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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)
Subject:	Critical Medicines Act - Comments from delegations

Delegations will find enclosed the comments from the delegations on the first Presidency's compromise text on the Critical Medicines Act (ST 12773/25).

Written contributions from delegations

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AUSTRIA

Chapter III **Enabling conditions for investment**			
SECTION I			
CRITERIA AND PROCEDURE FOR THE RECOGNITION OF STRATEGIC PROJECTS			
Article 5			
Strategic Projects			
A project located in the Union and related to creating**,** **modernising** or increasing manufacturing capacity **of critical medicinal products**			

shall be considered as a strategic project if it meets at least one of the following criteria:			
(a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances;			
(b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency;			
(c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more			

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critical medicinal products or their active substances;			
(d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.		AT: (d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing **or supply** of one or more critical medicinal products, their active substances or key inputs.	AT: There are digital technologies emerging that relate to innovation in supply chain management (raw materials/components or finished goods), forecasting disruption and taking steps to mitigate. This is separate to 'manufacture' of the dosage form itself. All can relate to alleviation of supply shortage mitigation.
Article 6			AT: approves of the changes that were made to this article.
Recognition of Strategic Projects			
1. Each Member State shall designate an authority ('the designated authority') that shall assess ~~and verify~~ whether or not a project meets at least one of the criteria set out in Article 5 and therefore ~~constitutes~~**may be recognised**~~constitutes~~ **as** a strategic project.			

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2. A **project** promoter ~~may~~ **shall** request the designated authority to assess whether a project is a strategic project. **The designated authority shall provide its assessment to the project promoter without undue delay.**			
~~Any Member State authority may request the designated authority to verify its determination of whether a project is a strategic project.~~			
The submission of a request for a project to be recognised as a strategic project as provided for in this paragraph does not preclude the project promoter from simultaneously submitting applications to other			AT: Should this information be shared with the designated authority with the submission of the project? To facilitate coordination of authorities?

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authorities for the permits needed for the project.			
2.**3.** Member States shall communicate to the Commission ~~what is~~ the designated authority for the purposes of paragraph 1~~.~~ **and Article 16(2).**			
~~3.~~**4.** The Commission shall provide a simple, accessible webpage on which the contact details and other relevant information on the **tasks of** Member States' designated authorities shall be clearly listed.			
~~4.~~**5.** Any other ~~Member State~~ authority **in the Member State** that receives a request from a **project** promoter concerning Articles 8 to ~~14~~**15** shall **rely on the decision of the designated**			

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authority pursuant to paragraph 1 as to~~assess~~ whether that given project **may be recognised as**~~meets the criteria to be considered~~ a strategic project ~~as provided for in Article 5 and where necessary, request the verification of its determination from the designated authority~~.			
~~5. Where the verification whether a project is a strategic project has been performed by an authority in accordance with this Article, any other authority shall rely on that verification.~~			
6. Where a project promoter submits a request to the designated authority pursuant to paragraph 2 as to whether a project is a strategic project, the project promoter			AT: It might be helpful to inform other concerned authorities?

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shall notify the relevant competent authority for medicinal products in the Member State of the project promoter's intention to submit a request pursuant to Article 11(1).			
SECTION III			
FINANCIAL INCENTIVES			
Article 15			AT : We suggest considering the possibility of introducing appropriate sanctions, for example in the form of repayment of the financial support, if pre-agreed obligations concerning the supply in the Union are not fulfilled.
Financial support by Member States			
1. Without prejudice to Articles 107 and 108 TFEU, Member States may prioritise			

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financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines **Coordination** Group **('CMCG')** referred to in Article 26(2) point (a).			
2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from financial support for a strategic project shall prioritise supply to the Union market and use its very best efforts to ensure that the critical medicinal product remains			AT: We welcome the fact that subsidies and financial support are linked to the priority supply of the EU market.

