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CONTRIBUTION

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

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

Critical Medicines Act – Chapter IV Deadline: ***12 July 2025***

From: AT, BE, BG, CY, CZ, DE, EE, ES, FI, FR, HU, IE, IT, LT, MT's, RO, SE **Updated: 18/07/2025 09:07**

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Guidelines to be followed

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

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

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

Thank you for your cooperation!

Commission proposal	Drafting suggestions and Comments
General comments	BG (Comments): The proposed harmonisation legal basis (Art. 114 TFEU) accompanied by no impact assessment is of genuine concern. The suggested demand side measures concern matters which are national competence. It appears that in future public health and in particular health budgets are supposed to serve the Internal market and in particular – to make up for the relocation of production in the EU. This lacks political willingness; contradicts basic principles of EU and national law about the fundamental importance of health, and is in obvious contradiction with the EU primary law (Art. 168 (7) TFEU). In order to avoid legal uncertainty, the CMA should at least be based on a dual legal basis – Art. 168 and Art. 114 TFEU, with necessary references to Art. 168 (7) in the recitals. This approach is already established e.g. in Regulation No 2021/2282 (HTA Regulation). The alternative solution is deletion of a number of proposed measures.

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	CZ (Comments): For CZ is key to establish a system that supports the medicines manufacture in the EU through the strategic projects, financial incentives and public procurement. Moreover, it should be ensured that these medicines will be bought and used in EU Member States as the aim is to ensure long lasting and safe supply chains for these medicines. Nevertheless, the manufacture in the EU should be better defined not only in relation to public procurement, but also to strategic projects and financial incentives. At the same time, CZ considers it important to clarify, in which way medicinal products of common interest will be determined and where their list at the EU level will be published. DE (Comments): We have a general scrutiny reservation and therefore reserve the right to send in additional comments RO (Comments): Romania welcomes the proposed Critical Medicines Act and believes that it is absolutely necessary in order to strengthen supply chains for critical medicines at EU level. In the current international context, marked by geopolitical tensions, instability in global supply and emerging risks to public health, it is essential that Member States (MS) strengthen their strategic autonomy and rapid response capacity. In the meantime, our

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	collaboration between MS, coordinated by the Commission is also essential. However, from the perspective of the main considerations regarding the public procurement provisions thereof, we have identified several aspects and general terms, that need to be properly addressed for the sake of providing a consistent coherence and an easy and effective applicability of the proposed rules. Therefore, in terms of formal inconsistencies among the provisions of the proposed regulation, the following need to be mentioned: • the use of terms such as ”where justified by market analysis”, ”social rights” or „national programmes, including in public procurement procedures” without any clear and explicit details on how these should be translated into practice by the contracting authorities, may be problematic and sometimes confusing, creating real difficulties in practice. • the generic use of „procurement requirements” when mainly referring to award criteria, but not limited to, is not in compliance with the terminology of the Directive 2014/24/EU and it may result in misleading interpretations of the legal provisions with negative outcomes on the public procurement procedures. (e.g. it is necessary to understand whether they refer only to award criteria or also to selection criteria along the entire procurement process or to a specific award mechanism, such as framework agreement) SE (Comments): SE has a general scrutiny reservation for the whole proposal.
	AT

Commission proposal	Drafting suggestions and Comments
	(Drafting suggestions): **Art. 3** **(4) 'critical medicinal product' means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients as defined in Article 4 point (13) of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and classified according to Commission Regulation (EC) No 213/2008 of the European Parliament and of the Council on the Common Procurement Vocabulary (CPV);** AT (Comments): The definitions relating to the application of Art. 18 to 24 should be defined in accordance with the provisions of public procurement law. For this reason, the definition of "**critical medicinal product"** for the application of Art. 18 to 24 should be referring to the CPV-Code 33600000-6 "Pharmaceutical products" as set out in Regulation 2195/2002 (which was amended by Regulation 213/2008). This definition provides legal certainty, since contracting authority has to use the CPV-Code in the contract notices.
Chapter IV **Demand side measures**	AT (Comments): The wording/terminology of the provisions in CMA differs from the procurement directive 2014/24/EU. This leads to legal insecurity, therefore the terminology of Directive 2014/24/EU should be used.

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SECTION I	AT (Comments): General Remarks: The Union has already included provisions on public procurement in several sectoral legal acts. In AT's opinion the CMA should be aligned and designed coherently with other - already existing – legal provisions in the procurement area dealing with the topic of resilience [cf. inter alia Art. 25 et seq. of Regulation (EU) 2024/1735, NZIA and Art. 3e of Regulation (EU) 2024/1610 (HDV)].
AWARD CRITERIA AND OTHER PROCUREMENT REQUIREMENTS AND RELATED MEASURES	CZ (Comments): CZ would like to point out that the changes to the public procurement area should be made in a way that they will be in accordance with the horizontal EU legislation on public procurement to ensure a clear framework for the contracting authorities, suppliers and control authorities.
Article 18	CZ (Comments): CZ believes it is necessary to consider the impact of the other existing tools (IPI, FSR) or ECJ case law to create coherent functional system for public procurement of medicines. EE

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	(Comments): We support the inclusion of demand-side measures to enhance the security of supply of critical medicinal products. However, Article 18 introduces several novel procurement concepts and terminology that lack sufficient legal clarity and could result in inconsistencies with existing EU public procurement law. For example, in this Article the term "procurement requirements" for public procurement criteria is used. In the public procurement directives, however, the criteria for a specific public procurement are, depending on their specifics, either "award criteria", "selection criteria", or "contract performance conditions ". Precision in wording is important so that the contracting authority knows how it can fulfil the requirements set out in the regulation – whether the respective criteria can be used only to select the successful tenderer or whether they can also be established as a condition for the performance of the public contract. The relationship between the obligations set out in this Article and the existing public procurement directives need clarifying. It must be specified whether these provisions constitute a derogation or merely offer additional guidance. HU (Drafting suggestions): In general, we support the idea to introduce a European preference principle in the public procurement of critical medicines, however, the future Regulation has to be appropriate for direct application in public procurement procedures by contracting authoritites. Therefore, legal onligations have to be formulated unequivocaly and in line with the public procurement legal framework. From a legal perspective, the current text is contradictory, unclear, insufficiently precise, and not always coherent with the public procurement directives, which may cause

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	significant interpretative difficulties for contracting authorities and might hinder the achievement of the Article's objectives. It is not clear which rules are mandatory („shall apply", „such as"), and which are optional („may relate to"), what are the conditions for application ("shall, where justified"), some key terms are not defined (e.g. „significant proportion", „market analysis", "public health considerations"), so the normative content of the text is weak.
Incentivising resilience, sustainability and positive social impacts in public procurement procedures	DE (Drafting suggestions): Incentivising resilience~~, sustainability and positive social impacts~~ in public procurement procedures
1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery.	AT (Drafting suggestions): 1. For **public procurement procedures** falling within the scope of Directive 2014/24/EU, where contracts have critical medicinal products as part of their subject matter, contracting authorities shall apply selection criteria, technical specifications, contract performance clauses or award criteria regarding the resilience of supply in the Union. Those requirements shall be defined in accordance with Directive 2014/24/EU and may, inter alia, relate to stockholding obligations, the number of diversified suppliers, the monitoring of supply chains, their transparency to the contracting authority or to the timely delivery of products. AT (Comments):

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	Award procedures: Contracting authorities shall apply "*procurement requirements*" in "***award procedures***" that strengthen the resilience of supply chains in the Union. As the EC answered in the working party on 3rd of July the provision is intended to mean that the requirement shall be applied in "***procurement procedures***" and not just in the award phase within the procurement procedure. Therefore, the term "*procurement procedure*" should be used instead of "award procedure". **Procurement requirements:** As the EC answered in the working party on 3rd of July the definition "***Procurement requirements*****"** is functional and is supposed to cover all kinds of requirements. This term must be defined in Article 3 "*Definitions*", or a complete list of possible requirements must be provided in this article. **Timely Delivery of Goods**: A supply contract typically includes clauses relating to the **timely delivery of goods**. Therefore, **every supply** contract **already meets the requirements of the proposed provision**. The EC should issue **guidance** in the form of non-binding templates for contracting entities. This would also serve to ensure legal certainty in application practice. BE (Drafting suggestions): **1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/UE of the European Parliament and of**

Commission proposal	Drafting suggestions and Comments
	the Council shall base the award on the most economically advantageous tender. **Contracting authorities shall make use of multi-award approaches to ensure that all market actors remain on the market.** **Contracting authorities shall also apply mandatory requirements which, where applicable, shall take the form, where appropriate, of:** **a) Technical specifications or requirements within the meaning of Article 42 of the Directive 2014/24/EU, or;** **b) Contract performance clauses within the meaning of Article 70 of the Directive 2014/24/EU.** **These mandatory requirements shall not prejudice Article 20.** BE (Comments): Clarification is needed, there are terminology ambiguities in the current text. MEAT concerns the award criteria and some elements included in the text do not fall under this qualification, e.g. stockholding obligations and clauses with specific conditions regarding the execution. To strengthen supply resilience and avoid excessive concentration (with all the unwanted side-effects of it), we advocate for the use of multi-award frameworks. This allow for : prevention of market distortions; securing of supply and preservation of the role of small MAH. This means that we have to give them market perspectives.

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	BG (Drafting suggestions): 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States ~~**shall**~~ **may** apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. BG (Comments): The mandatory introduction of the MEAT criteria is an interference in the Member States competence for the organisation and financing of the healthcare systems. It contradicts Art. 168 (7) TFEU and undermines the legality of the instrument. There is no data, which demonstrates that most of the Member States apply MEAT criteria instead of the price – in fact the common practice appears to be the opposite. Thus, the scaled-up solution will likely result in problems for the majority of the Member States: reduced affordability, increased spending on pharmaceuticals, reduced funding for other priorities. This obligation will be particularly detrimental for lower GDP Member States. The article has to be a possibility, not an obligation for Member States.

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	CZ (Comments): CZ believes that suggested proposal introducing the term "procurement requirements" is too vague/wide. We are of the opinion that terms used in horizontal EU legislation "award criteria" and "participation in the public procurement procedure" should not be interchanged. These terms have different legal and application regimes. DE (Drafting suggestions): 1. For ~~award procedures~~ **public procurement procedures** of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria ~~such as procurement requirements~~ that promote the resilience of supply in the Union. **Member States may define t**hose procurement requirements ~~shall be defined~~ in accordance with Directive 2014/24/EU**.**~~and~~ **The procurement requirements** may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. DE (Comments): There is a need for a clarification on who defines the procurement requirements. Concrete criteria shall be adapted to national circumstances and be harmonized on Member States Level. Changes are necessary as public procurement in Germany is organized by self-governing bodies**,** however they are bound by legal requirements.

