

Revision of EU pharmaceutical legislation

OVERVIEW

On 10 April 2024, the European Parliament adopted its position at first reading on two European Commission proposals to revise the EU's pharmaceutical legislation. The revision seeks to enhance the security of supply of medicines, making them more available, accessible and affordable across EU countries, while supporting the attractiveness of the EU pharmaceutical industry by fostering research and innovation. The 'pharmaceutical package' includes proposals for a new directive and a new regulation that would replace the existing pharmaceutical legislation, including the legislation on medicines for children and for rare diseases. The Council has not yet adopted its position.

(A) Proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.

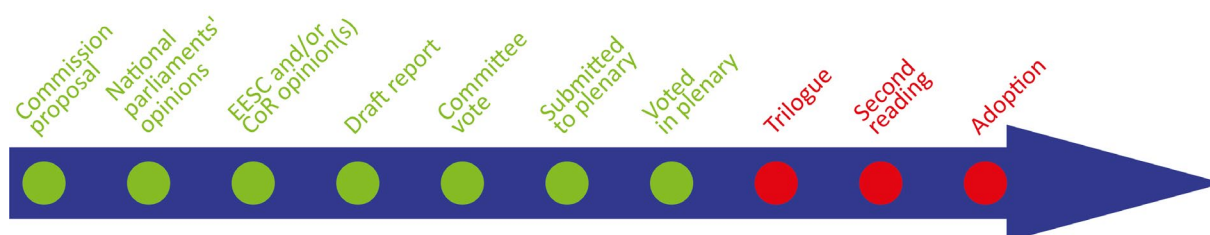
(B) Proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.

Committee responsible: Committee on the Environment, Public Health and Food Safety (ENVI) (A) COM(2023) 193
(B) COM(2023) 192
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Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')

Next steps expected: Trilogue negotiations



Introduction

EU policy on pharmaceuticals for human use dates back to 1965 ([Council Directive 65/65/EEC](#)).

The last major revision took place in 2004 (adoption of [Regulation \(EC\) No 726/2004](#) and revision of [Directive 2001/83/EEC](#), commonly referred to as the 'EU general pharmaceutical legislation'). This 'general legislation' is complemented by 'specific legislation', such as for medicines for rare diseases ([Regulation \(EC\) No 141/2000](#)) and for children ([Regulation \(EC\) No 1901/2006](#)).

In November 2020, the European Commission adopted a pharmaceutical strategy for Europe aimed at reinforcing the EU pharmaceutical system by making it more patient-centred and resistant to crises. The proposed revision is a follow-up to the strategy.

Parliament's starting position

The European Parliament has consistently promoted the establishment of a coherent policy on pharmaceuticals that takes both public health interest and industrial aspects into account.

Parliament has adopted several resolutions denouncing the existence of inequities between Member States in access to medicines and healthcare services, and has several times expressed its concerns on medicine shortages ([resolution](#) of 2 March 2017, [resolution](#) of 17 September 2020, [resolution](#) of 24 November 2021).

Members of the European Parliament have also submitted a large number of [written questions](#) to the Commission on aspects of the implementation of the EU general pharmaceutical legislation.

Council starting position

In its [conclusions](#) of 17 June 2016, the Council stressed that the functioning of the pharmaceutical system in the EU depends on a complex set of interactions between marketing authorisation and measures to promote innovation, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment of medicinal products.

In its [conclusions](#) of 18 December 2020, the Council called upon the Commission to cooperate with the Member States to develop an ambitious implementation agenda to implement concrete action under the pharmaceutical strategy for Europe. In its [conclusions](#) of 15 June 2021, the Council underlined that access to medicinal products and medical devices, their availability and affordability, are paramount objectives which constitute major challenges to health systems in the EU. This was underlined in its [conclusions](#) of 7 December 2021 on strengthening the European Health Union.

