will help **addressing systemic shortages at all times**. The new legislation will enhance the **monitoring and mitigation of medicines shortages**, in particular critical shortages, at national level and by EMA. Pharmaceutical companies will have to report shortages of medicines more quickly and establish shortage prevention plans.

Pharmaceutical companies will have to **address critical shortages**, and report on the results of the measures taken (such as the increase or reorganisation of manufacturing capacity or the adjustment of distribution to improve supply).

In addition, an **EU list of critical medicines -** i.e. medicines considered to be most critical for health systems at all times **-**

will be established. Recommendations on measures to be taken will be made to companies and other relevant stakeholders to strengthen the supply chains of those medicines, to ensure continuity and security of supply for EU citizens. The legislation will also allow the Commission to introduce, through an implementing act, measures to strengthen security of supply, including requirements to establish contingency stocks.

11. Will the pharma reform address strategic autonomy and reshoring?

The pharmaceutical reform aims to enhance security of supply of medicines for EU patients and health systems, through preventative and reactive measures. It does so by proposing concrete measures, including the earlier notification of shortages and withdrawals, a company requirement to maintain shortage prevention plans for all medicines and the adoption of an EU list of critical medicines. The intention is to ensure the security of supply of those critical medicines, through recommendations on measures to be taken by supply chain stakeholders, and in certain cases by reinforcing those recommendations by imposing stronger obligations through Commission implementing acts.

Security of manufacturing and supply is a crucial element to ensure continued availability of medicines. **Strategic autonomy and reshoring are not directly addressed** in the proposal. However, there is sufficient flexibility to target specific vulnerabilities, including problematic dependencies, through those provisions described.

In parallel, the Commission is setting up the **EU FAB flexible manufacturing project**, which is a network of vaccine producers in the EU. It reserves manufacturing capacity and requires participating companies to ensure that we have the required capacity to produce medical countermeasures in the EU.

HERA has also established the **Joint Industrial Cooperation Forum** to find solutions to supply chain bottlenecks and vulnerabilities as well raw materials for medical countermeasures.

HERA is also working on a **financial pull incentive for antimicrobials**, notably in form of revenue guarantee.

The **Important Project of Common European Interest on Health** will allow participating EU countries to allocate state aid to support innovative EU projects in health, including those relevant for security of supply.

Finally, we have recently come forward with a **proposal for Critical Raw Materials** which also covers essential components to produce medicines and other medical countermeasures.

12. How will the fight against the environmental impact of medicines be enhanced?

Scientific evidence shows that the production, use and improper disposal of pharmaceuticals may have negative impacts on the environment. In addition, **antimicrobials** have been detected in wastewater treatment, manufacturing effluent, surface, and ground waters. This is concerning, as this boosts antimicrobial resistance. **Endocrine disruptors** are another major group of medicines that may pose a risk to the environment and public health.

In line with earlier commitments in the Strategic Approach to Pharmaceuticals in the Environment, the reform strengthens the **environmental risk assessment (ERA) of medicines** to limit the potential adverse impacts of medicines on the environment and public health. The ERA is mandatory for all pharmaceutical companies placing their medicines on the EU market. Marketing authorisation may be refused when companies do not provide adequate evidence that environmental risks were evaluated, and risk mitigation measures were taken.

13. What is the economic weight of the EU's pharmaceutical industry?

The pharmaceutical industry is a key sector for the EU's economy.

In 2020, EU companies invested more than **€26,5 billion in Research and Development (R&D)** and they are responsible for around 840,000 direct jobs. **The EU, UK and**

Switzerland is the second biggest R&D investor in pharmaceuticals (€39.7 billion in 2020) after the US, which has invested €63,5 billion in 2020 (EFPIA data).

In terms of manufacturing high-tech medicines, the EU is a clear global leader. Exports have increased from €50 billion in 2002 to €235 billion in 2021, while imports grew from €32 billion to €100 billion in the same period. The EU's trade surplus in medicinal and pharmaceutical products reached €136 billion in 2021, the highest value on record (Eurostat).

At the same time, the EU is the second largest market in the world for pharmaceuticals. The EU's total pharmaceutical spending was around €230 billion in 2021 or 1,5% of the EU GDP, according to IQVIA MIDAS database.

14. When can we expect this new legislation to be in place?

The proposal will now be discussed by the Parliament and the Council. The discussions will start as soon as possible, but we cannot predict the timing for adoption at this stage.

For more information:

EU Action on Antimicrobial Resistance

Press release

Questions and Answers on the Recommendation on Antimicrobial Resistance (AMR)

Factsheet on putting patients in the centre

Factsheet on driving innovation for pharmaceutical industry

Factsheet on tackling antimicrobial resistance

Pharmaceutical Strategy for Europe

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[1] A regulatory sandbox can under certain conditions be linked to an adapted framework, tailored to the characteristics or methods inherent to certain, especially novel medicines, without lowering the high standards of quality, safety, and efficacy.

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