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	If health policy is affected, as is the case here, the Union must nevertheless comply with Article 168 VII TFEU. Such an authorization of the Member States is possible in accordance with Article 2 (1) sentence 2 TFEU. EE (Drafting suggestions): For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall**, except where justified by market analysis or considerations related to the financing of health services,** apply procurement requirements other than price-only award criteria, such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. EE (Comments): We stress the importance of maintaining flexibility for Member States, particularly in smaller markets or low-competition contexts. The application of MEAT criteria should remain flexible and must not become mandatory where it risks undermining competition or procurement feasibility. We therefore propose to integrate the substance of paragraph 5 directly into paragraph 1, by clarifying that criteria beyond the basis of price only shall apply, except where justified by market analysis or considerations related to the financing of health services. This adjustment ensures legal

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	clarity and avoids the misinterpretation that qualitative criteria are mandatory in all cases. It reflects the need to allow contracting authorities to tailor procurement procedures to local market conditions, while still promoting resilience objectives where appropriate. This formulation maintains alignment with Directive 2014/24/EU and better supports the operational and financial realities of small Member States. FI (Comments): When awarding contracts, it is essential to avoid imposing excessive requirements on tenderers, as this could discourage participation and undermine the effectiveness of competitive tendering. Using other than price-only award criteria may increase the health costs of Member States, giving extra burden to their health budgets. FR (Drafting suggestions): For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. **These security of supply considerations shall be specified by the Commission through dedicated guidelines.**

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	FR (Comments): the 'security of supply' and sustainability dimensions (as referred in 18.3), such as 'environmental' and "social rights" requirements, could be tackled by means of non-binding guidelines, proposing to purchasers' relevant criteria that could be incorporated into public procurement contracts to assess these dimensions (whether as award criteria, performance clauses, etc.). There could still be an obligation to use 'security of supply' criteria, potentially with a minimum weighting, although the way in which this is assessed would not be prescriptive as security of supply considerations can be specific to national healthcare systems. While guidelines are mentioned in the recital it will be worthwhile to also have them mentioned in the article as well. Such a framework would allow to keep flexibility and simplify the work of buyers. HU (Drafting suggestions): Article 18 para (1) would prohibit the use of price-only award criteria, and then lists exemplary security of supply requirements that fall more into the category of contract performance conditions. These are different institutions of public procurement law, so it is not clear what the obligation of contracting authorities implies. It is suggested that consideration is given to what the added value of this paragraph is, contracts currently already contain clauses on timely delivery and contracting authorities will be looking for the simplest way to comply with the legal requirement. Where specific requirements for public procurement can be defined, these should be set out in legislation.

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	IT (Drafting suggestions): For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States ~~**shall**~~ ***should*** apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency IT (Comments): Italy expresses a general scrutiny reservation on Article 18, particularly with regard to paragraph 1. We believe that the use of the term "SHALL" is excessively binding and does not allow Member States the necessary flexibility and autonomy in managing public procurement procedures. Therefore we suggest to consider a possible rewording of the provision as we'd rather replace "SHALL" with "SHOULD". Requesting contracting authorities of the Member States to apply awarding criteria other than the one based solely on price to the procurement procedures for critical medicines, should be a recommendation rather than an obligation. LT (Comments): LT: We believe that the application of MEAT criteria should not be mandatory, but rather a right of each Member State, taking into account the

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	specific circumstances related to the availability of a particular medicinal product. In certain cases, applying MEAT criteria in the public procurement of critical medicinal products may further hinder their accessibility, as additional requirements may discourage suppliers from participating in tenders (due to reduced competition) or may lead to increased medicinal products prices as suppliers seek to recover the costs associated with meeting these additional criteria. MT's (Comments): Malta acknowledges that if the EU were to invest to reshore the manufacturing of critical medicines to the EU, it is important that there is a market for these products. This is essential for the long-term viability of these strategic projects. The obligatory MEAT criteria is the option pursued by the Commission, which Malta is willing to work on. However, it is important that the proposed system is aligned with current EU public procurement regulations (PPR), and it should be clear within the CMA when we are deviating from the PPR. In this regard Article 18 would have to be beefed up to clarify the interlink with the PPR and if possible, to streamline the terminology. It is also important that it remains the prerogative of the individual MS to determine their MEAT criteria and to decide on the weight to be attributed to the individual criteria in the selection process, including the extent of how much the criteria favour products manufactured in the EU.

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	The specificities and different realities of the individual Member States needs to be duly considered. It is important that the MEAT criteria strengthen the security of supply, and do not create additional constraints which may make public procurement even more complicated and the outcomes even more uncertain, thereby undermining the security of supply. In this regard more legal clarity is required within the text, also to make the procurement process more robust. RO (Comments): Regarding the „transparency to the contracting authority" - we would like to clarify the meaning of this phrase; can it refer to the additional costs that an MAH incurs as a result of manufacturing in the EU? the expected impacts of such mandatory provisions on the contracting authorities in the Member States for the award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU when implementing new non-price criteria**, need a comprehensive analysis underpinning this proposal**. The mandatory use of other requirements than price for critical medicines according to paragraph (1) article 18 may be challenging for the contracting authorities considering that MEAT including non-price criteria (such as technical and functional aspects, environmental and social criteria, but not the above-mentioned „procurement requirements" – see general comments) is used only in a minority of public procurement procedures. Including these new criteria may result in higher prices, meaning that their mandatory use requires an impact assessement regarding the readiness of the contracting authorities

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	to pay for the added value generated thereby, which can create a barrier to using MEAT with non-price criteria. Also, the practice of contracting authorities has highlighted the possibility of using MEAT criteria including non-price criteria in situations where there is competition on the market, i.e. at least 2 suppliers. Therefore, in specific market conditions, with little competition these criteria may result in disproportionate cost for the contracting authorities and/or discourage participation, and the price may be the only criterion to decide between suppliers, not all suppliers being able to fulfill these new non-price criteria (e.g. obligation to stockpilling). A particular case is the one with single-bidder tenders, wherein the evaluation proccess in point of number of diversified suppliers could become inefficient or unapplicable when setting the score. On the other hand, it is necessary to understand that the use of these additional criteria requires dedicated resources, available to develop and assess these other non-price. Consideration should be given to situations involving the national applicable ex-post controlling rules or the legal appeals when contracts are awarded based on other criteria, in which cases long and burdensome litigations become an obstacle both for the contracting authorities and the suppliers SE (Comments): Comments regarding Article 18 paragraphs 1-5 There is an ongoing horizontal discussion on how public procurement should be used to promote European production. It is problematic that this article pre-empts the outcome of that discussion. It risks leading to a

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	fragmented and more complex procurement framework with leal uncertainty, unnecessary administrative burden an reduced competition. Furthermore, SE considers that the Article is neither easy to apply for contracting authorities, consistent with the terminology in the procurement directives nor likely to achieve the objective. SE is in favour of multiple winners as a measure to promote security of supply. However, it should be up to the contracting authority to assess on a case by case-bases whether it is appropriate and possible. SE rejects obligations to use certain award criteria, this should be decided at the discretion of the contracting authority.
	RO (Comments): In view of the above, we express our real concern and reservation in regard to **imposing** the use of non-price MEAT criteria for MSs contracting authorities.
2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments.	AT (Drafting suggestions): **2a**. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, **the Commission shall adopt an implementing act that specifies the selection criteria, technical specifications or contract performance clauses favouring economic operators which manufacture a minimum proportion of these critical medicinal products in the Union. The minimum proportion shall be determined by the Commission in the implementing act, where necessary to apply the imposed requirements**."

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	AT (Comments): As the EC explained in the WP, the term '*significant proportion'* relates to the outcome of the vulnerability evaluation. A specific contracting authority (for example on a local or regional level) is unable to check the vulnerability evaluation reports and determine what a significant proportion would be. Therefore, the significant proportion and the suitable procurement requirements must be defined by the EC or an EU Agency and published in a legal act. The issue of how to define and assess a product's origin or the origin of a supplier is not addressed in the drafting suggestion and must be discussed in the WP. : **Conditions** **Vulnerability evaluation:** The conditions for the application of the provision are not clearly formulated. Article 3 Paragraph 7 defines the concept of 'vulnerability evaluation' with reference to Regulation COM(2023) 193, which is still to be adopted, but does not define a clear benchmark from which a vulnerability evaluation indicates dependence on one or a limited number of third countries. It is not clear whether the results of the evaluations will be published in the Official Journal of the EU and whether this is any type of legal act. For reasons of a user-friendly applicability, this should be based on transparent decisions that make it clear whether this provision should be applied. **"where justified":** This condition has no content. It should be deleted or given clear content.

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	Consequences "**Significant Share**": It is not determined what a "*significant share*" is. **"suppliers that manufacture in the Union":** Critical medicinal products subject to the CMA are also covered by the scope of international agreements (for ex. the GPA). How can the provision be implemented in accordance with international agreements, such as the GPA? Should the contracting authority treat US production in the same way as EU production? **Other Topics:** The ECs proposal leaves several aspects open – for ex. how to proceed with wholesalers who are not themselves producers of critical medical products. Another topic would be how to tackle urgent needs of supply which cannot be satisfied in time by EU suppliers (missing "escape clause" of EU preference/resilience requirement; escape clause in para 5 does not help), or where major suppliers are placed in 3rd countries and EU suppliers cannot fully meet the EU demands. BE (Drafting suggestions): 2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, **use award criteria or technical specifications that favours suppliers that manufacture a significant proportion of these critical products in the Union as technical specification or as**

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	award criteria. These **criteria** shall be applied in compliance with the Union's international commitments. BE (Comments): Clarification of the terminology. BG (Drafting suggestions): 2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities ~~**shall**~~ **may**, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments. CZ (Comments): In relation to the vulnerability evaluation, CZ considers it necessary to indicate where the results of this evaluation can be found at the EU level in order to make it clear for the contracting authority what requirements it is obliged to meet. Ideally, such publication of the vulnerability evaluation results should be stated in the Pharmaceutical Package. DE

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	(Drafting suggestions): 2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. **The requirements may be defined by the Member States.** These requirements shall be applied in compliance with the Union's international commitments. DE (Comments): Concrete criteria shall be adapted to national circumstances and be harmonized on Member States Level. Changes are necessary as public procurement in Germany is organized by self-governing bodies. As per Article 4 TEU the Union shall respect the Member States' national identities, inherent in their fundamental structures, political and constitutional. EE (Drafting suggestions): 2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that **supply medicinal products manufactured in significant proportion** in the Union. These requirements shall be applied in compliance with the Union's international commitments.

