



Council of the European Union
General Secretariat

**Interinstitutional files:
2025/0102 (COD)**

Brussels, 23 July 2025

WK 9967/2025 ADD 2

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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Critical Medicines Act)
N° Cion doc.:	ST 6872 2025 INIT
Subject:	Critical Medicines Act - Comments from the Slovenian delegation

Delegations will find enclosed additional comments from the Slovenian delegation on chapter IV of the Critical Medicines Act (ST 6872/25).

Guidelines to be followed

Please add your contributions in the table below, only in the columns '**Drafting**' and/or '**Comments**'

Name of document: please rename the MS Word document by adding the **two initials** of your delegation's Country followed by a space.

Only then you may add any text to the file name, for example, for Austria: **AT comments ondocx** .

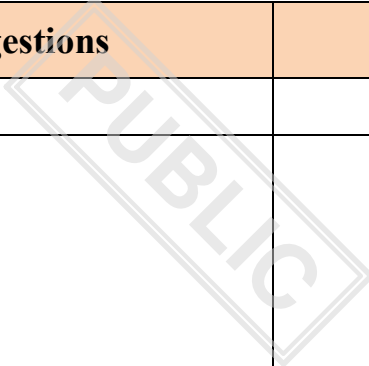
Thank you for your cooperation!

Commission proposal	Drafting suggestions	Comments
General comments		
Chapter IV Demand side measures		
SECTION I		
AWARD CRITERIA AND OTHER PROCUREMENT REQUIREMENTS AND RELATED MEASURES		

Commission proposal	Drafting suggestions	Comments
<i>Article 18</i>		
<i>Incentivising resilience, sustainability and positive social impacts in public procurement procedures</i>		
<p>1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency</p>		

Commission proposal	Drafting suggestions	Comments
to the contracting authority and contract performance clauses on timely delivery.		
<p>2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. These requirements shall be applied in compliance with the Union’s international commitments.</p>		
<p>3. With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities may apply procurement</p>		

Commission proposal	Drafting suggestions	Comments
<p>requirements that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union’s international commitments.</p>		
<p>4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights.</p>		
<p>5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2 and 3 where justified by market analysis or considerations related to the financing of health services.</p>		
<p><i>Article 19</i></p>		
<p><i>Programmes supporting sustainability and resilience in public procurement procedures</i></p>		

Commission proposal	Drafting suggestions	Comments
<p>1. By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures.</p>		
<p>2. Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Group. The Commission shall ensure the distribution to all</p>		

Commission proposal	Drafting suggestions	Comments
<p>members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion aiming to ensure coordination of national programmes including as regards the application of criteria mentioned in Article 18(2) and may issue opinions. Where the Critical Medicines Group issues an opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes.</p>		
<i>Article 20</i>		
<p><i>Safeguards related to Member States’ contingency stocks requirements and other security of supply measures</i></p>		
<p>Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States</p>		

Commission proposal	Drafting suggestions	Comments
shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks.		
Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity.		
SECTION II		
COLLABORATIVE PROCUREMENTS		
<i>Article 21</i>		
<i>Commission facilitated Member States' cross-border procurement</i>		

Commission proposal	Drafting suggestions	Comments
<p>1. Upon a reasoned request of three or more Member States (‘the request’), the Commission may act as facilitator for the requesting Member States’ cross-border procurement as laid down in Article 39 of Directive of the European Parliament and of the Council 2014/24/EC¹ for medicinal products of common interest.</p>		
<p>2. Having received the request, the Commission shall inform all other Member States of the initiative and set an appropriate deadline for them to declare interest. Such a deadline shall not exceed three weeks.</p>		
<p>3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall communicate to the interested</p>		

¹ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC ([OJ L 94, 28.3.2014, p. 65](https://eur-lex.europa.eu/eli/dir/2014/24/2024-01-01), ELI: <http://data.europa.eu/eli/dir/2014/24/2024-01-01>).

