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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 I, II, V, VI and VIII of the Critical Medicines Act (ST 6872/25).

Critical Medicines Act – Chapter I, II, V, VI and VIII Deadline: ***29 July 2025***

From: AT, BE, BG, CZ, EE, ES, FI, FR, HU, IT, LU, LV, MT, SI **Updated: 31/07/2025 16:37**

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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): BG reiterates its concern regarding the proposed legal basis of the proposal. Art. 114 TFEU suggests harmonisation in an area, where harmonisation is explicitly excluded by the Treaties (s. Art. 168 (5) and (7)). The aim of the proposal: to strengthen security of supply and availability in particular by supporting manufacturers of certain products may be a legitimate goal in the current global situation; however the idea that the Union can utilize the national healthcare budgets for industrial support is a goal neither legally, nor ethically justifiable. The Union can only act within the limits of the powers conferred upon it by the Treaties: the aforementioned distribution and redirection of national health budgets for priorities other than those identified at national level contradicts in particular the requirement that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care", as well as the exclusion of the management of health services and medical care and the allocation of the resources assigned to them from Union competence (Art. 168 TFEU).

Commission proposal	Drafting suggestions and Comments
	National healthcare budgets are tailored to national needs and resources available: supporting industrial goals with these anyways limited health funds with drain the systems from resources for other health priorities. In some Member States this will further deprive the health system from funds, and result in less access. The good intentions behind some measures in the proposal, namely, to resolve issues that some Member states face, cannot serve to circumvent the primary law restrictions and confer powers on the Commission in areas where the Union has no competence. The level that is capable of most effectively addressing these matters remains the national level. If the Union genuinely wishes to support manufacturers of critical medicinal products, this should be done by common EU budget line, not at the expense of national health budgets. The extension of the scope with the vague notion "products of common interest" is particularly unjustified and disproportionate in that context. It implies difficulties of legal and practical nature in unpredictable scale, not backed by any impact assessment. Joint tender procedures will restrict national autonomy on decisions on amounts and prices. On the one hand, one could expect price harmonisation, supply limitations and pressure on prices for non-participating countries etc.). On the other hand, there is a risk of limiting competition by driving out of the market smaller manufacturers, with limited production capacity. In case of countries with lower GDP this will negatively impact affordability and hence result in less access, even in case of increased supply. Bulgaria therefore horizontally does not support extension of the scope beyond critical medicines, and requests the deletion of the additional category "medicines of common interest" from all related provisions, incl. definitions. We note that the absence of this category does in no way prevent cooperation as attested by several ongoing regional cooperation initiatives. The inclusion of this category in the scope, en revanche, leads

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Commission proposal	Drafting suggestions and Comments
	to legality problems, implications on competences, as well as practical issues that can undermine the main purpose of an act supposed to be focused on critical medicines. We expect an in-depth analysis in the SWD on the experiences so far, and realistic assessment of the expected positive and the negative effects (such as the ones described above). FR (Comments): The French authorities would like to ask the Presidency to consider having the working group of the MSSG presenting the planned vulnerability assessment methodology in one of the future meetings of the WPPMD. From the last few meetings, it seems that Member States do not share the same level of information on this crucial element of the regulation. The methodology is expected in October and will be presented to the MSSG before the end of the year.
Chapter I **General provisions**	
Article 1	LV (Comments): We would like to emphasize that for us it is very important to retain medicinal products of common interest within the scope of the CMA.

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Commission proposal	Drafting suggestions and Comments
Objectives and subject matter	
1. The objective of this Regulation is to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.	BG (Drafting suggestions): 1. The objective of this Regulation is to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the security of the Union. ~~The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.~~ **This Regulation is without prejudice to Member States responsibilities in healthcare, including pricing and reimbursement and other policies that are part of the management of health services and medical care as well as the allocation of human and budgetary resources at national level.** BG (Comments): The introduction of objectives that go beyond the strict provision of critical medicinal products, in particular "improving the availability and accessibility of other medicinal products, where the functioning of the market does not ensure sufficient availability and accessibility", is not justified and will lead to interference in national health policies. This will compromise the usual supply chain of medicinal products delivery. Bulgaria insists the objectives to be refined and to be focused solely on critical medicinal products and to avoid expanding the scope without