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	EE (Comments): It should be explicitly stated whether this paragraph constitutes a derogation from the public procurement directives. Specifically, under the public procurement directives, bidders can't be favored based on the location of their production. If the regulation intends to grant contracting authorities an additional option for selecting tenderers, this should be expressed more clearly. Generally, we support the development of concept of „European preference ". However, it should be clear how to uniformly apply and fit the concept into the public procurement framework. It is necessary to clarify that other economic operators are considered as suppliers in this context, too. In Estonia usually the wholesale distributors participate in tenders, not the manufacturers. It is important that we do not limit the circle of current bidders, therefore the wholesale distributors must be provided with equal opportunities to participate in procurements. This ensures a competitive market environment and helps maintain a robust supply chain. It would also be necessary to clarify what is meant by "significant proportion" – we see this could be clarified in Commission's guidelines. FI (Comments): Further efforts should aim to align procurement provisions with the WTO Agreement on Government Procurement and other international commitments of the EU. For example, Article IV of the Agreement outlines general principles of non-discrimination, requiring that parties do not treat goods, services, or suppliers from other parties less favorably. This includes:

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	(a) avoiding preferential treatment of domestic goods, services, and suppliers; (b) refraining from discrimination against locally established suppliers based on their foreign affiliation or ownership. More clarification is needed to terms. What is the real meaning of " significant proportion" or "at least a significant proportion"? FR (Drafting suggestions): With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation ~~pointing to the high level of dependency on a single or a limited number of third countries~~, the contracting authorities shall, ~~where justified~~, apply **an award criterion** ~~procurement requirements~~ that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. ~~These requirements shall be applied in compliance with the Union's international commitments~~ FR (Comments): **Pursuant to the discussions held last week, and the need for harmonisation amidst flexibility it will be important to specify for the resilience criterion (i) its format (eligibility, attribution, contract performance clause …) (ii) the associated weighting (iii) the conditions for triggering the criterion (iv) the way in which it is assessed/defined (v) how it interacts with the Union's international commitments. The 'Made in EU' criterion appears to be an essential criterion for which harmonisation is necessary in order to send a clear signal to manufacturers and enable a coherent policy between strengthening supply and demand.**

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	[Format of the resilience criterion] The terminology used in the articles relating to public contracts needs to be consistent with that of the public procurement directives and notably 2014/24 which will be revised next year. The article also needs to be sufficiently precise to avoid the need to have recourse to implementing acts or delegated acts for its application. That being said, we would be in favour of using the resilience criterion as an attribution criterion in tenders for critical medicines. While the use of a local content criterion is slightly distortive by design, applying it as an attribution criterion rather than an eligibility requirement doesn't narrow competition as it incentivizes EU-based production without excluding non-EU manufacturers from participating in the tender. **[Weighting of the resilience criterion]** Using the resilience criterion as an attribution parameter will only have an impact if a minimum weight is assigned to the latter in comparison with other criteria (price, quality). Work is ongoing with internal experts to define propose specific weightings for this criterion. **[Eligibility of resilience criterion]** The Commission's proposal is based on the prior verification of a number of conditions – such as (i) vulnerability assessment, (ii) demonstration of dependency on one or more countries and (iii) justification on a case-by-case basis with "when justified" - the wording of which remains too

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	imprecise to provide an effective framework for the introduction of a resilience or 'made in EU' criterion. - In its current wording, the mechanism presents two main risks: (i) it could excessively restrict the scope of the products concerned, (ii) it would make its application more complex, with the risk of generating heterogeneous implementation between Member States and a lack of clarity for manufacturers, which would therefore create a less favourable signal. With this in mind, we are in favour of simplifying the eligibility conditions for the resilience criterion, as defined in Article 18.2, by proposing to delete the references to: o 'high level of dependency on a single or a limited number of third countries' o 'where justified'. Suppressing these references would (i) allow a clearer signal (ii) simplify the work of buyers, which would just need to refer to the list of the products of the Union List that are vulnerable based on the analysis of the EMA. **Definition/assessment of the Resilience criterion:** The current definition: "significant proportion of these critical medicinal products in the Union" is too vague and ambiguous to lead to harmonised yet flexible application of the resilience criterion. A European methodology for assessing the industrial vulnerability of critical medicines is due to be developed by the MSSG and EMA in October 2025.

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	Without prejudging the outcome of this work, a resilience/production location indicator is currently being considered and a careful alignment with this work should be considered as the MSSG/EMA: (i) Will carry out the vulnerability evaluation, a requirement to use the resilience criterion (ii) Will have access to updated data on production data and will rank overall vulnerability Taking this into consideration, the Made in EU criterion could usefully be computed, for a given product, on the % of volumes of active ingredients produced in Europe and the % of volumes of finished products produced in Europe in the bidder's offer. This approach allows for a graduated and measurable assessment, rewarding bidders proportionally to the extent of their EU-based manufacturing footprint. Focusing on production volumes rather than the simple location of production sites enables the establishment of data-driven, nuanced thresholds instead of a binary yes/no evaluation. This not only makes the criterion more transparent but also better captures the actual exposure to supply chain vulnerabilities. Volume-based metrics provide a clearer picture of strategic dependence: a bidder sourcing 90% of its APIs from the EU faces a very different risk profile than one sourcing only 10%, even if both maintain at least one EU production facility. Thus, weighting offers by the share of EU-based production aligns incentives with resilience objectives, while still preserving openness to international suppliers that contribute meaningfully to European supply security. **The Union's International Commitments**

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	We propose removing the reference to the Union's international commitments for the sake of clarity, as these obligations apply by default. Their omission from the regulation would in no way exempt Member States from complying with them. HU (Drafting suggestions): It is not clear how the principle of "European preference" should be applied. While public procurement legislation and international agreements governing access to public procurement use the "origin of goods" of the Customs Code as the underlying concept, the text of the proposal is about the "manufacturing of a significant proportion of medicines" in the EU. It is not clear whether the place of manufacture is the same as the concept of the origin of goods used in other rules, how the significant proportion is to be assessed, (e.g. for the total quantity of critical medicines included in a procurement?) or how preference is to be given (e.g. by using preferential award criteria or simply excluding foreign medicines?). IT (Drafting suggestions): With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities ~~**shall**~~ ***should***, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments. IT

Commission proposal	Drafting suggestions and Comments
	(Comments): Italy has a scrutiny reservation on this provision. Certain wordings utilised in this provision, in particular “limited number of third countries” and “significant proportion” appear ambiguous and generic, leaving too much room to different interpretations. As mentioned above, we believe that the use of the term "SHALL" is excessively binding and does not allow Member States the necessary flexibility and autonomy in managing public procurement procedures. We therefore request that a possible rewording of the provision be considered, We would therefore prefer replacing "SHALL" with "SHOULD". LT (Comments): LT: The criterion established in paragraph 2 for critical medicinal products and in paragraph 3 for medicinal products of common interest—that a significant proportion of these medicinal products must be manufactured within the Union—does not ensure legal clarity. We support that guidelines prepared by the Commission should be developed to clarify this term. RO (Comments): General terms as *'high level of dependency…, significant proportion of these critical medicines producted in the Union'* should be more clearly defined and quantified. With reference to the assessment of vulnerabilities in the supply chain of critical medicines, in the context in which MSSG is responsible for this

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	analysis, how does the Commission assess that these analyses will be communicated? It will be a methodology defined or some results of its application, periodically published, it will be the MS periodically informed through the MSSG representative?
	AT (Drafting suggestions): 2b. **For public procurement procedures falling within the scope of 2014/24/EU, where contracts have critical medicinal products as part of their subject matter, contracting authorities and contracting entities shall apply procurement requirements established in the implementing act referred to in paragraph 2 of this Article.** These requirements shall be applied in compliance with the Union's international commitments. AT (Comments): Text Origin: NZIA
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 that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments.	BE (Drafting suggestions): 3. With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities may, **use award criteria or technical specifications that favours suppliers that manufacture a significant proportion of these critical products in the Union as technical**

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	specification or as award criteria. These **criteria** shall be applied in compliance with the Union's international commitments. BE (Comments): Clarification of the terminology. BG (Drafting suggestions): ~~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 that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments.~~ BG (Comments): The scope of the CMA has to be limited to critical medicines. Even for these medicines, concrete data are needed in order to assess whether the impact on the CMA measures is not too burdensome on the national budgets. Extending the scope beyond critical medicines, with the unclear notion "medicines of common interest" is not justified and in any case disproportionate. CZ (Comments): CZ asks for clarification of the way in which the market analysis is meant to be conducted and how the public health considerations will be taken into account.

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	In our opinion we should assess the market from the Union point of view (not only the Member State perspective) to ensure the security of medicines supply in the EU. The Member State perspective may not reflect the whole picture on the EU market of the other medicinal product of common interest. DE (Drafting suggestions): 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 that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union. **The requirements may be defined by the Member States.** These requirements shall be applied in compliance with the Union's international commitments. EE (Drafting suggestions): 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 that favour suppliers that **supply medicinal products manufactured in significant proportion** in the Union. These requirements shall be applied in compliance with the Union's international commitments. EE (Comments): See previous comment. FR

Commission proposal	Drafting suggestions and Comments
	(Drafting suggestions): 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 that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments FR (Comments): We agree that the provision should remain non-binding. Therefore, providing broad or vague justifications "market analysis" or "public health considerations") appears unnecessary, given that the use of the criteria is entirely optional. HU (Drafting suggestions): Regarding Article 18(3), it is not clear, what the objective of this paragraph would be: does the proposal wish to make it conditional upon a market analysis for contracting authoritites to prefer such goods which are entitled to equal treatment in the EU public procurement market? We would like to note that already based on the current legal situation, contracting authoritites can decide to prefer such goods against those products originating in third countries and not entitled to equal treatment in EU public procurements according to international agreements on public procurement. IT (Comments): As mentioned above, the wording appears ambiguous, with particular regards to "significant proportion"

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Commission proposal	Drafting suggestions and Comments
	CZ (Drafting suggestions): 3a. The Commission shall create and maintain a database containing information on other than price award criteria, including if the significant proportion of the critical medicinal product or other medicinal product of common interest was manufactured in the Union. The database shall allow the contracting authority to verify such information. CZ (Comments): Although CZ supports other than price-only requirements/criteria, their establishment may increase the administrative burden for the contracting authority, suppliers and the supervisory authorities. To minimalize the administrative burden, we suggest developing a system for contracting authority to verify (and for suppliers to demonstrate) that such medicine meets the stipulated requirements/criteria. We are open to change the suggested wording if needed. Please see the changes in wording proposed.
4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights.	FR (Comments): This section does not provide any legal obligations and simply states something that is already applicable.

