



Brussels, 28 November 2025  
(OR. en)

15902/25

LIMITE

SAN 772  
PHARM 177  
MI 951  
COMPET 1232  
VETER 125  
ENV 1274  
RECH 517  
CODEC 1912  
PI 204  
IA 207  
UK 241

---

**Interinstitutional Files:**  
2023/0132 (COD)  
2023/0131 (COD)

---

#### NOTE

---

From: General Secretariat of the Council  
To: Permanent Representatives Committee

---

Subject: Pharmaceutical package  
a) Directive on the Union code relating to medicinal products for human use  
b) Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency  
*- Preparation for the trilogue*

---

#### I. INTRODUCTION

1. On 26 April 2023 the Commission adopted a proposal for the revision of the pharmaceutical legislation, consisting of a Directive on the Union code relating to medicinal products for human use<sup>1</sup> and a Regulation on Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency<sup>2</sup>.

---

<sup>1</sup> 8759/23

<sup>2</sup> 8758/23

The two legislative proposals aim to adapt and simplify the current regulatory landscape, which consists of one Directive and three Regulations covering both general legislation and specific legislation on medicines for rare diseases and for children.

2. The general objectives of the two legislative proposals are ensuring the quality, safety and efficacy of medicines for EU patients and harmonising the internal market. They specifically aim to promote innovation and ensure access to innovative and affordable medicines; improve security of supply of medicines and address shortages; support innovation and competitiveness through reduced regulatory burden and through a simplified and flexible regulatory framework; and reduce the environmental impact of the pharmaceutical lifecycle.
3. On 24 October 2023, the Committee of the Regions (CoR) sent a renunciation letter regarding the consultation on the Regulation due to the little regional or local relevance of this proposal<sup>3</sup>. On 25 October 2023, the European Economic and Social Committee (EESC) adopted its opinion on the proposals<sup>4</sup>.
4. At the European Parliament, when the proposals were put forward by the Commission, the Committee on the Environment, Public Health and Food Safety (ENVI) was designated as responsible committee. The ENVI Committee adopted its report on both the legislative proposals on 19 March 2024, which was voted in plenary session on 10 April 2024. The responsibility for both legislative proposals transferred to the newly established Committee on Public Health (SANT) in 2025. The rapporteurs are Tiemo Wölken (S&D, Germany) for the Regulation and Dolors Montserrat (EPP, Spain) for the Directive.
5. On 4 June 2025, the Permanent Representatives Committee agreed on a mandate<sup>5</sup> for the Presidency to enter into negotiations with the European Parliament. On 1 October 2025, the Permanent Representatives Committee provided guidance on several political issues<sup>6</sup>. On 7 November, 2025 Coreper provided further guidance, as well as a targeted revised mandate<sup>7</sup>.

---

<sup>3</sup> 15273/23

<sup>4</sup> 14863/23

<sup>5</sup> 9270/25

<sup>6</sup> 13078/25

<sup>7</sup> 14576/25

## **II. STATE OF PLAY**

6. Three rounds of trilogues and 23 technical meetings have been held with the European Parliament and the Commission. These meetings have resulted in provisional agreements on provisions highlighted in green in the 4th column of the 4 column tables.
7. Following the guidance from the Working Party and as a result from the interinstitutional technical meetings as well as the previous political trilogues with the European Parliament, the Presidency submits a compromise package to serve as a basis for finalising the negotiations, with a view to reaching an overall balanced compromise. The main elements of the proposed mandate follow below.

## **III. PREPARATION FOR THE FOURTH TRILOGUE**

8. The political issues mentioned above were discussed at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 9 July, 22 September, 28-29 October and 24 November. The Presidency took note of these discussions and the guidance provided by Coreper on 1 October and 7 November, as well as the call for the Presidency to reach an agreement with the European Parliament by the end of this year. Based on the conclusions of those meetings and the inter institutional discussions so far it is clear that the current mandate will not provide the Presidency with a sufficient margin to complete the negotiations with the European Parliament. In this background the Presidency proposes the following.
  - a) **Market exclusivity for orphan medicinal products, regulatory protection periods and obligations for availability of medicines, including Bolar:** The Presidency sees these topics as politically interlinked based on the negotiations thus far with the European Parliament. It is the assessment that it will be possible to preserve the most important priorities for Member States on these issues, if some flexibility is granted as referred to below.

- i) **On the Regulatory Protection Periods and the access provision** (Directive Articles 80-83/lines 856-894), the Working Party indicated that the balance of 8 years of data protection and a cap of 11 years for regulatory protection is important for the Council to maintain a balance between innovation and affordability. When it comes to the modulation of market protection some Member States have indicated flexibility towards addressing the EP's concerns on the regulatory complexity of the modulation in the Council mandate. Others have indicated that the modulation in the Council Mandate is a priority, emphasizing the importance of meaningful modulation. The Presidency proposes to stand firm on 8 years of basic data protection, and 11 years as a cap for the overall protection periods. In addition, the Presidency will stand firm on keeping modulation on the market protection, but as a part of a larger compromise take steps towards addressing the European Parliament's concerns on the cumulative nature of the modulation in the Council mandate.
- ii) **On obligations for availability of medicines** (Directive Article 56a introduced by the Council/lines 708a-708r), the European Parliament has provisionally accepted the framework of 56a in the Council Mandate as basis for further negotiations, but on the clear condition that the concerns of the European Parliament on the punitive nature of the Article is addressed.

