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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 the 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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HAVE ADOPTED THIS REGULATION:

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			

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inputs necessary for the manufacturing of one or more 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**			

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recognised~~constitutes~~ **as** a strategic project.			
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			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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simultaneously submitting applications to other 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			

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project promoter concerning Articles 8 to ~~14~~**15** shall **rely on the decision of the designated 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			AT: It might be helpful to inform other concerned authorities?

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pursuant to paragraph 2 as to whether a project is a strategic project, the project promoter 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).			

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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 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			

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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 available in **all** the Member States where it is being marketed.			AT: We welcome the fact that subsidies and financial support are linked to the priority supply of the EU market.
This obligation shall apply for the duration of the strategic project, unless otherwise provided by the Member State under the			

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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 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			

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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, 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 should 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. Otherwise, the reference to contracts where such products are only "part" of the subject matter would lead to an overly broad application and would catch all contracts containing critical medicinal products. 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.

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>			

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(d) award criteria within the meaning of Article 67 of Directive 2014/24/EU.			
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			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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condition for the critical 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			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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represent at least [25] % or 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.			

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These requirements **set out in this paragraph** shall be 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			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 (even though it is a "may" provision). 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

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that~~ manufacture at least a significant proportion of these medicinal products~~ **supply these 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~~.			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.
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			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

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referred to in paragraph 3 the origin shall be determined in accordance with Regulation 952/2013/EU.			simplify EU legislation, AT therefore questions the practicality of determining the origin of medicinal products 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

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			separation or biotechnological 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 with Directive 2014/24/EU in			

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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			

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(c) their application would oblige that contracting authority to acquire critical medicinal products having disproportionate costs.		AT: (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.**	AT: seeks clarification of the phrase "disproportionate costs". Without further definition, the exception 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~~			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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~~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.			
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**			

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Article 26(2), point (b) on the 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			

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requirements ~~and other security of supply measures~~			
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~~			

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~~the scope and timing of any form 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			

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report on the main findings to the European Parliament, the 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.			

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3a. No later than [three years] after the date of application of a revision of 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.		3a. No later than [~~three~~ **one** years~~]~~ after the ***entry into force*** of a revision of 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.	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 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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BELGIUM

In light of our ongoing discussions of the first compromise text, we would like to come back on an issue we raised at the WPPMD of 25 September in the context of Article 19 (National Programmes) of the Critical Medicines Act. In doing so, we wish to underline the importance of retaining the strategic objectives of the regulation, using broad national programs to seize the current momentum for enhanced EU coordination, and preserving the political ambition that has driven this file forward**. We regret in particular the deletion of Article 4**, which we consider a cornerstone for ensuring coherence and long-term impact.

A) Context

We would like to introduce and briefly explain a text proposal that aims to reinforce the strategic direction of the regulation. This proposal merges key elements from Article 4 (strategic objectives, now paragraphs 1 and 2) and Article 19 (national programmes, now paragraphs 3 and 4), reflecting our conviction that a clear interplay between Union-level objectives and national strategy is essential for success.

The proposed Article retains, first and foremost, that the security of supply and availability of critical medicinal products for patients is a strategic objective of the Union, as set out under Art. 4 of the Commission proposal. We believe that explicitly stating this objective provides a strong foundation for coordinated action and policy coherence. The Critical Medicines Act is an opportunity to grasp the existing momentum on public health collaboration by leveraging the full potential of the internal market.

A central element of the proposal is the requirement for each Member State to establish a national programme, as first introduced under Article 19. While currently only focusing on procurement, these programmes could take a broader approach by integrating the Union's strategic objectives at national level, *while respecting the organisation of healthcare in each Member State*. Our proposal outlines a broad scope for these programmes, encompassing both supply-side and demand-side measures. This includes, for example, outlining potential initiatives on packaging and diversification of supply, consistent use of (private and public) procurement requirements, multi-winner approaches, and systematic monitoring of availability. **The intention is to create a framework that not only enables Member States to address supply challenges in ways that reflect their national contexts, but also actively fosters dialogue and the identification of synergies, so that opportunities and best practices emerging from national programmes can be shared and leveraged at Union level.**

The proposal foresees that the Commission will develop guidance and a template for national programmes. Member States would notify their programmes to the Commission, which would ensure their distribution within the Critical Medicines Coordination Group (CMCG). The CMCG would be tasked with discussing (non-binding) strategic goals to guide the ongoing revision of national programmes, further strengthening alignment and mutual learning.

Finally, the proposal clarifies the supportive role of the Commission in coordinating and, within its competences, assisting with the implementation of national measures.