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5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2 and 3 where justified by market analysis or considerations related to the financing of health services.	AT (Drafting suggestions): Contracting authorities may exceptionally decide not to apply this Article where justified by market analysis or ~~considerations related to the financing of health services~~ **the member states competence to allocate resources as set out in Art. 168 Paragraph 7 TFEU**. AT (Comments): **Condition 1**: The term "*market analysis"* is not defined in Directive 2014/24/EU. The Condition should be given clear content. If a vulnerability in the supply chain is confirmed, the decision not to procure medicinal products from the EU would very likely be justified by the competitive situation within the Union. The current form of this condition goes against the objective of this article. Additionally, in order to provide a level of coherence for contracting authorities between sectoral acts, the exemptions from NZIA and the Construction Products Regulation, should be reviewed and added here if applicable. In particular, it is necessary to consider substantial additional costs to contracting authorities **Condition 2:** EC clarified in the WP that the second exception is due to Article 168, Paragraph 7, and the relevant case law of the ECJ. The exception can be applied in instances where there is a conflict with the member state's competence to allocate resources. This should be clarified. BG (Drafting suggestions):

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	5. Contracting authorities may ~~**exceptionally**~~ decide not to apply paragraphs 1, 2 and 3 ~~**w**~~**here whenever these provisions impact the management of health services and medical care and the allocation of the resources assigned to them** ~~justified by market analysis or considerations related to the financing of health services.~~ BG (Comments): Contracting authorities should preserve their full autonomy in decision making and need not to justify their decisions. This is the status quo in accordance with the Treaties. CZ (Comments): CZ believes that the suggested system does not provide clear rules for the option to use the described exception not to apply rules above, especially in regard to justification by market analysis or the financing of healthcare services. DE (Drafting suggestions): 5. Contracting authorities may**, in compliance with national regulations,** exceptionally decide not to apply paragraphs 1, 2 and 3 where justified by market analysis or considerations related to the financing of health services. DE (Comments): Changes are necessary as public procurement in Germany is organized by self-governing bodies. We have to make sure that there self-governing

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	bodies comply with national law an cannot use EU law to circumvent national requirements. As per Article 4 TEU the Union shall respect the Member States' national identities, inherent in their fundamental structures, political and constitutional EE (Drafting suggestions): ~~5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2 and 3 where justified by market analysis or considerations related to the financing of health services.~~ EE (Comments): We propose to delete paragraph 5 and incorporate its substance into paragraph 1. This would provide greater legal clarity and reflects the need for a balanced, context-sensitive approach. Keeping it as a standalone provision would be redundant and could create ambiguity regarding the default applicability of paragraphs 1–3. FI (Comments): Good to have this exemption. FR (Comments): An exemption framework must be put in place to allow flexibility. This framework must allow buyers latitude in order to ensure a good balance between continuous supply and sovereignty.

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	However, this exemption framework should be precise to avoid distortion and allow the global framework to have impact. Relevant parameters for contracting authorities/entities not to apply requirements set out in paragraph 18.1 and 18.2 could, for instance, relate to situations in which: i. The critical medicinal product can only be provided by a specific economic operator ii. Previous procurement processes (over the past two years) have resulted in no appropriate offers in the market. iii. Compliance with the requirements would result in excessive costs (of x%) or technical incompatibilities within the healthcare system. iv. Contracting authorities may assume that cost deviations exceeding X% are disproportionate. We are still working on precise amendments HU (Drafting suggestions): In Article 18 paragraph (5), there is also a need for a clear provision on the conditions under which contracting authorities may derogate from the application of a legal obligation. Regarding possible derogations, we agree that room should be provided for contracting authoritites to take into account financial aspects. LT (Comments):

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	LT: An exception is foreseen whereby paragraphs 1, 2, and 3 may be waived if justified by market analysis or considerations related to the financing of healthcare services. This raises the question of what scope and level of analysis and justification are required to adequately substantiate the application of such exceptions. RO (Drafting suggestions): Contracting authorities may ~~**exceptionally**~~ decide not to apply paragraphs 1, 2 and 3 where justified by market analysis or considerations related to the financing of health services. RO (Comments): we request the deletion of the term "exceptional"; we consider it necessary for the competent authorities to decide on the application of these non-price MEAT criteria according to the national context, including the budget dedicated to spending on medicines and their special medical needs, and the specifics of each procurement procedure (existence of multiple suppliers/type of medicine - e.g. in the case of vaccines, stocking obligations cannot be taken into account given their limited shelf life etc.).
	BE (Drafting suggestions):

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	5a. The Commission shall adopt an implementing act specifying minimum mandatory requirements or criteria to be used by public authorities for the public procurement procedures and setting the basic requirements for multi-award frameworks. **The Commission shall develop guidance on the implementation of MEAT criteria, including templates and model clauses.** BE (Comments): We need a more structured orientation, we believe it would be achieved through the establishment of mandatory (in whole or via a "menu" provision) requirements to be used by contracting authorities. This would : - Help these authorities to implement these rules as easily and swiftly as possible; - Ensure coherent and uniform application within the EU to avoid fragmentation of the market. Contracting authorities need reassurance when it comes to applying MEAT criteria linked to the security of supply. EE (Drafting suggestions): **European Commission shall issue guidelines to assist Member States in implementing their obligations under this Article.** EE

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	(Comments): We stress the need for practical implementation guidance, including model criteria and examples from the Commission, to avoid excessive administrative burden and ensure proportional and effective application across Member States.
Article 19	BE (Drafting suggestions): *Article 4* EE (Drafting suggestions): ~~*Article 19*~~ EE (Comments): We don't understand the added value of this Article and therefore suggest deletion. FR (Comments): we are in favour of a programme that follows broad common principles in order to maximise the harmonisation of criteria in public procurement. However, the scope of the national programmes needs to be clarified to focus on clear, common themes, as the current wording is too vague. We would point out that pricing is a national competence.

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Programmes supporting sustainability and resilience in public procurement procedures	BE (Drafting suggestions): *Strategic objective of the Union* EE (Drafting suggestions): ~~*Programmes supporting sustainability and resilience in public procurement procedures*~~ IT (Comments): Italy has a scrutiny reservation. The Italian National Health Service provides for several levels of contracting authorities (national, interregional, and regional), and we assume other Member States may have similar structures. Therefore, it is difficult to imagine how this provision could be practically implemented. In any case, we consider the six-month deadline set by the Regulation for implementing these national programmes could be hardly complied with, and we propose extending it to a minimum of twelve months. Furthermore, Italy has specific concern to the establishment of a new European Coordination Group (i.e. Critical Medicines Group); in fact there may be a concrete risk that its competences could overlap with other groups dedicated to shortages (i.e. MSSG, Critical Medicines Alliance, SPOC). We assume this will be discussed in deeper detail in Chapter IV. However, to have a comprehensive view of the entire article, we believe that certain

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	critical issues related to the proposal of this new group should already be taken into account.
	BE (Drafting suggestions): *[...]*
1. By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures.	AT (Comments): The provision does not clarify if the national programmes have to be legally binding or non-binding programmes. The EC explained that they can be binding or non-binding acts. This should be clarified. AT suggests extending the time period to 12 months instead of 6. BE (Drafting suggestions): 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. **By 6 months after entry into force of this Regulation each Member State or each competent public authority according to the constitutional organisation of the Member State shall establish a**

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	national program supporting security of supply and continuous availability of critical medicinal products. These programs shall include demand-side measures relating, but not limited to, public procurements especially regarding consistent use of criteria and/or requirements as well as multi-winner approaches, where beneficial in light of the market analysis. Such programs should also concern other measures concerning private procurements, pricing and reimbursement supporting security of supply of those products, or supply-side measures such as stock monitoring while ensuring that these programs are enforceable. **2a. Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Group. The Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion aiming to ensure coordination of national programmes including as regards the application of criteria mentioned in Article 18(2) and may issue opinions. Where the Critical Medicines Group issues an opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes.**

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	3. The Commission shall support the coordinated efforts of the Member States. The Commission shall adopt an implementing act to provide a structured approach for the drafting of the national programmes. It shall also provide guidance for an harmonised implementation . BE (Comments): We believe that, given the diversity of the measures aimed at guaranteeing security of supply, we believe that this provision should take into account the constitutional realities of MS and the division of competences on both national and regional level. Furthermore, we think that these programmes will reveal inherently cross-cutting and that they should be integrated in Article 4 of the Regulation which concerns supply-side measures as well as demand-side measures. These programs will define the approach taken by MS when it comes to the measures foreseen in this legislation. To that end: - We believe we should go beyond what is currently proposed and other measures : such as private procurements, stock monitoring, …. - We support that there is flexibility, however the Commission should provide some sort of "blueprint" for what should be

Commission proposal	Drafting suggestions and Comments
	included in these programmes. This would provide for harmonised frameworks. - Differing approaches may lead to discrepancies in the implementation, Commission should provide guidance to ensure a coherent, consistent and effective implementation of these programs and better alignment with the objectives and obligation set out under this Regulation. BG (Drafting suggestions): 1. ~~By 6 months~~ **If necessary and justified**, after entry into force of this Regulation each Member State ~~**shall**~~ **may decide to** establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes ~~**shall**~~ **may** promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the needs **and capacities** of the **respective healthcare system** ~~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.~~ BG (Comments): The goal of the provision is unclear. Unless backed by analysis, data and clarifications, the article should be at best deleted. The 6-month deadline is manifestly inappropriate and unrealistic, given the lack of clarity on the substance of this obligation. The pricing and reimbursement measures are anyways national competence, the Union does not need to allow for actions. This contradicts with the principles of subsidiarity and proportionality.

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	It is necessary to make corrections, so that the nature of the article is clearly voluntary. CZ (Drafting suggestions): 1. By 6 months after the adoption of delegated/implementing act according to paragraph 2a. ~~entry into force of this Regulation~~ each Member State shall establish a binding national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures. CZ (Comments): In relation to the national programmes supporting security of medicines supply, the CZ considers it important that there is a related delegated act or implementing act so that Member States adopt a harmonised approach to ensure consistent use of procurement requirements/criteria. From our point of view, the guidelines set in the recital are not sufficient. Moreover, the Member States should be obliged to establish a national programme 6 months after such delegated or implementing act is adopted. Such a national programme should be legally binding. CZ also supports the multi-winner approach.