The Presidency intends to defend the principles in art. 56a that ensures a tool for Member States to bring pharmaceutical companies to the negotiating table when MAHs do not engage with interested Member States. However, to meet the concerns of the Parliament, the Presidency seeks flexibility to convert the open-ended approach to a fixed list; introduce safeguards in the text to clarify what is required to fulfil obligations posed by the Member States and when the consequences for non-compliance would be triggered; and to prevent the use of art. 56 as an opportunity for parallel trade by introducing further safeguards on enforcement of limitations on parallel trade with Member States where regulatory protection still exists.

- iii) **On the Bolar provision** (Directive Article 85.1.ad/line 906c), the outstanding point from the technical inter- institutional negotiations is the Council’s introduction of procurement tenders in the scope of the article. For the rest of the article the EP has provisionally agreed to the Council Mandate.

The Presidency will defend the substantive element in the Council Mandate that will ensure that generics are available on day one after protection periods expire. However, the Presidency seeks limited flexibility to clarify the wording, to accommodate the European Parliaments concerns of ambiguity while maintaining a clear Bolar provision. The Presidency has already indicated to the European Parliament that notification requirements and limiting the scope to SPCs would not meet this requirement in the Council mandate.

- iv) **On market exclusivity for orphan medicinal products**, (Regulation Articles 70-72 / lines 679-705), the Working Party indicated that there may be openness towards the narrower scope, however, there were also concerns that this narrow approach could reduce incentives to develop improved treatments for rare diseases and disincentivise smaller companies working on new and improved treatments for rare diseases. As part of a larger compromise, the Presidency seeks flexibility to reintroduce a narrow and clear derivative concept of “Orphan medicinal products addressing a rare disease with no current medicinal treatment – *Breakthrough orphan medicinal products*”. Regarding protection periods for orphans, some Member States have indicated a preference for the timelines proposed by the Commission of 9 years for general orphan medicinal products and 10 years for high unmet medical need. The European Parliament, however, sets great value in extending the protection period for “breakthrough products” to 11 years noting that this would only encompass very few products. The Presidency proposes to show flexibility on 11 years towards the European Parliament as part of a global agreement and taking into account the provisions ensuring that generics and biosimilars can be available on day one after the market exclusivity expires (art. 71(6)) allowing the products to enter the market earlier than in the current framework.

***Can Member States support the suggested framework of a compromise for regulatory protection periods, obligations for availability of medicines, Bolar and market exclusivity?***

- b) On **Security of supply** the Presidency expects that a possible compromise lies within a balance made up of increased transparency and a proactive role for MSSG (along the lines of the issues raised by the European Court of Auditors recent report on security of supply), a proportionate role for the Commission and manageable administrative burden imposed on the national competent authorities (NCA's) as in the Council mandate.
- i) **On the role of the Commission** (Regulation, Article 134) the Presidency proposes to defend the Council Mandate on protecting the Member State's central role in building up and maintaining stocks of medicines, but would like to hear if there are flexibilities on strengthening the role of the MSSG and developing a framework for a solidarity mechanism to address shortages.
  - ii) **On obligations for wholesalers** (Regulation, Article 120(1a)) the Presidency would like to hear Member States flexibility on limiting monitoring requirements and trade limitations to critical medicines only on the proposal from Parliament to target the obligation to where it is necessary rather than taking an umbrella approach to limiting wholesalers' activities.
  - iii) **On shortage Prevention Plan and timeframe for monitoring** (Article 117 and 116) the Presidency proposes as part of a broader compromise to show flexibility towards widening the scope of which medicines must have a shortage protection plan on the condition that this does not impose an increased monitoring task for NCA's. The Presidency also proposes to show some flexibility on a longer timeframe than the three months in the Council mandate for notifying expected supply disruptions.

***Can Member States indicate flexibility on the proposed issues?***

- c) **Repeals, Transposition, Entry into force and transition periods** (Directive Articles 217-291/lines 1975-1976, 1979-1985, 1987. Regulation article 181/line 1622).

As part of a larger compromise the Presidency proposes to show flexibility towards a shorter time period than the 36 months, however the Presidency is concerned that the Parliaments position of 18 months is too short considering the complexity of the file and the budgetary implications that some new initiatives will have for the Member States. The Presidency considers to include the possibility of a differentiated model for lower timelines for security of supply, sandboxes, and AMR-voucher, as proposed by the Commission in the Working Party, and seeks flexibility to take steps in that direction.

*Can Member States support the proposed framework? And indicate flexibility on the differentiated model?*

- d) **Other issues**

For the issues discussed in COREPER in October, the Presidency would defend the Council Mandate, but to ensure a global compromise with the European Parliament, the Presidency would ask the Member States to indicate flexibilities to be able to ensure the most sensitive issues in the Council position.

- i) **On Voting rights in CHMP and membership of PRAC** (Regulation Article 148(4)/line 1316a, Article 149(2)(c) and (d)/lines, 1332 and 1333) the Presidency will defend the Council mandate, but would like to stress the importance for the European Parliament of voting rights, and hear if the Council has any flexibility on this issue.
- ii) **On Derogation for national legislation on contraceptives and abortifacients** (Directive Article 1(10)(a)/line 179), the Presidency will defend the Council Mandate but would like to hear the Councils flexibility on this issue.

- iii) **On marketing authorisation application timelines** (Regulation Article 6(6)/line 226; Directive Article 30/line 495), the European Parliament is concerned that the Council mandate will not simplify administrative processes in order to lower barriers for market entry of pharmaceutical products in the EU. On this background, the Presidency would ask the Council to indicate flexibility on the European Parliaments position of 180 days.

*Can Member States indicate flexibility on the proposed issues?*

#### **IV. CONCLUSION**

9. The Permanent Representatives Committee is invited to examine the Presidency's compromise suggestions as set out in this note and annexed four-column table with a view to provide the Presidency with a mandate for the negotiations with the European Parliament at the upcoming trilogues, scheduled to take place on 10 December 2025.
-