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	adequate legal justification and impact assessment on national health budgets. FR (Drafting suggestions): The objective of this Regulation is to strengthen the security of supply and the availability of critical medicinal products within the Union, notably by reducing critical dependencies, thereby ensuring a high level of public health protection and supporting the security of the Union. FR (Comments): As stated during the WPPMD, the French authorities would like to encourage the reduction of dependencies in the supply for critical medicines. France sees it as a valuable means to reach this regulation's objectives. IT (Comments): IT COMMENT: IT welcomes the general objectives of the proposal, but shares some concerns about the inclusion of the collaborative procurement procedures referred to in point (c). IT would like to reiterate the need for collaborative procurement procedures to be mainly used in specific situations to address difficulties in ensuring the availability and access to medicines, also in light of recital 32. Additionally, the use of existing instruments, such as the procurement framework, could be strengthened. LU (Drafting suggestions): The objective of this Regulation is to strengthen the security of supply**,** ~~**and**~~ the availability **and the free movement** of critical medicinal products within the ~~**Union**~~ **internal market**, thereby ensuring a high level

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	of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products. LU (Comments): LU believes that the legal basis for the proposal, namely Article 114 TFEU, must be reflected in the objective of the text. Article 114 TFEU aims at the convergence of the laws of the Member States with a view to improving the functioning of the internal market. This is supported by recital 8 of the proposal, which emphasises the importance of avoiding the disruption of the internal market and the need for greater harmonisation. Consequently, such a reference should be included in Article 1. MT (Drafting suggestions): The objective of this Regulation is to strengthen **access and** the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products. MT

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Commission proposal	Drafting suggestions and Comments
	(Comments): Measures such as the public service obligations which may be imposed on the Market Authorisation holder are intended to improve access.
2. To achieve the objectives referred to in paragraph 1, the Regulation sets out a framework to:	
(a) facilitate investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union;	FR (Drafting suggestions): facilitate investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union that contribute to reducing dependencies and diversifying supply. FR (Comments): Similar rationale to the comment above. IT (Drafting suggestions): (a) facilitate investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union, ***reducing dependencies on foreign sources***; IT (Comments): IT COMMENT: IT supports the need to reduce dependencies from third countries, by the increasing production in the EU.

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Commission proposal	Drafting suggestions and Comments
(b) lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures of critical medicinal products and other medicinal products of common interest;	
	CZ (Drafting suggestions): ba) strengthen the availability of medicinal products by harmonising the principles related to contingency stock of medicinal products in order to prevent shortages and ensure transparency among Member States in this area; CZ (Comments): CZ is of the opinion that the Article on objectives and subject matter should also include strengthening the availability of medicinal products by harmonising the principles related to contingency stock of medicinal products in order to prevent shortages and ensure transparency among Member States in this area. Unlike other parts of the draft Regulation this topic has been left out of this Article. Please see the proposed text.
(c) leverage the aggregated demand of participating Member States through collaborative procurement procedures, and	

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Commission proposal	Drafting suggestions and Comments
(d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.	
Article 2	LV (Comments): We would like to emphasize that it is very important for us to retain medicinal products of common interest within the scope of the CMA. At the same time, we agree that the text should more clearly specify which provisions apply to each category of medicinal products, or to both.
Scope	
1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products referred to in Article 131 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final].	BG (Comments): There is a need to clarify and specify to which critical medicinal products does the Regulation apply.
2. Chapter IV and Article 26(2) point (c) also apply to medicinal products of common interest. Chapter III does not apply to medicinal products of common interest.	AT (Drafting suggestions): AT:

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	2. Chapter IV and Article 26(2) point (c) also apply to medicinal products of common interest ***as defined in Article 3(5)***. Chapter III does not apply to medicinal products of common interest. AT (Comments): AT: without a common understanding/legal definition "medicinal product of common interest" could be defined in several different ways depending on the context. Therefore, it is considered important to be specific, which is why we suggest adding the phrase "as defined in Article 3(5)" in this paragraph BE (Drafting suggestions): 2. Chapter IV and Article 26(2) point (c) also apply to medicinal products of common interest. ~~Chapter III does not apply to medicinal products of common interest.~~ BE (Comments): Scope is not precise enough. It is paramount that this article is 100% clear. If only Chapter IV and Article 26(2), point c) apply then it is unnecessary and confusing to specify that Chapter III does not apply. BG (Drafting suggestions): ~~2. Chapter IV and Article 26(2) point (c) also apply to medicinal products of common interest. Chapter III does not apply to medicinal products of common interest.~~ BG