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	Please see the changes in wording proposed. DE (Drafting suggestions): 1. By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. **Such programmes can also be legislative changes on Member State level.** Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures. DE (Comments): We suggest a clarification. EE (Drafting suggestions): ~~By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures.~~

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	FI (Comments): The timing should be changed, 6 months is not enough to create the practices in Member States. The timing should consider the transition period of the Regulation – or at least it should be 12 months. IT (Drafting suggestions): By ~~**6**~~ ***12*** months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures. LT (Comments): LT: Member States are required to develop a national programme supporting the security of supply for critical medicinal products, including public procurement procedures, within six months of the Regulation's entry into force. It should be considered whether the core requirements for developing national programmes ought to be harmonised at the Union level or set out

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	in the dedicated guidelines. Furthermore, the six-month timeframe for preparing the national programme is insufficient. MT's (Comments): This obligation should be clarified, since it is not clear whether these are guidelines or legally binding measures. The six-month period is however relatively short if a market analysis is required to justify certain measures. One must also consider the interaction between this legislation and the revised pharmaceutical framework also when setting timelines. The national programmes should be set within the context of the new framework; thus the final transposition and implementation period of the revised framework should be considered. RO (Drafting suggestions): By **12 months** after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products (…)**~~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.~~** RO (Comments):

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	given the complexity of such a strategy, we consider the proposed deadline insufficient and therefore request that it be extended to at least 12 months. Regarding the use of multi-winner awards, the legislation in force regulates this approach by using the framework agreement, whose advantages consist in increasing the competition and addressing the security of supply. Nevertheless, there should be taken into consideration the situations of smaller markets, limited number of suppliers normally operating, capacity to supply, unfeasible splitting of contracts, de-centralised procurement across UE, which make the single winner award remain common for at least some medicines. As regards the inclusion of pricing and reimbursement measures to support the security of supply of critical medicines that are not procured through public procurement procedures, while we agree with the need for specific pricing & reimbursement policies for critical medicines as part of a strategy to ensure availability, **we emphasize that according to the EU Treaties pricing & reimbursement is an exclusively national competence and the prerogative to intervene in national policies lies within the national authorities**. Additionally, we consider that a prioritization of non-price criteria is required. SE (Comments): SE does not see the proposed timeline as realistic.

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2. Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Group. The Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion aiming to ensure coordination of national programmes including as regards the application of criteria mentioned in Article 18(2) and may issue opinions. Where the Critical Medicines Group issues an opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes.	BG (Drafting suggestions): 2. Member States ~~shall~~ **may share** ~~notify~~ their programmes ~~to the Commission in its role of the secretariat of~~ **with** the Critical Medicines Group. **In those cases**, ~~T~~the Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion aiming to ensure ~~coordination of~~ **best practice exchanges on** 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.~~ The Critical Medicines Group shall act in an advisory capacity only. Its opinions shall be non-binding and shall not entail an obligation for Member States to adapt or revise national programmes. BG (Comments): In its current form, the role of the Critical Medicines Group (CMG) goes beyond coordination and enters the domain of influencing national policymaking. Phrases such as “shall give due consideration” create the potential for indirect pressure on Member States to align their national programmes. This approach is not compatible with the principle of national competence in the organisation and financing of healthcare systems (Article 168(7) TFEU), nor with the spirit of voluntary cooperation within the Union. We therefore propose that the CMG’s role be clearly defined as purely advisory, with no obligation—express or implied—for Member States to revise their national programmes based on its opinions. CZ

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	(Comments): The CZ supports sharing of information related to national programmes with other members of Critical Medicines Group through the Commission and other related steps. DE (Drafting suggestions): 2. Member States ~~shall notify their programmes to~~ **inform** the Commission in its role of the secretariat of the Critical Medicines Group **about their programmes**. The Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion aiming to ensure coordination of national programmes including as regards the application of criteria mentioned in Article 18(2) and may issue opinions. Where the Critical Medicines Group issues an opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes. DE (Comments): We suggest a clarification that no formal notification is needed. EE (Drafting suggestions): ~~Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Group. The Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion aiming to ensure coordination of national programmes including as regards the application of criteria mentioned in Article 18(2) and may issue opinions. Where the Critical Medicines Group issues an~~

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	~~opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes.~~ RO (Comments): What exactly does a national program entail? Could be understood that this is a strategic industrial programme, mandatory included a financial component as an obligation of the MS? We believe that the criteria on the basis of which the Coordination Group carries out the evaluation should be defined in the act.
	CZ (Drafting suggestions): 2a. The Commission shall adopt delegated/implementing acts to support Member States in implementing their obligations according to this Article to use procurement requirements/criteria, including award criteria beyond price considerations with a view to strengthen the security of medicine supply. CZ (Comments): In accordance with the CZ comment on para 1 of this Article above, please see the changes in wording proposed.
Article 20	EE (Comments): We strongly support the principles outlined in Article 20, particularly the emphasis on transparency, proportionality, and solidarity in the

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	application of contingency stock obligations. It is essential to avoid unintended negative impacts on the supply security of other Member States, especially smaller markets that may already face limited access to certain products. However, the current text lacks clarity on the practical mechanisms for identifying, monitoring, and preventing such cross-border impacts. The absence of transparency makes it difficult to assess when a contingency stocks measure becomes problematic for others. We therefore recommend developing common principles or baseline thresholds (e.g. minimum/maximum stock volumes, reasonable holding periods), as well as a notification or transparency mechanism to promote mutual awareness and cooperation. The ability to redistribute contingency stocks across borders in EU in times of need, without restrictions based on location or jurisdiction, should be explicitly encouraged as part of a flexible and resilient internal market response. FR (Comments): The French authorities consider that this article seems to cover a much broader field than that of critical medicinal products and does not seem to have a direct link with industrial vulnerability, nor with the measures carried by the CMA. We would like the European Commission to provide information and data to assess the real impact of “stocks” on medicine shortages. The causes of shortages caused by stocks are not described in the pie chart on page 2 of

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	the RCMA. It is crucial to have this information in order to objectively assess the real impact and take effective corrective measures. - FR will also recall that there are other general provisions already applied, such as the notification obligation in accordance with Directive (EU) 2015/1535, which already ensure that national measures concerning stock obligations already in force do not create obstacles to the free movement of goods, and therefore do not have a negative impact in other countries. Consequently, the principles of transparency and the absence of negative impact on other countries are already ensured as the provisions stand. In addition, FR strongly supports the solidarity mechanism. It is an effective lever for dealing with periods of supply tension. This mechanism is already working (several Member States have been able to share medicines initially intended for them with other Member States). It does not seem necessary to give it legal status or to mention it in a legal text. It is important to maintain a degree of flexibility in order to find appropriate solutions to shortages. - In addition, the revision of pharmaceutical legislation puts in place a number of general measures to deal with shortages. - The overall framework of Article 20 remains unclear. Here again, we question its place within the articles of the regulation. At this stage, FR recommends that it be included in a recital. - Lastly, it is necessary to clarify the types of stock being referred to: Rolling stock (routine logistical flows) / Strategic stock (emergency reserves) / Or both?

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	A harmonized definition of these terms is essential to ensure a shared understanding and to avoid ambiguity in the implementation of stockpilling policies.
Safeguards related to Member States' contingency stocks requirements and other security of supply measures	BG (Drafting suggestions): *Safeguards related to Member States' contingency stocks requirements* ~~*and other security of supply measures*~~ ES (Comments): Need to establish a definition of ´contingency stocks´. RO (Comments): In order to optimize production and distribution strategies and prevent wastage of medicines, it should be taken into consideration an EU-wide interoperable database, implementing real-time tracking systems and emergency storage measures to increase transparency and stability of the supply chain. ESMP can be used to provide real-time data on stock levels, product status (unfinished/finished medicines), availability for redistribution and stock utilization.
	CZ (Drafting suggestions): "contingency stock" means - the contingency stock of mandated supplier of medicines when there is a requirement imposed by an authority (such as a government or

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	regulatory body), but the responsibility for maintaining and owning the stock remains with the supplier, and - the contingency stock done, managed and controlled by the Member States related to supply chain disruptions and the prevention of shortages of medicinal products (strategic reserves of Member States or EU intended for use during emergencies, such as health threats, natural disasters, economic crises are excluded) CZ (Comments): CZ considers it necessary to define contingency stocks as the term is not uniformly interpreted (add to Article 3 on Definitions). Please see the changes in wording proposed to Article 3.
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 proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks.	AT (Comments): The practical implementation of this provision raises several problems. This provision needs clarification. As the EC explained, this provision is targeting the Member States. If a Member State increases demand for medicinal products through a procurement procedure, this will have a negative impact in other Member States. The requirement that "**any** negative impact" must be avoided makes this provision a de facto prohibition for other MS to set measures on SoS. Therefore the wording must be improved and clarified. BE (Drafting suggestions):

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	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 proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. **Member States shall ensure that these requirements are without prejudice to any obligation to ensure appropriate and continued supplies so that the needs of patients are covered pursuant to Article 81 of Directive 2001/83/EC.** BE (Comments): The principle of "serve the patient first" should be embedded to ensure that MAH prioritise fulfilling their obligation to ensure appropriate and continued supplies to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the MS are covered. BG (Drafting suggestions): Measures on **contingency stocks** ~~security of supply~~ applied **on MAH** in one Member State shall not result in ~~any~~ negative impact **on supply** in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. BG (Comments):

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	It is necessary to make clear that contingency stocks are only related to the MAH. The national stockpiles and state reserves should not be covered in the scope. CZ (Drafting suggestions): 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 proposing and defining the scope and timing of any form of requirements for public or private entities ~~companies~~ to hold contingency stocks. CZ (Comments): CZ welcomes the introduction of this provision. Nevertheless, CZ considers it important to specify the obligation to notify as well as how the enforceability of this safeguard will be ensured while applying of national procedures. Moreover, CZ is in favour to specify the rules on annulment of taken measures in one Member State in case that national procedure in that Member State will jeopardize the medicines availability in the other Member State. Last, but not least, distinguishing between public and private entities is proposed. Please see the changes in wording proposed. DE (Drafting suggestions): ~~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~~ **ensure that measures aimed at safeguarding the security of supply do not compromise**

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	the security of supply in other Member States when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. DE (Comments): We support the suggestion of FI and SE regarding this paragraph. ES (Comments): To establish specific criteria for defining such `negative impact´. FI (Drafting suggestions): FI-SE proposal for the article 20: ~~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~~ **ensure that measures aimed at safeguarding the security of supply do not compromise the security of supply in other Member States** when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. FI (Comments): The negative impact of existing stockpiles on the internal market and other Member States is not self-evident. Potential negative impacts are mainly limited to the establishment phase of the stockpiles, when the demand of

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	pharmaceuticals may rapidly increase. The extent of the impact is largely determined by the length of the transition period and thus, the long lead times of the pharmaceutical industry should be taken into account when transition period will be set. This enables the adjustment of production capacities to meet increased demand in order to minimize negative impacts. The emphasis should be placed on coordinated planning and solidarity, rather than unilateral national measures. We underline that through allowing sufficient transitional periods for stock adjustments, disruptions to the single market can be avoided. The focus of possible measures should be on ensuring adequate planning with a view to adapt to the internal market requirements taking into account other Member States' needs and also informing them in advance. The addition of the need to inform other Member States is in line with the TFEU, Article 347 and will be a bridge between Chapter X in the Pharma package to the CMA being in line with the proposed article 134 of the Regulation on Pharma package, which states that the Commission may draw up recommendations for national measures to improve security of supply of medicinal products included in the Union list of critical medicinal products. IT (Drafting suggestions): ~~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~~ **ensure that measures aimed at safeguarding the security of supply do not compromise the security of supply in other Member States** when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks.