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B) Text proposal

Article X
Strategic objective of the Union

1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.

2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market.

3. **By 12 months after entry into force of this Regulation each Member State shall, with due respect to the organisation of the healthcare in the Member States, establish a national programme supporting the realisation of this objective [security of supply of critical medicinal products]. These national programmes shall include supply-side measures, which may include initiatives on the packaging and diversification of supply, as well as demand-side measures, including consistent use of the requirement referred to in Article 18 in public procurement procedures, multi-winner approaches, or other measures when the critical medicinal products are not purchased through public procurements. These programmes may also include other measures concerning the monitoring of the availability of critical medicinal products.**

The Commission shall develop guidance for the establishment of these national programmes, including by making available a template to assist the Member States in their drafting.

Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Coordination Group. The Commission shall ensure the distribution to all members of the Critical Medicines Coordination Group forthwith.

The Critical Medicines Coordination Group shall set up strategic goals that Member States shall take into account when revising their programmes.

4. **The Commission shall support the coordinated efforts of the Member States or groups of Member States and, within the limits of its competences, the implementation of the measures included in their respective national programmes.**

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FRANCE

Proposition de règlement établissant un cadre visant à renforcer la disponibilité et la sécurité de l'approvisionnement en médicaments critiques ainsi que la disponibilité et l'accessibilité des médicaments d'intérêt commun – France

Proposal for a regulation establishing a framework to strengthen the availability and security of supply of critical medicines and the availability and accessibility of medicines of common interest – France

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Article 6 (4)– NEW: Information sharing regarding strategic projects

Text proposed by the Presidency	*Amendment*
	Member States shall share with the CMCG the decision of the designated authority pursuant to paragraph 1.
Justification: *It would be particularly useful to share the results of these analyses with other Member States via the CMCG to avoid duplication and improving overall coordination.*	

Article 18 – 2

Text proposed by the Presidency	*Amendment*
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** that **supply these critical medicinal products originating** manufacture a significant 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.**	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 requirements that favour economic operators that supply these critical 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.~~
Justification: *It is proposed to simplify the eligibility of the resilience criterion. Removing the existing reference of third countries would provide a clearer signal and facilitate the work of purchasers, Moreover, it appears relevant to specify the nature of the dependency of critical medicines that are identified as vulnerable or are likely to become vulnerable in the near future.* *The concept of dependence on one or more third countries, which the French authorities consider problematic because it excessively restricts the scope of the products concerned. For example, a critical medicine produced by a single laboratory located in the EU remains vulnerable, but could not be classified as such under the current wording, as there is no dependence on a third country. In conclusion, the French authorities are in favor of removing the concept of third countries and would like to see the criterion triggered only for products designated as vulnerable following the EMA's analysis.* *Removing the notion of international commitments: In light of recent Council discussions, it would seem more appropriate to delete explicit references to the Union's international commitments. It would be unfortunate to have the Union's hands tied.* *A European preference in public procurement must ensure that only EU-based suppliers and producers,*	

and not those from third countries, are eligible to benefit from this mechanism.

Article 18 – 2(a)

Text proposed by the Presidency	*Amendment*
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 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 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.*	*The requirements referred to in ~~sub~~paragraph ~~1~~* ***2*** *shall take the form of* ***a****:* (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 medicinal products supplied or provided in the execution and duration of the contract such as delivery process and delivery security; or~~ ***Such criteria shall account for at least X% of the overall weighting applied to the award of the contract****.* *(b)* ***Additionally, contracting authorities may use*** *contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU,* ***to ensure that economic operators comply with the requirements referred to in subparagraph 2*** *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]~~* ***[Y] %*** *or 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.*
Justification: *We support the use of an award criterion for the resilience requirement. To have an impact it should be assorted with a minimum weighting applied to the award contract. In the Council, we should strive, based on empirical data, to define the percentage (X) to apply in order to find the right level of incentives for EU producers while not resulting in an excessive impact on affordability.* *Opting for a mandatory award criterion, complemented by the optional use of contract performance clauses (CPCs), strikes a balance between ensuring impact at the tender stage and preserving flexibility during contract execution. Combining both mechanisms ensures both ex ante differentiation*	

and ex post verification, maximising the effectiveness of the resilience criterion.

Moreover, we see several limitations in the current wording of the CPC. Such a mechanism risks unduly restricting competition (in already concentrated and vulnerable markets) by excluding otherwise reliable suppliers who cannot meet the threshold (25%) due to globalised supply chains. It would also require the creation of numerous exemption cases (e.g. where no EU production capacity exists), which could dilute the ambition and consistency of the measure. Moreover, the sole recourse to the CPC would be in many cases insufficient to valorise EU-production based on an excessively binary approach. In any case, if it were to be adopted, Member States, within the council should work towards defining the right percentage (Y).