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	(Comments): S. general comments above. CZ (Drafting suggestions): 2. ~~Chapter IV and Article 26(2) point (c) also apply to medicinal products of common interest.~~ This Regulation applies to medicinal products of common interest, except for Chapter III ~~does not apply to medicinal products of common interest~~. CZ (Comments): From the CZ perspective, it is important to clarify that this paragraph is related to medicinal products of common interest. The paragraph sets out both a positive and a negative list, and these provisions do not completely overlap, which could subsequently make the draft Regulation difficult to interpret and implement. CZ considers it appropriate to indicate which Chapters/Articles apply to medicinal products of common interest. Please see the proposed text. HU (Comments): HU considers it necessary to clearly define what provisions of the CMA will cover medicinal products of common interest. During the WPPMD meeting on July 23-24, the Commission informed the MSs that in regard of Chapters not stipulated in paragraph 2, the MSs will decide on a case by case basis whether these provisions will be applied on medicinal products of common interest. HU does not believe that it is a workable solution. We consider it necessary to clearly define when and how CMA will apply to medicinal products of common interest. Also, it is necessary

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	to create consistency through the text: for example, paragraph 2 states that Chapter IV on Demand side measures applies to medicinal products of common interest, but it does not stipulate the situation of Chapter V on Critical Medicines Group, even though the Group has competency in collaborative procurements. IT (Comments): IT COMMENT: With reference to paragraph 2, IT would like to reiterate its concerns regarding the application of the provisions of Chapter IV to medicinal products of common interest. In fact, we see the risk that, by including 'medicinal products of common interest' as defined in Article 3(5) below, the scope of procurement will become excessively broad. IT therefore prefers to limit the application of the provisions of Chapter IV to medicines for rare and ultra-rare diseases. Alternatively, IT would like the definition of medicinal products of common interest to be limited in its scope. Please see comment to Art. 3(5). MT (Drafting suggestions): ~~**Chapter IV and Article 26(2) point (c) also apply to medicinal products of common interest.**~~ Chapter III does not apply to medicinal products of common interest. MT (Comments): The deleted text is not required and creates confusion since this paragraph mentions what is in the scope and what is not. So, it raises questions on the status of the rest of the text.

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Article 3	HU (Comments): HU declares scrutiny reservation on all the definitions, as many definitions refers to the Pharmaceutical Package, which is still under negotiation
Definitions	
For the purpose of this Regulation, the following definitions shall apply:	IT (Comments): IT COMMENT: Preliminarily, IT would like to reiterate that the definitions contained in this proposal need to be in line with those of the pharmaceutical package, given the direct link between such legislative acts.
(1) 'medicinal product' means a medicinal product as defined in Article 4 point (1) of Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];	
(2) 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including primary packaging materials, excipients, solvents and reagents;	FR (Comments):

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	The French authorities believe it is relevant to further clarify which key inputs are most critical and relevant in the context of critical medicines manufacturing. A useful lever would be to use the MSSG and the ongoing work on the methodology to assess supply chain vulnerabilities to inform on most critical key inputs. In any case, such clarification should also be made in article 5 related to the eligibility of strategic projects.
(3) 'active substance' means an active substance as defined in Article 4 point (3) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];	
(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];	BE (Drafting suggestions): (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]; BE (Comments): The definition defines the term and makes a reference to the pharma package. Both are identical. We only need one and in order to ensure

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	coherence between the pharma package and the CMA it would be better to align with the definition under the pharma framework. BG (Comments): The discussions demonstrated that there is a need to clarify and agree on the notion of "critical medicinal products". IT (Drafting suggestions): (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; IT (Comments): IT COMMENT: IT would like to stress the need for the definition of 'critical medicinal product' included herein to be identical to that in the pharmaceutical package. In addition, the definition should be such as to generate a more limited list compared with the current one. SI (Comments): SI highlights the importance to have a clear and workable definition of a critical medicinal product, as it plays a key role in the triggering of measures in CMA.
(5) 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which in three or	AT (Drafting suggestions):

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more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States;	AT: 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States ***and there is no alternative treatment option available on the market of the respective Member States;*** AT (Comments): AT: to ensure a clear scope that is not too broad, we suggest adding the phrase "*and there is no alternative treatment option available on the market of the respective Member States*" BG (Drafting suggestions): ~~(5) 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States;~~ BG (Comments): S. general comments above. We understand the willingness from several Member States to transfer the responsibility for solutions of national problems at Union level, but we note that this is a legally questionable approach in an area where the