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	LT (Comments): LT: We consider that the provisions on the establishment of contingency stocks to ensure supply security are of a general nature, referring to the principles of proportionality, transparency, and solidarity. However, they do not provide legal clarity on how these principles are to be implemented, how negative impacts on other Member States would be avoided, or what consequences would follow from non-compliance with these principles. It would be appropriate to establish more specific and detailed provisions. Furthermore, Recital 31 refers to an obligation for Member States to maintain contingency stocks and to guidelines prepared by the Commission. However, Article 20 does not regulate this matter, nor does it foresee the issuance of Commission guidelines. In addition, the relationship between the provisions on contingency stocks for ensuring supply security and the ongoing revisions of the EU pharmaceutical legislation Regulation remains unclear. MT's (Comments):

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	Whilst Malta understands the intention of this article, the wording of this proposal is vague and does provide certainty on the limits of the obligation on the Member State. One should also align this with the wording of Article 134 of the Pharma framework Regulation, which however is still subject to negotiation with the European Parliament, thereby making the alignment somehow challenging at this point in time. RO (Comments): Legal clarity is needed in this article by defining the following terms: *negative impact in other MS* (what is in addition to the application of TRIS obligations?) and *general stocks* vs *contingency stocks* Since contingency stockpiles must be shaped to respond to specific vulnerabilities, one fits all approaches may be ineffective and disruptive. Special, adjusted regimes, where justified, should be promoted, for special product categories. SE (Drafting suggestions): **FI-SE draft proposal for the article 20 of the proposed CMA - regulation:** *Article 20* *Safeguards related to Member States' contingency stocks requirements and other security of supply measures* ~~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~~ **ensure that measures aimed at**

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	safeguarding the security of supply do not compromise the security of supply in other Member States when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. **Member State shall, if such measures are deemed necessary, inform other Member States of its intentions in the Critical Medicines Coordination Group as specified in Article 26.** SE (Comments): Our preliminary position is to support the intent of this article but we do have some proposals for amendments Like FI expressed during the meeting the negative impact of existing stockpiles on the internal market and other MS is not self-evident and we believe that emphasis in this article should be placed on coordinated planning and solidarity rather than unilateral national measures. Further on, there might be a need for more explicit wording regarding tan obligation to exchange information on any measures concerning stocks in the proposed Critical Medicines group. We also recognise that there may be practical difficulties for the contracting authorities to access the possible negative consequences in all MS.
	BE

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	(Drafting suggestions): **The Commission, in collaboration with the MSSG, shall identify and address the existing regulatory barriers hindering effective stock reallocation pursuant to the solidarity mechanism.** BE (Comments): The MSSG would be well placed to assess such barriers and issue recommendations. If necessary, the Commission should be empowered to introduce regulatory flexibilities to ensure the effective operation of the solidarity mechanism. For instance, scenarios where a shortage in one Member State could be alleviated through reallocation of stock from a different marketing authorisation holder in another Member State require clear guidance and sufficient flexibility to facilitate timely interventions.
Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity.	AT (Comments): Provision not necessary since this already follows from TFEU. CZ (Drafting suggestions): Member States shall ensure that any requirements they impose on public or private entities ~~companies~~ in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. CZ (Comments):

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	CZ generally supports the establishment of the common principles for contingency stocks. However, CZ believes that these principles should apply not just in case of critical medicines and other medicines of common interest, but also in the case of other medicines in general. CZ also believes that all public or private entities which have obligation to create and maintain contingency stock related to medicines, not only the companies in the supply chain, should be included into this provision. Please see the changes in wording proposed. DE (Comments): We support the Commission's proposal. The FI and SE suggestion "Member State shall, if such measures are deemed necessary, inform other Member States of its intentions in the Critical Medicines Coordination Group as specified in Article 26." would create a double notification obligation because in the pharmaceutical package Article 121(2)(f) already requires the competent authority to inform the EMA of any actions foreseen or taken measures. ES (Comments): ES supports the approach explained by the Commission that contingency stocks are to be realised in case any other Member State has a shortage of a medicinal product. FI (Drafting suggestions): Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. **Member State shall, if such**

Commission proposal	Drafting suggestions and Comments
	measures are deemed necessary, inform other Member States of its intentions in the Critical Medicines Coordination Group as specified in Article 26. IE (Comments): IE support the intent behind this provision, though IE would note that it could be challenging to implement. Article 20 should also be considered in the context of the ongoing discussions in relation to Art 134 of the draft Regulation as part of the review of the general pharmaceutical legislation, and it should be ensured that both provisions are consistent and complementary to each other. IT (Drafting suggestions): Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. **Member State shall, if such measures are deemed necessary, inform other Member States of its intentions.** RO (Comments): Contingency stock obligations for vulnerable critical medicines should be time limited and reassessed after a certain time frame. There should be a clear methodology when a product is no longer considered vulnerable and therefore no longer needs to be in contingency stock. This ensures

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	measures remain targeted and workable. Maximum thresholds both at national and EU level should provide an adequate "upper limit" for contingency stocks, above which the stock would be deemed unnecessary and with a potential disruptive effect to supply within the EU
	BE (Drafting suggestions): **The Commission, in collaboration with the MSSG, shall develop guidelines relating to the effective implementation of this article, including preparedness stockpiles and mandatory contingency stocks.** BE (Comments): Belgium considers this necessary to mitigate distortions in the pharmaceutical market, one could consider the necessity to go beyond critical medicines. These guidelines should consider waste prevention systems such as rotating stockholding obligations.
	BE (Drafting suggestions): **Article X : EU Platform relating to the stockholding requirements on critical medicines.** CZ (Drafting suggestions): new 3. The Commission shall create and maintain a database containing information on contingency stocks. The database shall include at least information on API, size of the package, ATC group, the quantity of stocks and the possibility to share such medicinal products with other Member States in case of need.

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	new 4. The Commission may create Union contingency stocks to ensure security of medicine supply. CZ (Comments): CZ suggests the creation of EU database of the contingency stocks to ensure the transparency between Member States. This database should include information related to medicines supplies (at least API, size of the package, ATC group and the quantity of medicine stocks) including the information about possibility to share these medicine supplies with other Member States in accordance with the solidarity principle in case of need. Moreover, CZ suggests to include establishment of the common EU contingency stocks into this provision to prevent medicine shortages and to secure the availability of the medicines for EU patients. We are open to change the suggested wording if needed. Please see the changes in wording proposed.
	BE (Drafting suggestions): **1. The Commission shall set up, maintain, and manage a restricted IT Platform relating to the contingency stocks requirements and other security of supply measures.** **The Platform shall be used to provide information on contingency stockholding requirements and on the levels of contingency stocks.**

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	The Platform shall also be used to enhance transparency and to support the reallocation of critical medicines through the solidarity mechanism. **2. The Commission shall adopt a delegated act to specify the data which is to be reported into the Platform.** **3. The Commission shall adopt an implementing act to further specify how MS will report the data referred to in paragraph 2.** BE (Comments): In order to enhance the transparency and coordination, we propose to create an EU-wide Platform that provides information on stocks of critical medicines. This would help the identification of available stock and it would support the reallocation through the solidarity mechanism when necessary. CZ (Drafting suggestions): new 5. The critical medicinal products shall have an English universal Union packaging. CZ (Comments): CZ believes that the text should also include some of the other regulatory measures to increase the availability and reallocation flexibility of medicines between Member States (i.e.: universal EU package for critical medicines). We are open to change the suggested wording if needed. Please see the changes in wording proposed.

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SECTION II	AT (Comments): In order to ensure legal certainty and consistency the instruments should be aligned (see, for ex Article 36 et seq. of Regulation (EU) 2024/2747 IMERA).
COLLABORATIVE PROCUREMENTS	CZ (Comments): CZ supports the Member State´s right to decide about participation in the collaborative procurement. However, CZ considers it important to take into account the potential impact on the availability of medicines for those Member States which decide not to participate in collaborative procurement. CZ is of the opinion that it is important to adopt EU legislation which will ensure that we avoid the situation when the collaborative procurement would be the only possibility for Member State to ensure the availability of such medicine for its patients. CZ believes that collaborative procurement should serve to ensure as broad as possible group of medicines. Therefore, we suggest some changes in the text. Please see more on this below in Article 22 para 1 letter b) and Article 23 para 2 letter b). Additionally, CZ supports the inclusion of the third countries into the collaborative procurement mechanism (similarly to the EP amendment in

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	Pharmaceutical Package for the joint procurement of centrally authorised medicines or to *the Recommendation for a Council Decision authorising the opening of negotiations for one or more agreement(s) with the Kingdom of Norway, the Republic of Iceland and the Principality of Liechtenstein on health emergency measures in the area of medical countermeasures*). These third countries could join the collaborative procurement while not interfering with the set conditions. This approach could help to increase the economic strength of the group of Member States involved in the collaborative procurement. Moreover, it could bring other benefits from the collaboration with other countries with the EU and it could strengthen bilateral relations as well. We would add to Article 27: *New 2.* Third countries are allowed to participate in the collaborative procurement according to Articles 21, 22 and 23. Third countries may not change the conditions of the collaborative procurement set by the Member States. We are open to change the suggested wording if needed.
Article 21	BE (Drafting suggestions): À rédiger. BE (Comments): Cf position BE : langues communes pour faciliter.

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	FR (Comments): Support in principle for this proposal, which (i) must remain voluntary and (ii) requires an assessment of the impact of these transfers on competition, the availability of medicines and prices in participating and non-participating states. the distinction between articles 22 and 23 must be clearly established. SE (Comments): Common comments regarding articles 21-23: These articles should be on a voluntary basis and include the principle of proportionality. We are preliminary positive, but our analysis shows that as there might be a need to mitigate risks for excessive use of coordinated procurement. SE sees a risk that if used too extensively it might risk undermining national incentives and creating unwanted market effects. We may come back with additional comments on these articles further on.
Commission facilitated Member States' cross-border procurement	BG (Comments): Bulgaria supports this provision, which may enhance regional initiatives. The advantage of such initiatives is that usually the participating Member States have similar needs and budgets, hence the negative effect of one single price (such as in Art. 22 and Art. 23) will be avoided. It has to be discussed however what the role of the Commission as a "facilitator" should be.

