Council of the European Union

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UK 168

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[1] 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[2].

[1] 8759/23
[2] 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[3]. On 25 October 2023, the European Economic and Social Committee (EESC) adopted its opinion on the proposals[4].

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[5] for the Presidency to enter into negotiations with the European Parliament.

3 15273/23
4 14863/23
5 9270/25

II. STATE OF PLAY

6. So far, one trilogue and seven technical meetings have been held with the European Parliament and the Commission. These meetings have allowed to discuss and provisionally agree on a number of provisions highlighted in green in the 4th column of the 4 column tables.

7. The discussions during the technical inter-institutional negotiations allowed to provisionally identify the following political issues to be discussed at the next political trilogues on 7 October 2025:

a) **European Medicines Agency governance:**

i) **Voting rights in the Committee for Medicinal Products for Human Use (CHMP)** (Regulation Article 148(4)/line 1316a), where the Council limits the voting rights to members appointed by each Member State and to the additional members chosen on the basis of their specific scientific competence, while the Parliament supports the Commission proposal of extending the rights to representatives of healthcare professionals' and patient organisations in the CHMP.

ii) **Membership of the Pharmacovigilance Risk Assessment Committee** (Regulation Article 149(2)(c) and (d)/lines, 1332 and 1333) where the Council reduced the number of representatives of healthcare professionals' and patient organisations, while the Parliament supports the number of representatives specified in the Commission proposal.

iii) **Scientific working parties and scientific advisory groups** (Regulation Article 150(2)(3)/line 1344), where the Parliament introduces more binding language regarding the establishment of working parties and keeps the scope limited to Environmental Risk Assessment, while the Council maintains the optional language in the proposal and extends the scope to include also paediatric and orphan medicines.

b) **Duration of examination of marketing authorisation application** (Regulation Article 6(6)/line 226; Directive Article 30/line 495) where the Council prefers to revert to the current maximum duration of 210 days, while the Parliament supports the proposal of maximum 180 days.

c) **Scope of the Environmental Risk Assessment** (Directive Article 4(1)(33)/line 256 and Article 22/lines 390-402), which the Parliament broadens to also include manufacturing of all medicines and where the Council supports the Commission's proposal where the environmental risk assessment is limited to manufacturing of antimicrobials with the aim of combating antimicrobial resistance.

d) **Derogation for national legislation on contraceptives and abortifacients** (Directive Article 1(10)(a)/line 179), which the Parliament seeks to remove from the scope of the proposal.

e) **The pharmacy exemption** (Directive Article 1(5)(a)/line 171 and Article 1(6)/line 174), where the Parliament supports the main elements of the Commission proposal, whereas the Council expands the advance preparation beyond hospital-serving pharmacies, which is allowed today in some Member States, and extends the maximum duration to four weeks, , with the magistral formula also referring to the preparation of medicines available without a medical prescription, based on the instruction of a doctor or another healthcare professional.

f) **Cross-border hospital exemption for advanced therapy medicinal products** (Directive Article 2(8a)/line 196a), introduced by the Parliament for justified cases of medical needs and in the absence of other solutions for the individual patient.

g) **Antimicrobials and antimicrobial resistance (AMR):**

i) **the antimicrobial access plan** (Directive Article 17(1)(a)/line 363), introduced by the Parliament;

ii) **the prescription status** (Directive Article 51(1)(e)/line 674), where the Parliament limits the scope of prescriptions to antibiotics and other antimicrobials for which there is an identified risk of AMR, while the Council requires prescriptions for all antimicrobials except those intended for topical use.

iii) **special information requirements** (Directive Article 69/lines 808-812b), where the Council removes the proposal for the 'awareness card' (line 810), while the Parliament maintains it. The Council introduces the global AMR symbol and additional information on the package leaflet as an alternative to the awareness card.

III. PREPARATION FOR THE TRILOGUE

8. The Presidency respects the political balance in the Council mandate of 4 June 2025, which was supported by 26 Member States. The Presidency notes that the Pharma Package is a sizeable and complex legislation with a significant number of changes in both mandates, but particularly in the Council mandate. The Presidency further acknowledges the Parliament's constructive approach during the interinstitutional negotiations, which has allowed to provisionally agree on a significant number of technical issues that are important for the implementation of the legislation.

9. Based on the inter-institutional discussions so far, it is clear that the current mandate will not provide the Presidency with a sufficient margin to complete negotiations with the European Parliament. However, the Presidency sees the need to further explore the flexibilities of the Parliament and the Council at the political level before requesting an updated mandate from Council at a later stage. In this regard the Presidency considers that, to be able to progress efficiently during the negotiations, further political guidance is needed.

10. The political issues mentioned above were discussed at the meetings of the Working Party on Pharmaceuticals and Medical Devices on 24 June, 9 July, and 22 and 25 September. Based on the conclusions of those meetings, the Presidency seeks guidance on the following:

a) The Presidency would like to explore **potential reciprocal flexibilities** between elements regarding marketing authorisation application timelines and the scope of the Environmental Risk Assessment. While not being interlinked elements, both elements are related to the workload of administrations. The European Parliament is concerned that the Council mandate on marketing authorisation application timelines will not **simplify administrative processes** in order to lower barriers for market entry of pharmaceutical products in the EU. The Parliament has also in many cases adopted a prescriptive approach that will increase administrative burden for the Member States. The Presidency is looking for greater flexibility from the Parliament on these issues and has identified the European Parliament's proposal for the **scope of the Environmental Risk Assessment**, which is extended to include manufacturing of pharmaceuticals. This could present sizeable administrative burden and establish barriers for new investments in pharmaceutical production sites in Europe and for market entry of new treatments. The Presidency seeks **guidance in view of potential reciprocal flexibilities** on these issues, as the Presidency sees the need to ensure a balance between reducing timelines for regulatory procedures and ensuring a corresponding flexibility that allows the Member States to reduce administrative burdens in their own systems.

b) The Presidency would like to **maintain the Council mandate** on the rest of the topics listed above, **with a certain degree of flexibility** on:

i) the **spirit** in the Parliament proposal for **cross-border hospital exemption for advanced therapy medicinal products** (Directive Article 2(8a)/line 196a), where the European Parliament aims to improve access to personal medicines by utilising European expertise across borders. Flexibility would be based on the provision that the concept is in line with patient safety and the operational framework, responsibility chain and data collection requirements of the receiving Member State.

ii) the **length of the period during which medicinal products may be prepared in advance by a pharmacy** (Directive Article 1(5)(a)/line 171 and Article 1(6)/line 174), or limiting the scope to only hospital-serving pharmacies as proposed in the Commission proposal. The Parliament has concerns that the Council mandate will lead to circumvention of the approval process, establishment of parallel production and imports from third countries. The Presidency is asking for political guidance on this issue.

11. On the rest of the topics listed in point 7, the Presidency intends to defend the Council mandate in the forthcoming trilogue.

IV. CONCLUSION

12. In light of the above, the Permanent Representatives Committee is invited to:

– take note of the four-column tables in documents 13168/25 and 13167/25;

– discuss the main political issues referred to in point 7 above and provide guidance on the proposed approach as outlined in point 10.