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	Union lacks competence. The "Internal market" in the area of pharmaceuticals is different from other markets, given the immense public finding, tailored to national priorities. The ECJ recognises clearly that limitations are possible in order to protect public health. Medicines are not ordinary goods. We disagree on a shift of competences, and reiterate the identifiable problems that will likely arise for other Member States in terms of supply and affordability, and for competition, incl. smaller manufacturers. CZ (Comments): In relation to the medicinal products of common interest, CZ considers it important to clarify the process of determining a medicinal product of common interest and where their list will be published at the EU level. When a Member State decides that a medicinal product meets the criteria (the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients), they should inform the Commission. If the Commission is informed by three or more Member States in case of a certain medicinal product, they shall communicate such information to the Member States and release the information publicly so that the concerned stakeholders are also informed. Please see the wording suggested in the new Article 3a below. Alternatively, an EU platform could be created to enable sharing of this kind of information between Member States and the stakeholders concerned as well. IT (Comments):

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	IT COMMENT: IT is of the opinion that the definition of 'medicinal products of common interest' may be too broad and should therefore be redefined (e.g. by increasing the minimum number of reporting Member States) or totally reconsidered. Please also see comment to Art. 2 para. 2. LV (Comments): We support the definition and the concept of medicinal products of common interest as outlined in the text, and we request that it be retained within the scope of the CMA to enable voluntary joint procurements. MT (Drafting suggestions): (5) medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which in ~~**three**~~ **two** or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States MT (Comments): Malta holds that support in long term collaborative procurement should be made available even when there is a request from two Member States. This should not be limited to one product but should lead to a more structured form of cooperation. Once there is set up for collaborative procurement between two Member States, this set-up may be used for the procurement of several products. SI (Drafting suggestions):

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	'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which in ~~**three**~~ **two** or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States; SI (Comments): SI highlights the importance to have a clear and workable definition of a medicinal product of common interest, as it plays a key role in the triggering of measures in CMA. SI considers that two or more Member States is more appropriate.
(6) 'vulnerability in the supply chains' means risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level, taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation, that compromise the continuous supply of such medicinal products to patients in the Union;	
(7) 'vulnerability evaluation' means the evaluation of the supply chains of critical medicinal products to identify their vulnerabilities performed by the MSSG in accordance with Regulation (EU) …/… of the	IT (Comments): IT COMMENT: IT would like to reiterate that in the vulnerability evaluation, the involvement of MSs should be strengthened. In addition, the concepts of 'criticality' and 'vulnerability' should remain separate but

Commission proposal	Drafting suggestions and Comments
European Parliament and of the Council1 [reference to be added after adoption cf. COM(2023) 193 final];	still related. It is also worth specifying that, in the context of the vulnerability evaluation, both structural and non-structural vulnerabilities in industrial supply chains should be taken into account and applied to the list of critical medicines. It should be noted that the above-described concepts need to be reflected in the pharmaceutical package, requiring consistency among the three legislative acts.
(8) 'common name' means a common name as defined in Article 4 point (48) of Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];	
(9) 'contracting authorities' means contracting authorities as defined in Article 2(1) point (1) of Directive 2014/24/EU;	
(10) 'strategic project' means an industrial project identified pursuant to the criteria set out in Article 5;	EE (Drafting suggestions): 'strategic project' means an industrial project designated pursuant to the criteria set out in Article 5 and Article 6;

[1] Regulation (EU) …. of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ …) *[D.G.: Title according to COM(2023) 193 final. Please check against latest version of this draft Regulation]*.

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Commission proposal	Drafting suggestions and Comments
	EE (Comments): For legal clarity, the strategic project should be defined as a project that meets the criteria in Article 5 and has been verified by the designated authority in accordance with Article 6.
(11) 'project promoter' means any undertaking or consortium of undertakings developing a strategic project;	
(12) 'permit granting process' means a process covering all relevant permits to build and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures;	FR (Drafting suggestions): (12) 'permit granting process' means a process covering all relevant permits to build and operate a strategic project, including but not limited to: building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures; FR (Comments): This amendment should ensure that, if any Member State requires permits beyond those explicitly listed, a strategic project promoter can still benefit from regulatory support.
(13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology,	FR (Drafting suggestions):

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including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform techniques, 3D manufacturing;	innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform techniques, 3D manufacturing, new synthetic routes, bioprocessing, process analytical technologies
(15) 'Member States' cross-border procurement' means a procurement procedure initiated between the contracting authorities from different Member States on the basis of Article 39 of Directive 2014/24/EC;	
(16) 'procurement on behalf of or in the name of the Member States' means a procurement procedure initiated at the request of Member States and mandating the Commission to act as a central purchasing body on behalf of, or in the name of, the requesting Member States, as provided for in Article 168(3) of Regulation (EU) 2024/2509;	BG (Drafting suggestions): ~~(16) 'procurement on behalf of or in the name of the Member States' means a procurement procedure initiated at the request of Member States and mandating the Commission to act as a central purchasing body on behalf of, or in the name of, the requesting Member States, as provided for in Article 168(3) of Regulation (EU) 2024/2509;~~ BG (Comments): In line with our comments on Chapter IV and in particular – the deletion of Art. 22 and Art. 23.