Preparation of the proposal

In its communication of 25 November 2020 on a [pharmaceutical strategy for Europe](#), which is a key pillar of the [European Health Union](#), the Commission stressed that the COVID-19 pandemic has demonstrated the criticality of ensuring timely access to safe, high quality and affordable medicines at all times. The strategy is intended to make the European pharmaceutical system patient-centred, future-proof and crisis-resistant. In its strategy, the Commission announced that it would launch several legislative and non-legislative actions. These would include, among other things, a revision of the basic pharmaceutical legislation (Directive 2001/83/EC and Regulation (EC) No 726/2004).

The revision was announced in the Commission's [2022 work programme](#). Information was then collected through consultations that took place between 30 March 2021 and 25 April 2022. These included a [call for evidence](#) on the Commission's combined evaluation roadmap/inception impact assessment; a [public consultation](#); a targeted stakeholder survey; interviews; validation workshops on the evaluation findings and on the impact assessment findings. Specific consultation activities

were carried out concerning the revision of the legislation on medicinal products for children and for rare diseases.

The ex-post evaluation of the implementation of the EU general pharmaceutical legislation was carried out in parallel to the ex-ante impact assessment of the revision (see [EPRS Implementation Appraisal briefing](#)).

EPRS published an [initial appraisal of the European Commission impact assessment](#) in September 2023.

The changes the proposal would bring

On 26 April 2023, the European Commission submitted two proposals, for a [directive](#) and for a [regulation](#), repealing the EU general pharmaceutical legislation (the directive and the regulation currently in force – [Directive 2001/83/EC](#), [Directive 2009/35/EC](#), [Regulation \(EC\) No 1394/2007](#) and [Regulation \(EU\) No 536/2014](#) – and the regulations on orphan ([Regulation \(EC\) No 141/2000](#)) and paediatric medicines ([Regulation \(EC\) No 1901/2006](#)), and amending related legislation on colouring substances that may be added to medicinal products ([Directive 2009/35/EC](#)), clinical trials on medicinal products for human use ([Regulation \(EU\) No 536/2014](#)) and the Advanced Therapy Medicinal Products Regulation ([Regulation \(EC\) No 1394/2007](#)).

The reform addresses the entire lifecycle of medicines. It aims to achieve the following six 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 and development and production of medicines in the EU;
- 3 drastically reduce the administrative burden by significantly speeding up procedures;
- 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 industries more environmentally sustainable.

The reform builds on the current high standards of quality, safety, and efficacy for the authorisation of medicines. The key proposed measures are:

- **Better access to innovative and affordable medicines for patients and national health systems:** new incentives would 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 would be facilitated, and market authorisation procedures simplified. Measures to ensure greater transparency of public funding for medicine development would be introduced and the generation of comparative clinical data would be incentivised.
- **Promotion of innovation and competitiveness through an efficient and simplified regulatory framework:** the reform would create an innovation-friendly regulatory environment for the development of new medicines and the repurposing of existing ones. The European Medicines Agency ([EMA](#)) would provide better early regulatory and scientific support for developers of promising medicines to facilitate the fast approval and help small and medium-sized enterprises (SMEs) and non-profit developers. The scientific evaluation and authorisation of medicines would be accelerated and the regulatory burden would be reduced through simplified procedures and digitisation.
- **Effective incentives for innovation:** regulatory protection of up to a maximum of 12 years for innovative medicines, combined with existing intellectual property rights, would ensure Europe remains an attractive hub for investment and innovation. To

create a single market for medicines, the reform would 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, a minimum period of regulatory protection of eight years is proposed, which could be extended in specific cases.

For medicines for **rare diseases**, the period of market exclusivity would be nine years. Companies could benefit from additional periods of market exclusivity if they address a high unmet medical need, launch the medicine in all Member States, or develop new therapeutic indications for an already authorised orphan medicine.

The combination of 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 patients' greatest needs and there is more timely and equitable patient access to medicines across the EU.

