Council of the European Union

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**NOTE**

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| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee |
| Subject: | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795<br>- Preparation for the trilogue |

## I. INTRODUCTION

1. On 11 March 2025, the Commission submitted to the Council and the European Parliament a proposal for a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest[1]. This proposal, referred to as the Critical Medicines Act (CMA), was adopted alongside a guidance on the application of state aid rules in the context of the CMA. The proposal was submitted without an Impact Assessment but a Commission

[1] 6872/25

staff working document[2] was published on 2 September 2025 summarising the evidence supporting the legislative proposal.

2. The objectives of the proposal, which complements the ongoing revision of the EU pharmaceutical legislation, are to improve the functioning of the internal market by establishing a framework to strengthen the security of supply and the availability of critical medicinal products within the Union. It further aims to improve the availability and accessibility of other medicinal products of common interest where the functioning of the market does not otherwise sufficiently ensure this, whilst giving due consideration to the affordability of those medicinal products.

3. The draft Regulation is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).

4. The European Economic and Social Committee delivered its opinion[3] on 18 June 2025 and the European Committee of the Regions delivered its opinion[4] on 10 December 2025.

5. The Senate of the Parliament of the Czech Republic and the Spanish Parliament, each submitted a positive assessment while raising concerns on certain aspects. The Romanian Senate submitted an opinion raising proportionality concerns and making several recommendations. The Italian Senate submitted two resolutions, being one positive and another raising proportionality concerns. The Italian Chamber of Deputies also submitted an opinion raising proportionality concerns. The Swedish Parliament and the French Senate, each submitted a reasoned opinion raising subsidiarity concerns on parts of the proposal.

6. In the European Parliament, the Committee on Public Health (SANT) has the lead responsibility and MEP Tomislav Sokol (EPP, HR) is the rapporteur. The SANT Committee adopted its report on 15 December 2025, followed by a vote in the Parliament plenary session on 20 January 2026.

7. The Council reached a General Approach[5] on 2 December 2025 and gave a mandate to the Presidency to start negotiations with the European Parliament.

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[2] 12444/25
[3] 10782/25
[4] 5223/26
[5] 15503/25

## II. STATE OF PLAY

8. So far, one trilogue and five technical meetings have been held with the European Parliament and the Commission. These meetings have allowed to discuss and tentatively agree on a number of provisions highlighted in green in the fourth column of the four-column table in document 6822/26.

9. The discussions during the inter-institutional negotiations held so far has allowed provisionally to identify the following relevant political issues to be discussed in the next political trilogue on 16 March 2026:

   a. Definition of medicinal products of common interest *(Article 3, row 73),* where the Parliament broadens the scope to include the orphans medicinal products, contraceptives and abortifacients and adds the term affordability.
   b. Extension of the scope of Chapter III *(Article 2, row 66),* where the Parliament proposes to extend the scope of the chapter to medicinal products of common interest while the Council only includes critical medicinal products as in the original Commission's proposal. For the Parliament, this Article is important. However, during the negotiations it signalled a certain degree of flexibility and suggested narrowing its requested scope, i.e. that medicinal products of common interest should only benefit from the accelerated permit-granting provisions of Chapter III and not the entirety of Chapter III as initially requested (i.e. excluding them from the provisions on financial support). The Parliament has also signalled a certain flexibility to limit its request to orphan medicinal products only and not all medicinal products of common interest.
   c. Recognition of strategic projects *(Article 6, rows 101,102,105e):* where the Parliament adds certain timelines: three months to appoint the designated authority and three months for the assessment to be carried out. The timeline for the assessment in the Council is without undue delay.
   d. Environmental assessment timelines *(Article 12, rows 131 and 132):* where the Council proposes to extend the deadline from 45 days in the Commission proposal to 90 days for a reasoned conclusion and from 15 days to 20 days for exceptional cases, which translates to a maximum total of 110 days, while the Parliament proposes to maintain the Commission's proposal of 45 days for a reasoned conclusion, an extra 45 days in duly justified cases and 15 days for exceptional cases.

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e. Strategic objective of the Union (*Article 4, rows 88-91):* where the Council deletes this article from the enacting terms and includes its content in a recital and the Parliament keeps the article adding further details to it.

f. Financial support from Member States (*Article 15, rows 143a, 144, 144a, 146a, 146b, 146c)*, where the Parliament adds several amendments including provisions allowing Member States to require to reserve manufacturing capacity, availability and affordability requirements for funded projects, establishes penalties and the possibility to fund recovery if obligations are not met and introduces the possibility of export restrictions. Likewise, the Parliament imposes a stricter obligation on project promoters to ensure continuity of supply by deleting 'use its very best efforts' in row 144. The Parliament is expected to show flexibility with the rest of the amendments in the Article if the 'use its very best efforts' is deleted.

g. Financial support from the Union *(Article 16, rows 147-149d),* where the Parliament adds amendments mirroring those in Article 15, insert references to the next MFF 2028-2034 and establishes a critical medicines security fund.

## III. PROPOSAL FOR A REVISED MANDATE

10. Based on the inter-institutional discussions so far, it is clear that the current mandate does not provide the Presidency with a sufficient margin to negotiate with the European Parliament. To be able to progress efficiently during the negotiations, the Presidency believes that this mandate needs to be updated.

11. The main political issues were discussed at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 5 March 2026. Based on that meeting and the state of play, the Presidency considers that with a view to preparing for the forthcoming discussion, the following approach could provide a good basis for negotiating with the European Parliament:

    a. On the definition of medicinal products of common interest, to show certain degree of flexibility towards the inclusion of orphan medicinal products but not on contraceptives and abortifacients nor affordability.
    b. On the extension of scope of Chapter III, to defend Council's mandate.
    c. On the timelines related to the recognition of strategic projects, to keep Council's mandate for both the appointment of the designated authority and the timing to assess the strategic project as undue delay.

d. On environmental assessment timelines, to show certain flexibility on Council's mandate by adjusting the maximum total days in a range between 75 and 100 days.
e. On the strategic objective of the Union, if needed, to show certain degree of flexibility by bringing back the Article to the enacting terms while taking due regard to legal considerations and reject attempts to further extend the original wording from the Commission proposal.
f. On the Financial support from Member States, to explore possibilities to strengthen the commitments of companies receiving financial support from Member States to prioritise supplies in the Union, while respecting the principle of proportionality.
g. On the Financial support from the Union, to keep Council's mandate.

12. On the extension of the scope of Chapter III, as per point 11(b), the Presidency requests guidance on whether Member States can show a degree of flexibility on the Parliament's proposal (as described in point 9(b)), including the possibility of limiting its scope further to only orphan medicinal products, with a view to identifying a potential compromise.

## IV. CONCLUSION

13. The Permanent Representatives Committee is therefore invited to:

- take note of the four-column table in 6822/26.
- take note of the main political issues referred to in point 9 above.
- examine the Presidency's compromise approach as outlined in point 11 and advise on the requested degree of flexibility outlined in point 12 to provide the Presidency with a mandate for the next trilogue with the European Parliament scheduled on 16 March 2026.

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