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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal 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 (Critical Medicines Act) - 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 staff working document[2] was published on 2 September 2025 summarising the evidence supporting the legislative proposal.

[1] 6872/25
[2] 12444/25

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

II. STATE OF PLAY

8. So far, two trilogues and 14 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 8570/26.

9. The discussions during the inter-institutional negotiations held so far have allowed provisionally to identify the following relevant political issues to be discussed in the next political trilogue on 11 May 2026:

   a. Public procurement requirements (*Article 18, row 157*): Where Council adds a mandatory resilience requirement, allowing different options for the contracting authorities to choose from (selection criteria, technical specifications, best price-quality ratio and contract performance clauses), the Parliament proposes to apply other than price-only award criteria that promotes resilience and take into account distance between manufacturing sites and point of delivery. It also encourages multi-winner procurements where the scope is designed based on clinical needs and the size of the patient population.

   b. Public procurement requirements – 'EU preference' *(Article 18, row 158*): Where the Parliament defines what 'significant proportion of manufacturing in the EU' is by giving specific criteria that should include 50% of active substances manufactured in the Union or 50% of the value of the medicinal product comes from manufacturing in the Union. The Parliament also broadens the 'EU preference' to include the EFTA countries. The Council, on the other hand, proposes guidelines to determine whether critical medicinal products or their active substances are manufactured in the Union, by removing the notion of significant proportion.

   c. Joint procurement (*article 23, rows 187-197*): Where the Council deleted the whole Article and the Parliament would like to retain it.

   d. Safeguards related to Member States' contingency stocks requirements (*Article 20, rows 166 and 167k)*: Where Parliament keeps a stronger wording using 'shall not result in any negative impact', the Council's mandate has a softer tone 'aim at avoiding negative impacts'. The Parliament also calls for EU countries to coordinate during health crisis with wholesalers to distribute critical medicines, including the option to use military or emergency services if needed.

   e. Union coordination mechanism (*Section Ia, rows 167l-167bg*): Where the Parliament proposes a Union coordination mechanism, led by the Commission, that will enable

the redistribution of national stockpiles to other countries. It also proposes a reporting system on national stockpiles and contingency stocks (Article 20d) and a Union stockpile (Article 20h) as a last-resort mechanism.

f. Critical distribution infrastructure capacity *(Article 1, row 63a, row 213):* Where the Parliament adds an objective to include investments in critical distribution infrastructure capacity.

In addition, it is expected that the co-legislators will revert on the issues partly discussed during the second trilogue:

g. Definition of medicinal products of common interest (MCPIs) *(Article 3, row 73),* where the Parliament broadens the scope to include the orphan medicinal products, contraceptives and abortifacients.

h. Extension of the scope of Chapter III *(Article 2, row 66),* where the Parliament proposes to extend the scope of the chapter to MCPIs while the Council only includes critical medicinal products as in the original Commission's proposal.

i. 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.

j. Financial support from the Union *(Article 16, rows 147 to 149d),* where the Parliament adds amendments mirroring those in Article 15, inserts 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 and to reach a political agreement, 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 28 April 2026. Based on that meeting and the

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state of play, the Presidency considers that with a view to reaching a political agreement, the following approach would provide a good basis for a compromise package with the European Parliament:

a. On Public procurement requirements to defend Council's mandate on the resilience requirements in Article 18(1) (row 157), maintain the exceptions for contracting authorities based on Article 18(5) (rows 161-161d), as well as maintain the issuing of guidelines by the Commission based on Article 18(6)(row 161f). At the same time, show some openness towards Parliament in Article 18(2) (row 158), by providing options to the contracting authority on how to implement the 'EU preference'. In this regard the contracting authority will have the **flexibility to choose between different options, for instance**:

   i. applying a best price-quality ratio as award criteria, within the meaning of Article 67 of Directive 2014/24/EU, that favours the suppliers that offer a significant proportion of medicinal products and their APIs manufactured in the Union;

   ii. applying a best price-quality ratio mechanism as per point i) and at the same time allocate additional points if the supplier manufactures over [50%] of the medicinal products and their APIs in the Union;

   iii. using technical specifications, within the meaning of Article 42 of Directive 2014/24/EU, requiring a threshold of at least [50%] of the volume manufactured in the Union for all lots and apply a multi-winner approach;

   iv. using contract performance clauses, within the meaning of Article 70 of Directive 2014/24/EU, requiring at least [50%] Union manufacturing by the contract's conclusion.

   The Parliament's position for the inclusion of EFTA countries as part of the 'EU preference' would be rejected. For the purpose of Article 18(2), manufacturing in the Union shall include all manufacturing steps carried out within the Union other than import, repackaging, packaging, labelling, quality testing and where applicable, certification. The implementation of 'EU preference' will be applied in compliance with the Union's international commitments and Article 18 would be subject to a review clause.

b. On Joint procurement, to defend Council's mandate, therefore keeping the deletion of Article 23.

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c. On the Union coordination mechanism and on safeguards related to Member States' contingency stocks requirements, the redistribution mechanism as conceived by the Parliament, the Union stockpiling and the inclusion of national stockpiles (Section Ia) will be rejected. However, in order to secure a compromise, the Presidency proposes:
    i. to show certain flexibility in relation to information sharing and reporting on the contingency stock requirements. Information will be shared through a digital platform established by the Commission.
    ii. when the Voluntary Solidarity Mechanism (VSM) is activated, and if requested by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), Member States shall provide up-to-date stock data of critical medicinal products subject to contingency stock requirements. Member States taking into account the inventory of the contingency stock of the concerned critical medicinal product could agree to reallocate it on a voluntary basis.
    iii. likewise, when the VSM has not resulted in a suitable solution, the MSSG may issue non-binding recommendations to Member States that could encompass, where appropriate, an invitation to Member States to consider adapting or suspending contingency stock requirements on a voluntary and temporary basis. This non-binding recommendations would only be issued in exceptional circumstances, at the request of the Member State that has activated the VSM.
    iv. allow for a stronger wording on the adverse impact of contingency stocks in row 166 while rejecting Parliament's amendment in row 167k.
d. On the definition of MCPIs (Article 3, row 73) and on the expansion of the scope of Chapter III (Article 2, row 66), to show certain flexibility by adding only orphan medicinal products in the MCPI definition but not contraceptives and abortifacients. In addition, to show some openness by considering a targeted extension of Chapter III's scope by including **only** orphan medicinal products. Strategic projects of orphan medicinal products would benefit from faster permit-granting procedures but would be excluded from financial and regulatory support (articles 11, 15 and 16). This would be part of the broader compromise package to secure an agreement with the Parliament.
e. On the Financial support from Member States and from the Union, to show some flexibility on including a stronger commitment by deleting "it's very best efforts" on

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row 144 and to ensure proportionality by limiting those obligations towards one Member State instead of all. Also, to show limited flexibility by exploring a very general reference to a possible financial contribution from the Union general budget. In exchange, we will reject all Parliament's amendments related to reserving manufacturing capacity, availability and affordability requirements for funded projects, penalties, fund recovery, export restrictions and references to the future MFF and the Critical Medicines Fund.

f. Critical distribution infrastructure capacity: to reject the Parliament's amendment.

IV. CONCLUSION

12. In view of the political trilogue on 11 May 2026, the Permanent Representatives Committee is therefore invited to:

- take note of the four-column table in 8570/26.
- agree on the proposed approach as described in point 11, indicating any possible strong reservations within this package proposal.

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