- **Address shortages of medicines and ensure security of supply:** the reform introduces new requirements for monitoring of shortages of medicines by national authorities and the EMA, as well as a stronger coordination role for the EMA. Obligations on companies would 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 would be established, and their supply chain vulnerabilities would be assessed, with specific recommendations on measures to be taken by companies and other supply chain stakeholders. The Commission could also adopt legally binding measures to strengthen security of supply for specific critical medicines.
- **Stronger protection of the environment:** better enforcement of current environmental requirements would limit the potential negative consequences of medicines on the environment and public health.
- **Tackle antimicrobial resistance (AMR):** the reform offers incentives, through transferable vouchers, to companies investing in novel antimicrobials that can treat resistant pathogens, addressing the current market failure. Measures for prudent use of antimicrobials, including adapted packaging and the introduction of a mandatory prescription requirement, would also be introduced to maintain antimicrobial effectiveness. The **proposal for a Council recommendation on AMR** contains complementary measures and targets to combat AMR in the fields of human health, animal health and the environment, through the 'One Health' approach.

As far as **rare diseases** are concerned, merging the Orphan Regulation and the Paediatric Regulation with the legislation applicable to all medicinal products would allow for simplification and increased coherence. Medicinal products for rare diseases and for children will continue to fall under the same provisions as any other medicinal products concerning their quality, safety and efficacy, for example concerning marketing authorisation procedures, pharmacovigilance and quality requirements. However, specific requirements would also continue to apply to these types of medicinal products to support their development. This is because market forces alone have proven insufficient to stimulate adequate research and development of medicinal products for children and patients suffering from a rare disease.

Advisory committees

The European Economic and Social Committee (EESC) and the European Committee of the Regions (CoR) were asked to provide opinions.

EESC adopted its [opinion](#) on 25 October 2023. It supports the aim of improving the availability and accessibility of affordable medicines and boosting the competitiveness and attractiveness of the EU

pharmaceutical industry. It notes that affordability and access continue to be key challenges. It believes that in addition to effective measures to reduce the use of antibiotics, the focus must be on alternative incentive models throughout the R&D cycle. It calls for a preliminary assessment on the possibility of setting up a special EU-level fund to ensure access to treatment for all patients suffering from rare diseases in the EU.

National parliaments

The deadline to submit reasoned opinions on the grounds of subsidiarity was 9 November 2023 for both the [proposal for a directive](#) and the [proposal for a regulation](#). No such opinion was delivered within the time limit.

Stakeholder views¹

The [European Consumer Organisation](#) (BEUC) welcomed the Commission's pharmaceutical package as an important step forward. However, it underlined that consumers would still need easier access to medicines, and made practical [recommendations](#) for more consumer-friendly pharmaceutical legislation. On [10 April 2024](#), while underlining that the European Parliament had proposed some positive changes to the pharmaceutical package, it regretted that 'these are unlikely to go far enough to significantly improve people's access to medicines'.

The [European Public Health Alliance](#) (EPHA) welcomed the proposals and called for a balanced debate so that the legislation adopted would serve the needs of all people living across the EU and not just provide incentives to the pharmaceutical sector.

The [European Patients' Forum](#) (EPF) called for greater involvement of patients and their representatives throughout the whole medicine development and evaluation cycle. In April 2024, it [welcomed](#) the adoption of European Parliament's first reading position.

The [Childhood Cancer International-Europe](#) (CCI-Europe) network of associations and the [European Society for Paediatric Oncology](#) (SIOP Europe) underlined the need to tackle inequalities and put the unmet medical needs of young cancer patients, survivors and their families at the centre of a European strategy for medicine development.

[EURORDIS-Rare Diseases Europe](#) welcomed the measures proposed by the Commission, from more rapid regulatory pathways for new products to more targeted incentives for companies to develop desperately needed medicines. In April 2024, it [welcomed](#) the European Parliament's commitment to an EU policy framework for rare diseases. It called on the Council of the EU 'to seize the opportunity that remained to further refine the legislation by incorporating an 'Orphan Drug Development Plan' in the legislation', to help navigate the path towards more and better rare disease treatment.

The [European Federation of Pharmaceutical Industries and Associations](#) (EFPIA) expressed serious concerns regarding research and the future attractiveness of investment in innovation in the EU. Commenting on the European Parliament's vote of 10 April 2024, it underlined that 'despite improvements, the pharmaceutical legislation has a long way to go to [restore Europe's competitive edge](#)'.