A volume-based approach (described in amendment 4) could be applied to evaluate the European share of contracts related to the CPC. This could then be balanced against the extent to which European-based supply chains are represented within the total contract value. Ongoing work aims to further refine this approach.

A European preference in public procurement must ensure that only EU-based suppliers and producers, and not those from third countries, are eligible to benefit from this mechanism.

NEW

Text proposed by the Presidency	*Amendment*
	For the purpose of the application subparagraph 2, the requirement, in the form of an award criterion, shall be defined as the combined assessment: ***(i) the planned proportion of the volumes of the critical medicinal product covered by the contract whose final production (FDF) would be carried out on sites located in the European Union; and*** ***(ii) the planned proportion of volumes of the critical medicinal product covered by contract whose active ingredient (API) would be manufactured on sites located in the European Union.*** ***The weighting of each aforelisted parameter could be relative to the degree of vulnerability observed per supply chain tier as per the vulnerability evaluation*** ***The rating awarded is graduated, depending on the degree of production involving European sites***

Justification:

Explicitly defining the 'resilience' criterion in the regulations increases the legal certainty of its application, by providing contracting authorities with a clear and objective framework, and can guarantee that the computation of this criteria will match the objective, which is to stimulate a demand for European-produced critical medicines with vulnerability. Basing the assessment of the resilience criterion on the location of production for the two critical steps of the value chain (API and FDF production), and taking into account production volumes, can allow greater granularity and avoid undesired effects (such as rewarding European production sites that are only used as back-up sites) and can also create a continuous incentive. An approach only based on custom-code could result in a binary effect creating absolutely no differentiation between a drug that would be in API-EU / FDF-EU and another one that would be API-extra-EU / FDF-EU. The proposed methodology would enable a gradual, proportionate, and transparent scoring system. It would maximise the differentiating power of the criterion by clearly distinguishing bids according to their degree of European integration.

Article 18 (2)(d)

Text proposed by the Presidency	*Amendment*
These requirements set out in this paragraph shall be 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.	***DELETED***
Justification: *In light of recent Council discussions, it would seem more appropriate to delete explicit references to the Union's international commitments. It would be unfortunate to have the Union's hands tied and suppressing this reference allows to have a further high-level political discussion about the desirable scope.* *A European preference in public procurement must ensure that only EU-based suppliers and producers, and not those from third countries, are eligible to benefit from this mechanism.*	

Article 18(3)

Text proposed by the Presidency	*Amendment*
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 accordance with Regulation 952/2013/EU.	***DELETED***
Justification: *At this stage, it remains uncertain whether the customs code would be an appropriate tool to determine the origin of medicinal products. The rules of non-preferential origin under the Union Customs Code rely primarily on concepts such as "last substantial transformation" (CTH/CTSH), which may not capture the specific vulnerabilities of pharmaceutical supply chains. For example, a product finished in Europe from an active ingredient manufactured entirely in a third country would typically be deemed of European origin, even though the critical dependency lies in the API. This raises doubts as to whether customs-based origin rules provide a sufficiently accurate or operational basis for a resilience criterion aimed at assessing and incentivising European production capacity. Further analysis is ongoing.*	

PUBLIC

Article 18(5)

Text proposed by the Presidency	*Amendment*
Contracting authorities may exceptionally decide not to apply paragraphs 1 and, 2 where**:** (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 authority to acquire critical medicinal products having disproportionate costs**.**	Contracting authorities may exceptionally decide not to apply paragraphs 1 and, 2 where**:** (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; **or** (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 authority to acquire critical medicinal products having disproportionate costs~~
Justification: *It would be relevant to delete the exemption related to excessive costs, with regard to the difficulty for contracting authorities to determine cost differences in relation to a weighted criterion linked to the origin of the planned proportion of the volumes of a product; and thus with regard to the excessive administrative burden and the particularly high risk of litigation.*	

Article 18(6)

Text proposed by the Presidency	*Amendment*
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.	*The Commission shall issue guidelines designed to support Member States in implementing the obligation to use requirements in public procurement procedures* ***referred to in paragraph 1*** *with a view to strengthening the security of supply.*
Justification: *Guidelines should accompany the use of requirements referred to in subparagraph 1. The relevant criterion to assess security of supply as well as the precise methods of assessment should not be defined in a prescriptive manner, as security of supply considerations may vary according to the specific features of national healthcare systems.*	