Commission proposal	Drafting suggestions	Comments
Member States its decision on whether it agrees, or not, to facilitate the proposed initiative within three weeks of receiving the request.		
4. If the Commission declines the request, it shall provide reasons for the refusal.		
5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the interested Member States. The Commission shall facilitate communication and cooperation between the involved Member States and provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products.		
6. The facilitation offered by the Commission shall be limited in time and end at the latest upon signature of the procurement		

Commission proposal	Drafting suggestions	Comments
contract by the participating contracting authorities.		
7. The Commission shall not be responsible, nor held liable, for any breaches of Union or national procurement laws by the participating contracting authorities. The Commission shall not bear any liability associated with the conduct of the procurement procedure by interested Member States and implementation of the contract resulting from the procedure.		
<i>Article 22</i>		
<i>Commission procurement on behalf of or in the name of Member States</i>		

Commission proposal	Drafting suggestions	Comments
<p>1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where nine or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission may initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below;</p>	<p>By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where nine three or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission may initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below;</p>	<p>SI believes that requiring at least nine member states to trigger this mechanism may limit its practical usability. SI therefore believes that the number of MS should be lowered and therefore proposes that at least three member states jointly request the triggering of this mechanism. We believe that this is important especially for smaller member states seeking to coordinate targeted purchases, such as SI.</p>
<p>(a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;</p>		
<p>(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European</p>		

Commission proposal	Drafting suggestions	Comments
<p>Parliament and the Council ², or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.</p>		
<p>2. The joint request referred to in paragraph 1 shall only be made where the medicinal product concerned fulfils one of the criteria set out in that paragraph and if the requested procurement procedure will help to improve the security of supply and availability of critical medicinal products in the Union or ensure the availability and accessibility of medicinal products of common interest, as applicable.</p>		
<p>3. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States</p>		

² Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, ELI: <http://data.europa.eu/eli/reg/2021/2282/oj>)

Commission proposal	Drafting suggestions	Comments
of the request, through the Critical Medicines Group, and invite them to join the procedure.		
4. The Commission shall assess the utility, necessity and proportionality of the request and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.		
5. The Commission shall inform the interested Member States within one month of the request of its decision and state its reasons in case of a refusal.		
6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the		

Commission proposal	Drafting suggestions	Comments
Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.		
7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509 ³ .		
<i>Article 23</i>		
<i>Joint Procurement</i>		
1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and	1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and	SI believes that a lower threshold of Member states would enhance responsiveness of joint procurements.

³ Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast) (OJ L, 26.9.2024, p. 1, ELI: <http://data.europa.eu/eli/reg/2024/2509/oj>).

Commission proposal	Drafting suggestions	Comments
<p>Member States, the Commission and at least nine Member States may engage, as contracting parties, in a joint procurement procedure.</p>	<p>Member States, the Commission and at least nine three Member States may engage, as contracting parties, in a joint procurement procedure.</p>	
<p>2. A joint procurement procedure may be organised following a request by the Member States or at the Commission’s initiative when the procurement relates to medicinal products belonging to one of the categories below:</p>		
<p>(a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;</p>		
<p>(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European</p>		

Commission proposal	Drafting suggestions	Comments
<p>Parliament and the Council ⁴, or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.</p>		
<p>3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply and availability of critical medicinal products in the Union or ensure the availability and accessibility of medicinal products of common interest, as applicable.</p>		
<p>4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure.</p>		

⁴ Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, ELI: <http://data.europa.eu/eli/reg/2021/2282/oj>)

Commission proposal	Drafting suggestions	Comments
<p>5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.</p>		
<p>6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.</p>		
<p>7. The Commission shall inform the interested Member States within one month of</p>		

Commission proposal	Drafting suggestions	Comments
the request of its decision and state its reasons in case of a refusal.		
8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.		
<i>Article 24</i>		
<i>Agreement concerning procedures under Articles 22 and 23</i>		
1. Member States participating in the procurement procedures covered by Articles 22 and 23 shall share with the Commission any information relevant for the procurement procedure. Member States shall provide resources necessary for the successful conclusion of the procedure, in particular		

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through involvement of staff with expertise and knowledge.		
2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process.		