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available in **all** the Member States where it is being marketed.			
This obligation shall apply for the duration of the strategic project, unless otherwise provided by the Member State under the conditions attached to the financial support.			
			AT: In our opinion, stricter conditions for financial support are important, coupled with priority supply to the Union.
3. The Member State that provided financial support to a strategic project may **require** ~~request~~ such undertaking to **prioritise supply and** provide the necessary supplies of a critical medicinal product, active substance or key inputs, as			

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applicable, to the Union market to avoid shortages in one or several Member States.			
Any Member State that encounters a threat of shortages of the critical medicinal product in question may **request** ~~demand~~ the Member State that provided financial support to submit a request on its behalf.			

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Chapter IV Demand side measures			AT: welcomes the PRY proposal for Article 18, which addresses the resilience of supply of critical medicinal products. The PCY compromise proposal goes in the right direction. However, AT has some remarks aimed at ensuring legal clarity and practical applicability, as outlined below. These relate, inter alia, to the subject matter of the contract, the definition of disproportionate costs, the practical verification of origin, the use of award criteria, and the timing and reference points for the review clause.
SECTION I			
AWARD CRITERIA AND OTHER PROCUREMENT REQUIREMENTS AND RELATED MEASURES			
Article 18			
Incentivising resilience~~, sustainability and positive social impacts~~ in public procurement procedures			

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1. For ~~award~~**public procurement** procedures ~~of critical medicinal products~~ falling within the scope of Directive 2014/24/EU ~~of the European Parliament and of the Council~~, **where contracts have critical medicinal products as part of their subject matter,** 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.		1. AT: For public procurement procedures falling within the scope of Directive 2014/24/EU, where contracts have critical medicinal products as ~~part of~~ their **main** subject matter, contracting authorities shall apply requirements that promote the resilience of supply in the Union.	AT: underlines that the scope of this provision might need to be limited to cases where critical medicinal products constitute the main subject matter of the contract which would be if the value exceeds e.g. 50% of the estd value of that contract. A reference to contracts where such products are only "part" of the subject matter would lead to an overly broad application. By way of example, since CAFFEINE is included in the Union List of Critical Medicinal Products, the provision would otherwise extend to any contract that happens to involve CAFFEINE (however small the value of CAFFEINE would be), which would not be appropriate.

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These requirements shall take the form of:			
(a) <u>selection criteria within the meaning of Article 58 of Directive 2014/24/EU;</u>			AT: the term "or" should be added to each letter at the end so as to clarify that all letters constitute an alternative.
(b) <u>technical specifications or requirements within the meaning of Article 42 of Directive 2014/24/EU;</u>			
(c) <u>contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU; or</u>			
(d) <u>award criteria within the</u>			AT: questions whether that point (d) should be deleted. The use of award criteria for this purpose

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meaning of Article 67 of Directive 2014/24/EU.			would significantly complicate the conduct of procurement procedures and risk driving up costs. The objectives of the provision can already be achieved through the use of selection criteria, technical specifications and contract performance clauses.
Th~~os~~e ~~procurement~~**resilience of supply** requirements ~~shall be defined in accordance with Directive 2014/24/EU and~~ may**, inter alia,** relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, ~~their~~ transparency **of the supply chains**~~to the contracting authority~~ and contract performance clauses on timely delivery. **Member States may specify such requirements in national laws, regulations,**			

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administrative provisions or in the national programmes referred to in Article 19 of this Regulation.			
2. ~~With regard to~~**For public procurement procedures, where contracts as part of their subject matter have** 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 **economic operators**~~suppliers~~ that **supply these critical medicinal products originating** ~~manufacture a significant~~		AT: For public procurement procedures, where contracts as part of their subject matter have 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, apply requirements that favour economic operators that supply these critical medicinal products originating in the Union, or in a third country which is a Party to the WTO Agreement on Government Procurement or in a third country with which the Union has concluded a free trade agreement covering government procurement	AT: The scope of the proposal regarding third countries that are Parties to the WTO Agreement on Government Procurement, or third countries with which the Union has concluded a free trade agreement covering government procurement, is too broad. Equal treatment should and must only be granted where international commitments explicitly provide for such equal treatment with regard to medicinal products (reciprocity). For example, the draft Mercosur Agreement incorporates the principle of equal treatment; however, medicinal products from Argentina are excluded. Article 18(2)(4) already provides the obligation to apply the criteria in compliance with international commitments.

