EUROPEAN
COMMISSION

Brussels, 29.9.2026
COM(2026) 526 final

2023/0132 (COD)

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

position of the Council on the adoption of 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

(Text with EEA relevance)

2023/0132 (COD)

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

position of the Council on the adoption of 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

(Text with EEA relevance)

1. BACKGROUND

Date of transmission of the proposal to the European Parliament and to the Council: (document COM(2023) 192 final – 2023/0132 (COD))	26 April 2023
Date of the opinion of the European Economic and Social Committee:	25 October 2023
Date of the position of the European Parliament, first reading:	10 April 2024
Date of transmission of the amended proposal:	N/A
Date of adoption of the position of the Council:	28 September 2026

2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The Commission proposals to revise the EU pharmaceutical framework are the first comprehensive reform of the EU pharmaceutical legislation in 20 years. The reform consists of two legal acts, a directive and a regulation. These are complementary and replace four existing legal acts: Directive 2001/83/EC and Regulation (EC) No 726/2004 on pharmaceutical legislation, Regulation (EC) No 1901/2006 on medicines for children (the 'Paediatric Regulation'), and Regulation (EC) No 141/2000 on medicines for rare diseases (the 'Orphan Regulation').

The reform aims to establish a regulatory framework that supports innovation and competitiveness in the research, development and manufacture of medicinal products in Europe, while ensuring their safety, efficacy, accessibility and continuous availability for patients. It promotes the development of new therapies, through notably appropriate incentives, in particular in areas of unmet medical need, including novel antimicrobials. It also provides for regulatory simplification and introduces new instruments, including platform approaches, regulatory sandboxes and adapted regulatory frameworks for certain innovative medicinal products. This aims at strengthening the Union's competitiveness and reducing administrative burden and costs for companies and competent authorities.

3. COMMENTS ON THE POSITION OF THE COUNCIL

The position of the Council as adopted at first reading fully reflects the political agreement reached between the European Parliament and the Council on 11 December 2025. The Commission supports this agreement, the main points of which are set out below.

- On regulatory protection periods (data and market protections), the European Parliament and the Council have agreed on a nine-year baseline protection consisting of eight years of data protection and one year of market protection. An additional year of market protection may be granted at the time of the initial marketing authorisation for a medicinal product addressing an unmet medical need. Alternatively, an additional year may be granted if the medicinal product contains a new active substance and uses evidence-based comparators in clinical trials, combined with either multinational trials in the EU or early application for EU marketing authorisation. There is also one year of market protection for an additional indication of significant clinical benefit, as provided for in the current legislation.
- On incentives for medicines for rare diseases ('orphan medicines'), a market exclusivity of nine years is granted for standard orphan medicines, with an additional two-year period granted for breakthrough orphans. Breakthrough orphans are orphan medicines that prevent, diagnose or treat conditions where no other method of prevention, diagnosis or treatment exists, and which provide a clinically relevant reduction in disease morbidity or mortality for the relevant patient population. Finally, an additional year of market exclusivity is possible twice for one or more therapeutic indications for a different orphan condition. All these additional years amount to a maximum 13 years of market exclusivity.
- On the Bolar exemption, which allows applicants for generic and biosimilar medicinal products to conduct research and testing necessary for their application before the patent of the reference medicinal product expires without this constituting patent infringement, the co-legislators have agreed to extend this exemption to ensure that generic and biosimilar medicinal products may enter the market on day one after the patent and the regulatory protection periods expire. This is made possible notably by the fact that the exemption extension allows applicants to apply for national procedures for health technology assessment, pricing and reimbursement decisions during the patent/supplementary protection certificate periods, and to participate in national medicine procurement procedures.
- On incentives for the development of 'priority antimicrobials', the co-legislators have agreed to maintain the Commission's proposal on transferable exclusivity vouchers (TEVs). TEVs reward companies that successfully develop a new 'priority antimicrobial' by granting an extra year of data protection which can be applied to the priority antimicrobial itself or transferred to another medicine under certain conditions. To avoid overcompensation, a 'blockbuster clause' was added by co-legislators. Under that clause, the voucher cannot be used in relation to products with annual gross sales over EUR 490 million during any of the first four years after their marketing authorisation. To receive a voucher, the application for marketing authorisation of the priority antimicrobial must be submitted in the EU no later than 180 days after the submission of the first application for marketing authorisation for that product outside the EU. TEVs can give antimicrobial developers a direct financial incentive for investing in such products and finding investors. In addition, developers may benefit from other incentives such as the 'subscription model' (see below).

- For antimicrobials, the co-legislators agreed to introduce the possibility of a voluntary 'subscription model' for joint procurement of antimicrobials, subject to certain safeguards for the Member States. This model intends to provide stable revenue and predictability for antimicrobial developers. This can help overcome market failure in this area and strengthen the security of supply of antimicrobials.
- On access to medicines, the European Parliament and the Council agreed on the establishment of a mechanism whereby Member States and companies cooperate in good faith to ensure new medicines reach patients in a timely manner irrespective of where they live in the EU. In this regard, Member States may require the marketing authorisation holder to carry out specific actions with a view to complying with its placing on the market and supply obligations. This is to ensure sufficient and continuous supply to meet the needs of patients in every Member State concerned.
- On security of supply, the European Parliament and the Council have agreed that:
  - the six-month timeline for notification of supply disruptions is coupled with monitoring of 'expected' and actual shortages by national competent authorities;
  - shortage prevention plans are mandatory as of six months after entry into force of the proposed regulation and cover only prescription medicines and certain medicines identified by the Commission;
  - the voluntary solidarity mechanism is included in the proposed regulation as a voluntary, last-resort and Member States-driven tool;
  - the Commission's role in EU-level measures on supply security of critical medicines is limited to issuing non-binding guidelines and recommendations.
- The European Parliament and the Council agreed on the reform of the scientific committees of the European Medicines Agency. This involves simplifying the committees' current structure (including reducing the number) and increasing their expertise-based capacity, the aim being to avoid duplication of work, increase efficiency and reduce medicines' evaluation times. The standard assessment timeline for medicines is shortened from 210 to 180 days, with the objective of speeding up access to medicines across the EU, while maintaining high standards of quality, safety and efficacy. On the rights of civil society representatives on the Committee for Medicinal Products for Human Use Activities (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC), the co-legislators have agreed that each committee would have two representatives of patients and two representatives of healthcare professionals, together with two alternates for each group and each committee, while providing for a single shared voting right for each group.
- On the environmental risk assessment, the co-legislators have agreed that environmental risk assessments include the manufacturing for antimicrobials.
- On transparency of public funding, the European Parliament and the Council have agreed to set obligations for companies to declare to the public any direct financial support received from any public authority, publicly funded body, philanthropic organisation, or not-for-profit organisation or fund.
- On abortifacients and contraceptives, the co-legislators have maintained the current status quo. Introducing any restriction on the placing on the market of such products is a national competence.

- As regards repeals, transposition and transition periods, the co-legislators have set the deadline for transposition/application at 24 months. However, certain provisions on the granting of TEVs for priority antimicrobials, regulatory sandboxes and the guidelines on the subscription model for antimicrobials will apply from the date the legislation enters into force. Member States will have the possibility to apply provisions on access already 12 months after the entry into force of the Directive in respect of medicinal products authorised after the entry into force of the Directive. The provisions for electronic product information will apply six months before the date of application.

4. CONCLUSION

The Commission supports the results of the interinstitutional negotiations and can accept the Council's position at first reading.