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	FI (Comments): FI supports this proposal IT (Comments): . Italy expresses a scrutiny reservation regarding Articles 21–23, which discuss the use of collaborative procurement tools. Though these tools can be beneficial for improving the procurement of medicines in certain situations—such as during emergencies or for specific categories of products like critical medicines or those for ultra-rare diseases—Italy believes that expanding the use of these tools as standard procurement channels for a wider range of medicines could negatively affect national price negotiations. Additionally, it may reduce the efficiency of these measures in circumstances where they would be most effective. There is also concern that joint participation in such procedures could create excessive dependence on a single supplier for multiple countries. From an implementation perspective, the practical execution of joint procurements among States with heterogeneous healthcare systems could prove complex, particularly regarding contract management and the potential emergence of disputes.

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1. Upon a reasoned request of three or more Member States ('the request'), the Commission may act as facilitator for the requesting Member States' cross-border procurement as laid down in Article 39 of Directive of the European Parliament and of the Council 2014/24/EC[1] for medicinal products of common interest.	CZ (Drafting suggestions): 1. Upon a reasoned request of three or more Member States ('the request'), the Commission ~~may~~shall act as facilitator for the requesting Member States' cross-border procurement as laid down in Article 39 of Directive of the European Parliament and of the Council 2014/24/EC[2] for medicinal products of common interest. The Commission may decline the request only if the request does not meet the conditions set in this Article. CZ (Comments): CZ believes that the Commission should automatically provide support according to this Article and act as a facilitator when Member States make such a request. Alternatively, specific conditions in which the Commission can refuse to do so should be set in this text. Please see the changes in wording proposed. EE (Comments): The term "cross-border procurements" is used. The substance is very similar to what is designated by the term "joint procurements" in other drafts (e.g., IMERA) or "common procurements" (e.g., SAFE). FI (Comments):

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

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

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	We need to keep in mind that joint procurement in the Union obviously favours manufacturers who have access to joint procurement. This may narrow the pharmaceutical market and reduce the availability of other medicines. In joint procurements, Member States may not have the possibility to influence the price of medicines or the length of processes. Joint procurement may in practice reduce Member States' ability to influence decisions and the use of medicines in the health system. However, we support this voluntary procedure. MT's (Comments): The scope of this article is unclear. Whilst the Commission explained that the intention is to support initiatives such as the BENELUXA initiative, the text in particular through para 6 seems to be restricted to supporting one off procurements of products. It is important that the setting up of new initiatives like BENELUXA are supported and the Commission may play an important role also in setting up such initiatives. Whilst the regulatory tools such as the wider use of multi country packs should be facilitated by the new revised framework, since this is also a market driven process, the adjustment is not always that easy and the Commission could play a role in supporting this change. Malta holds that the article should focus on long term collaborations rather to one off purchases. The start of the initiative is the most challenging and this should also be possible also with just two participating Member States, leaving it open to the participation of others.

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	Malta holds that whilst collaborative procurement through centralised procurement should be supported, one should also explore how we can stimulate collaborative procurement through the supply chain, such as through wholesale dealers. This would make the collaborative procurement more interoperable within the context of the different procurement methods of the Member States. The challenges related to low volumes is also experienced by wholesale distributors and it is important that their turnover volumes are increased to boost their negotiation and purchasing power to supply smaller markets. Whilst we understand the sensitivity of cross border distribution to some Member States, it represents a more effective and interoperable way of joint procurement for critical medicines which are predominately channelled through wholesale distributors. One should also include cross-border wholesale distribution within the scope of strategic projects.
2. Having received the request, the Commission shall inform all other Member States of the initiative and set an appropriate deadline for them to declare interest. Such a deadline shall not exceed three weeks.	
3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall communicate to the interested Member States its decision on whether it agrees, or not, to facilitate the proposed initiative within three weeks of receiving the request.	

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4. If the Commission declines the request, it shall provide reasons for the refusal.	
5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the interested Member States. The Commission shall facilitate communication and cooperation between the involved Member States and provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products.	BE (Drafting suggestions): 5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the interested Member States. The Commission shall facilitate communication and cooperation between the involved Member States and provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products. **In this context, the Commission may propose the use of an unilingual procedure in a commonly understood language to facilitate administrative coordination.** **The Commission and participating Member States shall also take into account packaging and labelling requirements when designing the procurement strategy.** BE (Comments): To facilitate procedures, the framework should also allow for a shared language for procurement processes, including the possibility of publishing tenders in a single commonly understood language among the

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	participating Member States. This would simplify administrative procedures while maintaining transparency. Additionally, the proposal should account for the specificities of the pharmaceutical market, where product presentations often differ between countries due to the limited use of multi-country packaging.
6. The facilitation offered by the Commission shall be limited in time and end at the latest upon signature of the procurement contract by the participating contracting authorities.	
7. The Commission shall not be responsible, nor held liable, for any breaches of Union or national procurement laws by the participating contracting authorities. The Commission shall not bear any liability associated with the conduct of the procurement procedure by interested Member States and implementation of the contract resulting from the procedure.	
Article 22	DE

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	(Drafting suggestions): ~~**Article 22**~~ DE (Comments): We suggest deleting articles 22 and 23. Rationale (manifold): In our view, 3 different processes provide for unnecessary bureaucratic burden. In addition, we are not supportive of the usage of Union funding outside of crises times (Art 23), as this is touching upon the competences of the MS (Art. 168, para 7 TFEU). Furthermore, we see a particular risk for critical medicines, which often are generics, for a concentration on few suppliers, which runs counter to the CMA's aims to diversify supply chains. As the collaborative procurement as delineated in Art 22 and 23 is also exclusive with procurement at national level, in order to unfold the full potential of the CMA's goals via measures in Art 18&19, those 2 articles (namely, Art. 22 and 23) warrant deletion. In our view, Art. 21 is best suited to address access problems.
	CY (Comments): .
Commission procurement on behalf of or in the name of Member States	BG (Comments):

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	Given the lack of an impact assessment combined with the proposed legal basis (Art. 114 TFEU), Bulgaria cannot support Art. 22 and Art. 23. We note the absence of any analysis that can justify the introduction of procedures, which will predictably result in price convergence, pressure and circumvention of national pricing and reimbursement rules. It is unclear how the likely side effects on non-participating countries (both in terms of supply and affordability), and on smaller manufacturers (unable to satisfy a big demand) will be addressed. Furthermore, the fact that the negotiator is detached from the fulfilment of the negotiated obligations will predictably result in contracts that are suboptimal for the Member States. Concrete safeguards are needed both in order to make sure that participation is indeed voluntary, and that the above-mentioned predictable problems are addressed. As long as these questions are not addressed by an impact assessment or a staff working document of a satisfying quality, and Art. 168 TFEU is not added to the legal basis, we cannot support none of the two articles; only Art. 21 is acceptable. Should these questions receive a satisfying answer, we are open to discuss Art. 22 with the proposed amendments.
1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where nine or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission may initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below;	CY (Comments): Cyprus maintains its position in favour of reducing the minimum number of participating MS from nine to three CZ (Drafting suggestions):

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	1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where ~~nine~~ three or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission ~~may~~shall initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below; CZ (Comments): CZ supports the idea to decrease the number of Member States which may request the Commission to procure on their behalf from 9 to 3. CZ believes the Commission should automatically initiate a procurement procedure according to this Article if the Member States request the Commission to do so once the conditions of this Article have been met. Alternatively, specific conditions in which Commission can refuse to do so should be set in this text. Please see the changes in wording proposed. EE (Drafting suggestions): 1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where **three** or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission may initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below; EE (Comments):

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	Requiring at least nine Member States to trigger this mechanism may limit its practical usability, especially for smaller Member States seeking to coordinate targeted purchases (e.g. for rare diseases or region-specific products). LT (Comments): LT: We welcome, in principle, the provisions promoting collaborative public procurement, the right of Member States to join joint procurements of critical medicinal products and medicinal products of common interest, after assessing the situation. However, we have doubts about envisaged requirement for the participation of nine Member States. It remains unclear why was this specific number selected.
	AT (Drafting suggestions): 1a. When requesting the Commission to act in accordance with paragraph 1 of this Article, Member States' contracting authorities shall be deemed to have complied with the requirements laid down in Directive 2014/24/EU, including where a contracting authority receives the medicinal products from the contracting authority requesting the Commission to procure on its behalf. AT (Comments):

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	Where the procurement procedure is conducted according to the Financial Regulation, it is necessary to provide that contracting authorities are considered to have fulfilled the requirements of Directive 2014/24/EU where they participate in such a joint procurement, whether they are directly participating in the procurement procedure or receiving the medicinal products from a participating national contracting authority (otherwise everyone would need to sign the contract; functionally, the signing contracting authority acts as an ad hoc central purchasing body). Consider that when in paragraph 1 the Member State is mentioned, it ultimately acts as a contracting authority requesting another contracting authority to act on its behalf. Text suggestion taken from Council position on EDIP, Article 19a and 21aa.
(a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;	IT (Comments): For this category, we would support a common procurement initiative on a voluntary basis
(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [3], or which have undergone a clinical assessment carried out under the	BG (Drafting suggestions): ~~(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [4], or which have undergone a clinical assessment carried out under the~~

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

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

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voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.	~~voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.~~ BG (Comments): We cannot support an extension of the scope beyond "critical medicines". CY (Comments): Cyprus continues to request that the scope be broadened to include all medicinal products assessed under the HTA R that is, all medicinal products for which Joint Clinical Assessment report will be issued. In this regards Cyprus aligns with the Commission argument. CZ (Comments): CZ considers the joint clinical assessment (JCA) condition too strict as there is a limited number of evaluators in the JCA and JCA only gradually covers the intended scope of the Regulation 2021/2282 of the European Parliament and the Council. Therefore, CZ suggests establishing as the condition only clinical assessment from one Member State while other Member States may decide if they will participate in a collaborative procurement in the context of this evaluation or not. This comment is also relevant for Article 23 para 2 letter b). IT (Comments): Firstly, and in particular with reference to the procedures provided for by the HTA Regulation (2021/2282), we would like to highlight the risk that such collaborative procurement mechanisms could lead to the

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	establishment of a sort of European reference price, thereby reducing the negotiating power of Member States that do not participate. This could have negative repercussions on the negotiation procedures of non-participating Member States, as well as adverse effects on public spending for the purchase of medicines and on market competition, potentially favoring excessive concentration among a few economic operators. Another critical issue concerns the possible link between collaborative procurements and the procedures provided for by the HTA Regulation (2021/2282): the risk is that, through the extension of the definition of "medicinal products of common interest," the scope of such procurements could be excessively broadened. We would prefer limiting the utilization of this provision to medicinal products for rare and ultra-rare diseases. MT's (Comments): MT would like to ask how the Joint Clinical Assessment (JCA) may impact HTA regulation, related Member States obligations and national processes? It is pertinent to note that a JCA is a scientific document tackling relative effectiveness; other aspects of HTA (e.g. financial implications, organisational and legal issues) are however tackled at the national level. Still every EU Member State has obligations to make use of these JCAs in their national HTA process to support the national decision-making procedures and report back on their use.