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~~proportion of these critical medicinal products~~ in the Union**, in a third country which is a Party to the WTO Agreement on Government Procurement or in a third country with which the Union has concluded a free trade agreement covering government procurement.**		provided that the critical medicinal products being the subject matter of the procurement procedure are covered by these Agreements.	
The requirements referred to in subparagraph 1 shall take the form of:			
(a) contract award criteria within the meaning of Article 67 of Directive 2014/24/EU, that include the best price-quality ratio, which may be assessed on the basis of criteria also relating to delivery condition for the critical			AT: highly critical whether point (a) should be deleted. The use of award criteria for this purpose would significantly complicate the conduct of procurement procedures and risk driving up costs. Finding operational viable and easy to apply non-discriminatory award criteria is a challenge.

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medicinal products supplied or provided in the execution and duration of the contract such as delivery process and delivery security; or			
(b) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU, that entail that critical medicinal products supplied or provided in the execution and duration of the contract and originating in the Union, in a third country which is a Party to the WTO Agreement on Government Procurement or in a third country with which the Union has concluded a free trade agreement covering government procurement represent at least [25] % or			AT: seeks clarification of the phrase *"irrespective of whether such products are supplied or provided directly by the successful tenderer or by a subcontractor"*. In the Union Customs Code, the determination of origin does not distinguish between direct suppliers and subcontractors. If it is required that the origin in the Union (a.s.o.) represents XX% the application of the rules of the Customs Code would already determine the value chain including the contractor, suppliers and subcontractors. AT therefore questions the added value and practical meaning of this wording in the context of procurement.

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more of the total value of the contract, irrespective of whether such products are supplied or provided directly by the successful tenderer or by a subcontractor.			
Where contracting authorities apply contract performance clauses as provided for in subparagraph 2, point (b) the contracting authorities must oblige the successful tenderer through a contract performance clause to provide to the contracting authority upon their request adequate evidence of the supply chain at the latest upon completion of the execution of the contract.			
These requirements **set out in this paragraph** shall be			

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applied in compliance with the Union's international commitments **including the Government Procurement Agreement in WTO and other international agreements of which the Union is bound**.			
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~~ requirements **in accordance with the requirements set out in paragraph 2** that favour **economic operators** ~~suppliers~~ that ~~manufacture at least a significant proportion of these medicinal products~~ **supply these**			AT: seeks clarification of the phrase "*where justified by market analysis and public health considerations*". It is unclear what type of market analysis and which public health considerations would be considered sufficient to justify the application of such procurement requirements. It is also unclear which market (national or EU) is to be analysed by whom (the contracting authority?). Further guidance would be needed in order to ensure legal certainty for contracting authorities. It has to be pointed out, that such an analysis would not be possible for small contracting authorities (lack of resources, lack of knowledge) and an analysis of the EU market would pose data problems.

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medicinal products originating in the Union**,** ~~,~~ **in a third country which is a Party to the WTO Agreement on Government Procurement or in a third country with which the Union has concluded a free trade agreement covering government procurement** ~~. These requirements shall be applied in compliance with the Union's international commitments~~.			
3a. For the purposes of determining the origin of critical medicinal products as referred to in paragraph 2 and the origin of medicinal products of common interest as referred to in paragraph 3 the origin shall be determined in			AT: is concerned regarding the reference to Regulation (EU) No 952/2013 (Union Customs Code). The application of customs origin rules is very complex (esp. for contracting authorities and procurement officers, who are not trained to apply customs legislation). Given the general thrust now to simplify EU legislation, AT therefore questions the practicality of determining the origin of medicinal products

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accordance with Regulation 952/2013/EU.			under this Regulation in the context of procurement procedures. AT stresses the importance of finding a simple to apply solution. The "rules" for determining the origin in the Customs Code are set out in "list rules" for each HS subchapter. These rules, however, are not legally binding. Free Trade Agreements (e.g. Mercosur) apply similar, though not identical, rules as legally binding provisions. For ex AT refers to the following examples: EC Non-binding list-rules HS Chapter 30 Chemical Reaction; Mixtures and blends; Purification; Change in particle size Standard Materials; Isomer Separation; Biotechnological Processes or country in which major portion of the materials originated. Mercosur HS Chapter 30 A chemical reaction, purification, production of standard materials, a change in particle size, isomer separation or biotechnological

