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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying 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 *- Guidance for further work*

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

[1] 6872/25

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 strengthen the security of supply and the availability of critical medicinal products across the Union, thereby ensuring a high level of public health protection and contributing to the Union's overall security. It further aims to improve the availability and accessibility of 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 proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).

II. STATE OF PLAY

4. The Polish Presidency organised one meeting of the Working Party on Pharmaceuticals and Medical Devices dedicated to presenting the proposal and held a policy debate at EPSCO (Health) on 20 June 2025. The Danish Presidency has devoted a total of 6 meetings spread over 10 days to the file, concluding the first examination of the proposal.

5. Based on the first examination of the proposal, on written comments from delegations, and building on discussions in the Working Party, the Danish Presidency has put forward a first revised text[3] which has been examined in three meetings on 25, 26 September and 8 October. The compromise text aims to keep the objectives of the proposal while addressing concerns raised by Member States. In particular, for the demand-side measures (Chapter IV) the Presidency introduced the following amendments, among others:
    - On public procurements (Article 18): aligned the terminology with the Public Procurement Directive (2014/24/EU) to enhance legal clarity and coherence; increased flexibility for Member States and contracting authorities by outlining different requirements -except price- to choose from in order to secure supply; the requirement

[2] 12444/25
[3] 12773/25 + COR1

to favour an economic operator when suppling critical medicines for which a vulnerability has been confirmed was kept ('European preference') and broadened to third countries with international trade agreements, thereby incentivising European production while at the same time providing a legally sound critical medicinal products framework promoting supply of critical medicines.

- On Commission facilitated Member States' cross-border procurement (Article 21); the voluntary nature of the provision was highlighted and the possibility of continuing the procedure without the Commission facilitation was introduced giving further flexibility to use existing expertise in the Member States.
- On Commission procurement on behalf of or in the name of Member States (Article 22): a lower threshold of six Member States for the Commission to act instead of nine was introduced, thus ensuring an accessible procedure while maintaining sufficient volume to benefit from an economy of scale, reduce transactional costs and ensure the attractiveness of tenders for potential suppliers.
- On Joint procurement, Article 23 was deleted following calls for a clearer, simplified and implementable framework of cross-border procurements and to avoid overlaps with other existing mechanisms providing the Commission with the legal basis to procure medicinal products when necessary.

III. OUTSTANDING ISSUES AND GUIDANCE FOR FURTHER WORK

6. The Presidency intends to continue working towards a sound compromise text that delegations can support. Although a lot of progress has been made at technical level, the examination of the proposal in the Working Party clearly highlighted that, further analysis and framing is needed for some of the issues, notably the public procurement criteria and requirements, how to utilise the 'EU preference' for public procurements procedures efficiently and in the best interests of patients and on the role of the Commission in the collaborative procurement articles.

7. While there was a general understanding of the motivation behind, the Working Party discussion on the public procurement of critical medicinal products showed differences in the willingness to oblige to the use other criteria than price with the purpose of enhancing security of supply to the Union. Since it is possible today – on a voluntary basis - under Directive 2014/24/EU to use other criteria than price, the Commission reasoned the inclusion of this obligation as a way to create stronger incentives facilitating security of supply in line with the

overall objective of the Union of a stronger (open) strategic autonomy. Member States in general agree on the overall objective, however, disagreement persist on whether to make it mandatory or not, where the main concern of some Member States seems to be the risk of high increases in prices of the medicines.

Following the discussion, the Danish Presidency created greater flexibility for Member States and contracting authorities by outlining different requirements -except price- to choose from in order to secure supply. For example, making it possible to use a model with threshold entry requirements to participate in calls for tenders and thereafter price being the determining factor or multi winner tenders.

8. Regarding the 'EU preference', the Working Party showed general agreement on the aim behind the concept, however two outstanding issues remain:
    a. some Member States have expressed doubts of the enforced language on Union's international commitments in the Presidency compromise, where they question if this would eliminate the gist of the EU preference. At the same time, other Member States underlined that international trade agreements (and strategic partnerships as referenced in Article 27) can be an important element in diversification of supply chains and the long-term sustainability of national health budgets, as well as patients' timely, equitable and affordable access to medicines.

       To accommodate these concerns, the Presidency proposes to keep Article 18 (2) as a shall-provision, while going back to the original and broader wording of the Commission regarding the Union's international commitments with the aim of promoting diversification and increasing the competitive nature of the market for critical medicinal products.
    b. Member States have called for more clarity on the definition of 'EU preference'. In its first compromise the Presidency proposed to use language similar to the customs code. Technical feedback in the Working Party clearly showed that this would not be appropriate, given the nature of critical medicinal products, since it is not always possible to have (all) components 'originating in the EU'. Hence, the Presidency proposes to go back to the original wording proposed by the Commission of 'manufactured in the EU'.

9. During the Working Party meetings Member States confirmed their general support for utilising the benefit from an economy of scale by using collaborative procurement to support the aim of improving availability and accessibility of relevant medicinal products. However,

some Member States are calling for a lower threshold in the number of Member States needed to initiate a collaborative procurement procedure, while others are still showing some skepticism towards the model of collaborative procurement all-together.

IV. CONCLUSION

10. Acknowledging the political nature of the outstanding issues highlighted above, Coreper is invited to provide guidance on the way forward, based on the following guiding questions, with the aim to facilitate and continue the work at technical level:
    - Considering the flexibilities currently included in the Presidency's compromise proposal for amending Article 18 (1) could you accept an obligation for Member States and contracting authorities to use resilience criteria rather than price when procuring critical medicines products listed in the Union list?
    - Bearing in mind affordability and the need to diversify supply chains, would you support the Presidency's proposal for a 'European Preference' provision (Article 18 (2)), with the changes indicated by the Presidency above in point 8 a and b?
    - Would you support the Presidency compromise proposal of collaborative procurements (Articles 21-23), including the lowered threshold of six Member States for the Commission to act in Article 22 and the deletion of Article 23?

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