Article 20

Text proposed by the Presidency	*Amendment*
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.**	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.~~
2. Member States shall ensure that any **contingency stocks** requirements **referred to in paragraph 1, including their scope and timing,** are proportionate and respect the principles of transparency and solidarity.	2. Member States shall ensure that any contingency stocks requirements ~~referred to in paragraph 1,~~ including their scope and timing, are proportionate and respect the principles of transparency**, subsidiarity** 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.	~~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.~~
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.	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.
Justification: *Regarding paragraph 1, which concerns the obligation of Member States to consider the impact of their security stock obligations on the supply of other Member States, we believe this obligation is already met through the notification under Directive (EU) 2015/1535, as set out in paragraph 4. That is why we propose deleting the paragraph 1.* *We also highlight the redundancy of introducing an obligation to inform the CMCG. As this notification is already accessible to all Member States, introducing such a provision would create an unnecessary administrative burden. That is why we propose deleting the paragraph 3.*	

Article 26 2(aa)

Text proposed by the Presidency	*Amendment*
(aa) enable the exchanges of information between the Member States and the Commission as referred to **in** Article 17 and, where necessary, facilitate coordination of respective actions aiming to attain the objectives of this Regulation	(aa) enable the exchanges of information between the Member States and the Commission as referred to in **Article 6(4),** Article 17 and, where necessary, facilitate coordination of respective actions aiming to attain the objectives of this Regulation
Justification: *This amendment mirrors amendment 1 which calls for information sharing regarding strategic project status to improve coordination.*	

GERMANY

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.

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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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HAVE ADOPTED THIS REGULATION:

Article 18	*Proposed amendment*	*Reasoning*
Incentivising resilience~~, sustainability and positive social impacts~~ in public procurement procedures		
2. 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		

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the resilience of supply in the Union.		
These requirements shall take the form of:	**These requirements shall take the form of:**	
(e) <u>selection criteria within the meaning of Article 58 of Directive 2014/24/EU;</u>	**~~selection criteria within the meaning of Article 58 of Directive 2014/24/EU;~~**	HU: We do not consider it feasible to prescribe the resilience criteria set out in Article 18(1) as selection criteria, as they do not fit into the scope of the criteria outlined in Article 58 and Annex XII of the Public Procurement Directive. Resilience can logically be presented as part of the technical specifications, performance criteria or evaluation criteria, rather than as a prerequisite for the suitability of the economic operator. **Therefore, we propose to delete Section (1) point a) of Art. 18.**
(f) <u>technical specifications or requirements within the meaning of Article 42 of Directive 2014/24/EU;</u>	**<u>technical specifications or requirements within the meaning of Article 42 of Directive 2014/24/EU;</u>**	

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(g) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU; or	**contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU; or**	
(h) award criteria within the meaning of Article 67 of Directive 2014/24/EU.	**award criteria within the meaning of Article 67 of Directive 2014/24/EU.**	
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**		

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requirements in national laws, regulations, 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 proportion of these critical medicinal products~~ in the Union**, in a third country which is a Party to the WTO Agreement on**		

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Government Procurement or in a third country with which the Union has concluded a free trade agreement covering government procurement.		
The requirements referred to in subparagraph 1 shall take the form of:		HU: The relationship between the resilience requirements listed in Article 18(1) and (2)-(3) and whether they should be applied in parallel or not is unclear. **In our view, it would be more appropriate for the Regulation to state/clarify that the obligation under paragraph (1) does not apply when paragraphs (2)-(3) are applied.** This approach is in line with the logic of the Public Procurement Directives, as paragraphs (2)-(3) already define a specific preferential system for products of EU or preferred origin, which covers resilience objectives as a lex specialis. However, cumulative application would cause legal and practical difficulties, as resilience criteria and origin-based preferences would have to be applied in parallel in the same procurement, and would represent a disproportionate administrative burden for contracting authorities.

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(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 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		

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procurement represent at least [25] % or 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.		PUBLIC
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.		
The~~se~~ requirements **set out in this paragraph** shall be 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 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**	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 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~~.	HU: It remains unclear how to interpret the terms "market analysis" and "public health reasons" as preconditions. **We therefore propose to delete the text in question.** We can accept the retention of these preconditions if the Commission develops a clear, uniform methodology for their application. In the latter case, we consider it necessary to lay down the Commission's obligation in this regard.

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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 accordance with Regulation 952/2013/EU.		
3b. This Article shall not preclude Member States from defining additional requirements in accordance 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		

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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.~~		
(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		

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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 authority to acquire critical medicinal products having disproportionate costs.		
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.		