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			processing is undergone; or MaxNOM 50 % (EXW). List Rules https://taxation-customs.ec.europa.eu/customs/international-affairs/origin-goods/non-preferential-rules-origin_en https://taxation-customs.ec.europa.eu/document/download/3c61fb99-11bd-4413-99cd-11f703f679d4_en?filename=SectionVI_ch28_38_HS2022.pdf Mercosur Draft – Chapter 3 Rules of Origin and Origin Procedures https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/9141598e-ec31-4f19-916c-d87733837154/details?download=true
3b. This Article shall not preclude Member States from defining additional requirements in accordance			

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with Directive 2014/24/EU in national laws, regulations, administrative provisions or in the national programmes referred to in Article 19 of this Regulation.			
4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social **considerations** ~~rights~~.			
5. Contracting authorities may exceptionally decide not to apply paragraphs 1 **and** ~~,~~ 2 ~~and 3~~ where**:** ~~justified by market analysis or considerations related to the financing of health services.~~			

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(a) the required critical medicinal product can only be supplied by a specific economic operator and no reasonable alternative or substitute exists and the absence of competition is not the result of an artificial narrowing down of the parameters of the public procurement procedure;			
(b) no suitable tenders or no suitable requests to participate have been submitted in response to a similar former public procurement procedure launched by the same contracting authority in the two years immediately before the commencement of the planned new procurement procedure; or			
(c) their application would oblige that contracting		AT:	AT: seeks clarification of the phrase "disproportionate costs". Without further definition, the exception

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authority to acquire critical medicinal products having disproportionate costs.		(c) their application would oblige that contracting authority to acquire critical medicinal products having disproportionate costs. **Estimated cost differences above 20 %, based on objective and transparent data, may be presumed by contracting authorities to be disproportionate.**	remains too vague and may lead to divergent application by contracting authorities. Moreover, it is unclear how contracting authorities should determine what constitutes disproportionate costs. If a contracting authority errs in this assessment, the procurement procedure might be challenged in a review procedure.AT therefore proposes to add a clarification along the approach implemented in NZIA. An alternative could be to have a dedicated wording in a specific Recital.
6. The Commission shall issue guidelines designed to support Member States in implementing the obligation to use requirements in public procurement procedures with a view to strengthening the security of supply.			AT supports the introduction of a deadline in this provision.

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Article 19			
Programmes supporting sustainability and resilience in public procurement procedures			
1. By **12**~~6~~ months after entry into force of this Regulation each Member State shall**, with due respect to the organisation of the procurement of medicinal products within the Member State,** 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 **in public procurement procedures** by contracting authorities within a given Member State~~ as well as multi-winner approaches~~, where			AT: seeks clarification of the phrase "beneficial in light of the market analysis". It is unclear what type of market analysis would be considered sufficient and what this phrase implies for the content of the national programme. Further guidance would be needed in order to ensure legal certainty for contracting authorities.

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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.			
2. Member States shall **inform**~~notify their programmes to~~ the Commission in its role of the secretariat of the ~~Critical Medicines Group~~ **CMCG about their programmes.** The Commission shall ensure the distribution to all members of the **CMCG**~~Critical Medicines Group~~ forthwith. The **CMCG**~~Critical Medicines Group~~ shall facilitate a discussion **as referred to in Article 26(2), point (b) on the**			

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national programmes ~~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~~.			
Article 20			AT: We regret that a comprehensive provision covering EU stockpiling (or contingency stocks) is not included in the CMA. AT is of the opinion that only an EU-wide stockpiling mechanism can prevent or mitigate shortages in the long term.
Safeguards related to Member States' contingency stocks requirements ~~*and other security of supply measures*~~			