Legislative process

On 26 April 2023, the European Commission proposed a revision of the EU's general pharmaceutical legislation. It put forward two legislative proposals: a proposal for a [regulation](#) and a proposal for a [directive](#). The 'package' was completed by a Council [Recommendation](#) to step up the fight against antimicrobial resistance, which was adopted in June 2023.

In the European Parliament, the files have been allocated to the Committee on the Environment, Public Health and Food Safety (ENVI). The rapporteurs are Tiemo Wölken (S&D, Germany) for the regulation and Pernille Weiss (EPP, Denmark) for the directive.

At the ENVI committee meeting on 26 April 2023, Stella Kyriakides, Commissioner for Health and Food Safety, presented the proposed reform. This was followed by an [exchange of views](#).

Work on the revision of the EU pharmaceutical legislation was among the priorities of the Swedish Presidency of the Council of the EU. An [informal meeting of health ministers](#) took place in Stockholm on 5 May 2023. They discussed challenges related to securing access to medicinal products in times of crises and how EU Member States can further strengthen the accessibility and affordability of medicines. A further informal discussion took place on 13 June 2023, during the [Employment, Social Policy, Health and Consumer Affairs Council](#). Work has continued during the subsequent presidencies.

On 20 September 2023, the Commission [presented](#) its proposals to the ENVI committee members.

On [19 March 2024](#), ENVI adopted its [report](#) on the proposal for a regulation (67 votes in favour, 6 against and 7 abstentions) and its [report](#) on the proposal for a directive (66 votes in favour, 2 against and 9 abstentions). To boost EU research and its market attractiveness, they ask for a regulatory data protection scheme of a minimum duration of seven and a half years for new medicines, in addition to a period of two years of market protection (during which generic, hybrid or biosimilar products may not be sold) following market authorisation. Longer protection periods would be granted under certain circumstances (e.g. unmet medical needs, clinical trials). Medicines developed to treat rare diseases ('[orphan drugs](#)') would benefit from up to 11 years of '[market exclusivity](#)' (protecting them from competition from similar medicines with similar indications, which could not be marketed during the exclusivity period) if they meet a 'high unmet medical need'. New measures would promote the prudent use of antimicrobials (e.g. prescription limited to the amount required for the treatment, limited duration) and encourage the development of new antimicrobials. New rules would require companies to submit an 'environmental risk assessment' when applying for market authorisation, which should cover the entire life cycle of medicines.

On 10 April 2024, the European Parliament supported the ENVI position in full without changes. It adopted its [positions at first reading](#) on the [proposed regulation](#) (488 votes in favour, 67 against and 34 abstentions) and on the [proposed directive](#) (with 495 votes in favour, 57 against and 45 abstentions) by very large majorities. Parliament reiterated its support for comprehensive reform of the pharmaceutical legislation to secure patient access to safe, efficient and high quality medicinal products, foster innovation and the development of medicines to address unmet medical needs, and boost research into novel antimicrobials to fight antimicrobial resistance.

The Council has not yet adopted its position. Work continues in the [Working Party on Pharmaceuticals and Medical Devices](#).

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

[European pharmaceutical research and development. Could public infrastructure overcome market failures?](#), STOA, EPRS, European Parliament, December 2021.

[Towards a new EU pharmaceutical strategy](#), STOA, EPRS, European Parliament, December 2022.

[Tackling antimicrobial resistance: From science to pharmaceuticals policy, briefing](#), STOA, EPRS, European Parliament, March 2023.

[Revision of the EU's general pharmaceutical legislation](#), Implementation appraisal, EPRS, European Parliament, May 2023.

[Revision of the EU legislation on medicines for children and rare diseases](#), Implementation appraisal, EPRS, European Parliament, June 2023.

[Revision of the EU pharmaceutical legislation](#), Initial appraisal of a European Commission impact assessment, EPRS, September 2023

OTHER SOURCES

[Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency](#) (regulation), Legislative Observatory (OEIL), European Parliament.

[Medicinal products for human use](#) (directive), Legislative Observatory (OEIL), European Parliament.

ENDNOTE

- ¹ This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'European Parliament supporting analysis'.

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