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Commission proposal	Drafting suggestions and Comments
	CZ (Drafting suggestions): New para 1 subpara 2. The Commission may decline the request only based on if the request by the Member States does not meet the conditions set in this Article. CZ (Comments): In accordance with the CZ comment above on Article 21 para 1, please see the changes in wording proposed.
2. The joint request referred to in paragraph 1 shall only be made where the medicinal product concerned fulfils one of the criteria set out in that paragraph and if the requested procurement procedure will help to improve the security of supply and availability of critical medicinal products in the Union or ensure the availability and accessibility of medicinal products of common interest, as applicable.	BG (Drafting suggestions): 2. The joint request referred to in paragraph 1 shall only be made where the medicinal product concerned fulfils one of the criteria set out in that paragraph and if the requested procurement procedure will help to improve the security of supply, ~~and~~ availability **and affordability** of critical medicinal products in the Union. ~~or ensure the availability and accessibility of medicinal products of common interest, as applicable.~~ LT (Comments): LT: The question arises as to how the criterion that public procurement procedure will help to improve the security of supply and availability of critical medicinal products and ensure the availability of medicinal products of common interest should be applied. We believe it would be

Commission proposal	Drafting suggestions and Comments
	appropriate to provide more detailed provisions regarding its implementation.
3. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request, through the Critical Medicines Group, and invite them to join the procedure.	
	BE (Drafting suggestions): **3a. To ensure efficient coordination and execution, the Commission may, with the agreement of the participating Member States, conduct the procedure in a commonly understood language.** **The Commission shall also take into account packaging and labelling considerations, including the absence of multi-country packaging, and may reflect such constraints in the tender specifications.** BE (Comments): See comment art. 21

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	BG (Drafting suggestions): **New paragraph.** **4. All interested Member States within one month of the request should inform the Commission about the quantities needed to cover their patients' needs on national level.** BG (Comments): There should be sufficient time for national decision making. The needs of the Member States should be determined by them.
4. The Commission shall assess the utility, necessity and proportionality of the request and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	
5. The Commission shall inform the interested Member States within one month of the request of its decision and state its reasons in case of a refusal.	BG (Drafting suggestions): **Within one month of the receipt of the information on the quantities requested by the Member States,** the Commission shall **summarise the information and** inform the interested Member States ~~**of the request**~~ of its decision and state its reasons in case of a refusal.

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Commission proposal	Drafting suggestions and Comments
6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.	BG (Drafting suggestions): ~~**If in light of the Commission assessment, it is necessary,**~~ In order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the **interested** Member States ~~**or to agree to minimum binding quantities**~~, the Commission agreement to pursue the procedure may be conditioned upon acceptance of **certain** ~~these~~ conditions by interested Member States. CY (Comments): In response to the Commission, Cyprus expresses concerns regarding the minimum procurement quantity for instance in the case of orphan medicines or products with high or very high cost. Cyprus would support a proportional approach to defining the quantity.
7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509[5].	
Article 23	BG (Drafting suggestions):

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

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Commission proposal	Drafting suggestions and Comments
	~~*Article 23*~~ DE (Drafting suggestions): ~~**Article 23**~~ DE (Comments): See above for explanation
Joint Procurement	BG (Drafting suggestions): ~~*Joint Procurement*~~
1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least nine Member States may engage, as contracting parties, in a joint procurement procedure.	BG (Drafting suggestions): ~~1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least nine Member States may engage, as contracting parties, in a joint procurement procedure.~~ CY (Comments): Cyprus maintains its position in favour of reducing the minimum number of participating MS from nine to three CZ

Commission proposal	Drafting suggestions and Comments
	(Drafting suggestions): 1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least ~~nine~~ three Member States may engage, as contracting parties, in a joint procurement procedure. CZ (Comments): CZ supports the idea to decrease the number of Member States which may request the Commission to engage in joint procurement procedure from 9 to 3. Please see the changes in wording proposed. EE (Drafting suggestions): 1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least **three** Member States may engage, as contracting parties, in a joint procurement procedure. EE (Comments): A lower threshold would be more consistent with existing EU joint procurement rules for MCM and enhance responsiveness. FI (Comments):

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	Access to national procurement critical to security of supply should be ensured, as the pricing of medicines and reimbursement of medicines fall within national competence, decisions on them should be made nationally, regardless of possible joint procurement, taking into account, for example, treatment practices and the funds available for pharmaceutical costs. LT (Comments): LT: We have doubts about envisaged requirement for the participation of nine Member States. It remains unclear why was this specific number selected. MT's (Comments): Malta supports the inclusion of this legal basis, yet it considers the requirement of 9 participating Member State excessive. The nine smallest MS have an aggregated population of 19 million and they vary from Malta having 563,000 to Ireland having 5,343,800, that is ten times more populated. The realities are substantially different and the market viabilities of the two is not comparable. Whilst it is understood that the Commission is concerned that a smaller group of MS would not be attractive to industry, one should also consider that there is no plan B other than to leave the Member State to procure the product individually, which is even less attractive to the industry. Malta proposed a dual requirement of 3 members states with a minimum population of 3 Million.

Commission proposal	Drafting suggestions and Comments
	It is also important that this article is better linked to the access incentives within the regulatory framework.
	AT (Drafting suggestions): 1a. When requesting the Commission to act in accordance with paragraph 1 of this Article, Member States' contracting authorities shall be deemed to have complied with the requirements laid down in Directive 2014/24/EU, including where a contracting authority receives the medicinal products from the contracting authority participating in the joint procurement procedure. AT (Comments): See explanation above.
2. A joint procurement procedure may be organised following a request by the Member States or at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below:	BG (Drafting suggestions): ~~2. A joint procurement procedure may be organised following a request by the Member States or at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below:~~ CZ (Drafting suggestions): 2. A joint procurement procedure ~~may~~shall be organised following a request by the Member States or may be organised at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below: CZ

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Commission proposal	Drafting suggestions and Comments
	(Comments): In accordance with the CZ comment on Article 21 para 1 above, please see the changes in wording proposed.
(a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;	BG (Drafting suggestions): ~~(a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;~~
(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [6], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.	BG (Drafting suggestions): ~~(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [7], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.~~ CY (Comments): Cyprus continues to request that the scope be broadened to include all med which Joint Clinical Assessment report will be issued. In this regards Cyp

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

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

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Commission proposal	Drafting suggestions and Comments
	CZ (Comments): CZ considers the JCA condition too strict as there is a limited number of evaluators in the JCA and JCA only gradually covers the intended scope of the Regulation 2021/2282 of the European Parliament and the Council. Therefore, CZ suggests establishing as the condition only clinical assessment from one Member State while other Member States may decide if they will participate in a collaborative procurement in the context of this evaluation or not. This comment is also relevant for Article 22 para 1 letter b). MT's (Comments): MT would like to ask how the Joint Clinical Assessment (JCA) may impact HTA regulation, related MSs obligations and national processes? It is pertinent to note that a JCA is a scientific document tackling relative effectiveness; other aspects of HTA (e.g. financial implications, organisational and legal issues) are however tackled at the national level. Still every EU Member State has obligations to make use of these JCAs in their national HTA process to support the national decision-making procedures and report back on their use.
	CZ (Drafting suggestions):

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Commission proposal	Drafting suggestions and Comments
	New para 2 subpara 2. The Commission may decline the request only if the request by the Member States does not meet the conditions set in this Article. CZ (Comments): In accordance with the CZ comment on Article 21 para 1 above, please see the changes in wording proposed.
3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply and availability of critical medicinal products in the Union or ensure the availability and accessibility of medicinal products of common interest, as applicable.	BG (Drafting suggestions): ~~3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply and availability of critical medicinal products in the Union or ensure the availability and accessibility of medicinal products of common interest, as applicable.~~ LT (Comments): LT: The question arises as to how the criterion that public procurement procedure will help to improve the security of supply and availability of critical medicinal products and ensure the availability of medicinal products of common interest should be applied. We believe it would be appropriate to provide more detailed provisions regarding its implementation.

Commission proposal	Drafting suggestions and Comments
4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure.	BG (Drafting suggestions): ~~4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure.~~
	BE (Drafting suggestions): **4a. With the agreement of participating Member States, the joint procurement procedure may be carried out in a commonly understood language.** **The Commission shall consider packaging and labelling barriers, including the lack of multi-country packaging, when preparing the procurement documents and shall, where appropriate, include relevant requirements or criteria in the tendering process.** BE (Comments): See comment art. 21
5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	BG (Drafting suggestions): ~~5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.~~

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Commission proposal	Drafting suggestions and Comments
6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.	BG (Drafting suggestions): ~~6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.~~ CY (Comments): In response to the Commission, Cyprus expresses concerns regarding the minimum procurement quantity for instance in the case of orphan medicines or products with high or very high cost. Cyprus would support a proportional approach to defining the quantity.
7. The Commission shall inform the interested Member States within one month of the request of its decision and state its reasons in case of a refusal.	BG (Drafting suggestions): ~~7. The Commission shall inform the interested Member States within one month of the request of its decision and state its reasons in case of a refusal.~~
8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.	BG (Drafting suggestions): ~~8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.~~

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Commission proposal	Drafting suggestions and Comments
Article 24	DE (Drafting suggestions): ~~**Article 24**~~ DE (Comments): Deletion of article 24 as a consequence of deletion of Art. 22 &23
Agreement concerning procedures under Articles 22 and 23	
1. Member States participating in the procurement procedures covered by Articles 22 and 23 shall share with the Commission any information relevant for the procurement procedure. Member States shall provide resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge.	FI (Comments): Member States resources should also be ensured
2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process.	BE (Drafting suggestions):

Commission proposal	Drafting suggestions and Comments
	2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. **The agreement may specify the use of a commonly understood language and the approach to be taken regarding packaging and labelling requirements for the effective implementation of the procedure** BE (Comments): See comment article 21

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