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1. ~~Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact~~ when **imposing requirements on marketing authorisation holders and other operators in the supply chain to hold contingency stocks for the purpose of safeguarding the security of supply of critical medicinal products within their territory shall aim at ensuring that any form of such requirements do not compromise the security of supply in other Member States.**~~proposing and defining the scope and timing of any form~~			

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~~of requirements for companies to hold contingency stocks.~~			
2. Member States shall ensure that any **contingency stocks** requirements **referred to in paragraph 1**~~they impose on companies in the supply chain to hold contingency stocks~~**,** **including their scope and timing,** are proportionate and respect the principles of transparency and solidarity.			
3. Member States shall, if contingency stocks requirements are deemed necessary, inform other Member States of their intention to impose these requirements, in the CMCG as specified in Article 26.			

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4. This Article is without prejudice to obligations under Union law for the notification of technical regulations and technical barriers to the internal market, including those set out in Directive (EU) 2015/1535.			
Article 30			
Evaluation			
1. By [OP please insert the date of:] five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the main findings to the European Parliament, the			

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Council, the European Economic and Social Committee, and the Committee of the Regions.			
2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1 have been achieved.			
3. The national authorities and the economic operators shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1.			
3a. No later than [three years] after the date of application of a revision of		3a. No later than [~~three~~ **one** years] after the ***entry into force*** of a revision of Directive 2014/24/EU, or no later than	AT proposes to replace the term *"date of application"* with *"entry into force"* since the former is unclear. In addition, AT suggests shortening the review period in

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Directive 2014/24/EU, or no later than [five years] after the date of application of this Regulation, whichever the earlier, the Commission shall review the scope, functioning and efficiency of Article 18 as well as coherence with the revised Directive 2014/24/EU, and shall report its findings to the European Parliament and to the Council.		[five years] after the date of application of this Regulation, whichever the earlier, the Commission shall review the scope, functioning and efficiency of Article 18 as well as coherence with the revised Directive 2014/24/EU, and shall report its findings to the European Parliament and to the Council.	the first part from *"three years"* to *"one year"*, in order to ensure an earlier assessment of the scope, functioning and efficiency of Article 18 and its coherence with the revised procurement framework.

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Art. 16 CMA-E – Financial support from the Union

- Drafting suggestion for Art. (1) 2: *"**An undertaking that has benefitted from financial support from the Union for a strategic project shall prioritise supply to the Union market**."*

- Rationale: We would like to propose the inclusion of a provision clarifying that a company that has received financial support from the Union should give priority to supplying the Union market. This will better address the CMA's objective of improving the supply of medicinal products and facilitating access to medicinal products. The addition would further be in line with the requirements in Art. 15.

Art. 17 CMA-E – Exchange of information on funded projects

- Drafting suggestion for Art. 17 (1) 2 and deletion (2): *"This obligation applies equally to the Commission with regard to planned financial support from the Union."*

- Rationale: In our view, the COM should inform the CMCG in advance of its intention to promote strategic projects. This is in line with the requirements for the obligation of the Member States set out in paragraph 1. Paragraph 2 shall thus be deleted.

Art. 21 CMA-E – Safeguards related to Member States' contingency stocks requirements

- Drafting suggestion for Art. 21 (6) 2: *"**Member states involved in the cross-border procurement shall procure at their cost only**"*

- Rationale: As we understand art. 21, the assistance provided by the COM does not include financial support. For clarification purposes we therefore suggest adding the above mentioned sentence.

Art. 22 CMA-E – Commission facilitated Member States' cross-border procurement

- Drafting suggestion for Art. 22 (1): "By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where six or more Member States jointly request ("the joint request") the Commission to procure on their behalf, or in their name ***and at their costs***, the Commission may initiate a procurement procedure under the conditions laid down in this Article…*"*

- Rationale: As we understand art. 22, the Commissions procurement on behalf or in the name of Member States does not include financial support from the COM. We would therefore like to suggest a clarifying addendum. From a German perspective, the use of EU funds would intervene with the obligation of Member States to finance their health system. Joint procurement for cross boarder health threads is already regulated (Regulation (EU) 2022/2371 on serious cross-border threats to health).

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