PUBLIC

ITALY

Italian comments on the first compromise text of the Critical Medicines Act following the working group of 25-26 September

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- **Article 5 -** ***Strategic Projects***
  We appreciate the introduction of the term "modernisation," which may include, among other elements, the technological and environmental improvement of an existing industrial process, thereby allowing the use of incentives not expressly dedicated to critical medicines and thus broadening the scope of available funding opportunities. Strategic projects may constitute an important opportunity to strengthen production within the national pharmaceutical sector. In other industrial sectors related to critical technologies, "strategic projects" have already been introduced in support of European production. The rules governing the management of strategic projects are laid down in the State aid regulations, the GBER, and the implementation guidelines for incentive measures already in place. It is therefore necessary, within the present Regulation, that the contextual criteria be defined as set out in Article 5, while leaving the management modalities to the provisions of State aid regulation.

- **Article 16 -** ***Financial support from the Union***
  The reference to the Multiannual Financial Framework 2021–2027 appears to be restrictive, given that discussions on the subsequent MFF have already been initiated. It would therefore be appropriate to replace the wording "under the Multiannual Financial Framework 2021–2027" with "Multiannual Financial Framework in force."

- **Article 18 -** ***Incentivising resilience in public procurement procedures***
  As underlined by Mario Draghi at the High-Level Conference organised by the European Commission "One year after the Draghi report: what has been achieved, what has changed", public procurement accounts for 16% of the EU's GDP, and allocating even a small share of this to European industries would create stable demand for innovation and strengthen strategic sectors. It is therefore important to stress the need to use, in public procurement procedures for critical medicines, award criteria beyond price alone, in particular the criterion of security of supply, giving preference, where possible, to European production.
  It would be appropriate to underline that the objective of public procurement, as foreseen in the proposed Regulation, is to stimulate demand in order to support European industrial production. It should also be ensured that the compromise text, Article 18(2), considers production concentrated in a single site within the EU to be vulnerable. The reference to the list of vulnerable medicines appears stronger and is therefore supported. Likewise, the proposal to replace the term "production" with "supply" does not appear consistent with the objectives set out above.
  With regard to the gradual application of European origin, the inclusion of the share of production of both APIs and finished products appears consistent with the observations previously expressed. Coordination with the revision of the Public Procurement Directive is desirable.

- **Article 20 -** ***Safeguards related to Member States' contingency stocks requirements***
  - The regulation merely requires the simple disclosure of information on contingency stocks, without providing for any form of "objection" or "coordination" between Member States;
  - Moreover, in our view, the establishment of a new group, i.e. the Coordination Group, might lead to possible overlaps in competences with existing groups (MSSG) and misalignments in the management of individual cases.

    It is therefore essential that the competences of the Coordination Group – which should be of an industrial nature – and those of the EMA and the existing groups – which have public health purposes – remain separate and clearly demarcated.

    On the basis of such need, Italy deems that information on contingency stocks - imposed by a Member State on marketing authorisation holders and/or other economic operators of the supply chain to establish buffer stocks of certain medicinal products to mitigate the risk of supply disruption - may have significant impacts from a public health perspective, also with regard to the management of shortages. Therefore, the information related to the imposition of contingency stocks should fall within the remit of EMA and the MSSG, rather than the Coordination Group.

    Should such information be conveyed to the Coordination Group, given its industrial nature, there might be delays for the national competent health authorities in adopting the appropriate measures. Furthermore, from a purely formal point of view, assigning public health competences to a more industry-oriented group would make it more difficult to distinguish its competences from those of the MSSG and EMA.

    In light of the above, Italy deems that the information of the contingency stocks shall be provided to EMA and MSSG, and therefore please see below the amendment Italy suggests to Article 20(3):

    "*Member States shall, if contingency stocks requirements are deemed necessary, inform* ***the Agency and the MSSG*** ~~***other Member States of their intention to impose these requirements, in the CMCG as specified in Article 26***~~."

- **Articles 21 -** ***Commission facilitated Member States' cross-border procurement*** **and Articles 22 -** ***Commission procurement on behalf of or in the name of Member States***

  It would be preferable to limit the use of collaborative procurements, as referred to in Articles 21 and 22, to exceptional situations (i.e. last resort), in order to acquire medicines in the event of shortages or medicines for rare diseases. The use of such procedures as ordinary purchasing tools for a very wide range of medicines might have a negative impact on national price negotiations. Moreover, such procedures may result in complex purchasing process, including in contractual terms (e.g. contract management, applicable law and jurisdiction in the event of disputes, withdrawal of one or more Member States).

- **Article 23 –** ***Joint Procurement***

  Italy is in favour of the deletion of Article 23.