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Commission proposal	Drafting suggestions and Comments
(17) 'joint procurement' means a procurement procedure carried out jointly by the Commission and Member States, as provided for in Article 168(2) of Regulation (EU) 2024/2509;	BG (Drafting suggestions): ~~(17) 'joint procurement' means a procurement procedure carried out jointly by the Commission and Member States, as provided for in Article 168(2) of Regulation (EU) 2024/2509;~~ BG (Comments): S. above. LU (Comments): The reference to Article 168(2) of Regulation 2024/2509 does not seem appropriate, insofar as this provision does not define what a 'joint procurement' is, but describes the procedures to be followed in the context of this type of public procurement. Furthermore, Regulation 2024/2509 does not provide an explicit definition of this concept.
(18) 'supplier' means the manufacturer or marketing authorisation holder of finished dosage forms, or manufacturer of key inputs or active substances;	
(19) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products	

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Commission proposal	Drafting suggestions and Comments
that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation.	
	CZ (Drafting suggestions): (20) “contingency stock” means the contingency stock of mandated supplier of critical medicinal products and medicinal products of common interest when there is a requirement imposed by an authority (such as a government or regulatory body), but the responsibility for maintaining and owning the stock remains with the supplier, and the contingency stock of critical medicinal products and medicinal products of common interest 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) (21) ‘manufacturing capacity in the Union” means (22) ‘significant proportion of manufacture of critical medicinal product in the Union’ means CZ (Comments): CZ considers it necessary to define contingency stock as the term is not uniformly interpreted across the Member States and the EU institutions.

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Commission proposal	Drafting suggestions and Comments
	To ensure the clarity of the text and its consequent applicability, CZ is in general of the opinion that the manufacture of medicines in the EU and its significant part should be defined in relation to strategic projects, financial incentives and public procurement. Please see the proposed text. Apart from that, CZ will send a proposal for the definition (point 21 and 22) related to manufacture in the EU at the later stage. ES (Drafting suggestions): **(20 new) '<u>supply disruption</u>' means the unexpected significant decrease in the availability of a critical medicine.** ES (Comments): Regulation (UE) 2024/1252 on Raw materials
	CZ (Drafting suggestions): *Article 3a* *Determining medicinal products of common interest* 1. When a Member State decides that the functioning of the market does not sufficiently ensure the availability and accessibility of a medicinal products to patients in the quantities and presentations necessary to cover the needs of patients they shall inform the Commission. 2. When the Commission is informed according to paragraph 1 by three or more Member States in case of a certain medicinal product they shall communicate such information to the Member States.

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	3. The Commission shall publish and update a list of medicinal products of common interest on its website. CZ (Comments): Please see the CZ comment related to the Article 3 para 5 above. ES (Drafting suggestions): **(21 new) '<u>critical medicines supply chain</u>' means all activities and processes of the critical medicines value chain up to the point where a critical medicine is used as an input for the manufacturing of intermediate or final products.** ES (Comments): Regulation (UE) 2024/1252 on Raw materials LU (Drafting suggestions): Article 3a *Free movement* Member States shall not prohibit, restrict or impede, for reasons relating to the aspects covered by this Regulation, the making available on the market of critical medicines and other medicinal products within the scope of this Regulation which comply with this Regulation. LU (Comments): LU regrets the absence of a free movement clause, given that this proposal is based on Article 114 TFEU and that one of its objectives is to

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	'*strengthen […] the availability of critical medicinal products within the Union'* and to '*improve the availability and accessibility of other medicinal products'*. In order to fulfil the objectives of this Regulation, namely to ensure the accessibility of critical medicinal products and other medicinal products throughout the Union, we suggest the insertion of a new Article 3a.
	ES (Drafting suggestions): **(22 new) '<u>national contingency stock requirements'</u>: an obligation imposed on one or several supply chain actors to establish buffer stocks of certain medicines in order to cover the consumption needs at a national level during a certain period of time and therefore mitigate the risk of supply disruption.** ES (Comments): A distinction should be drawn between 'national contingency stock requirements' imposed to supply chain actors to mitigate a risk of supply disruption/shortage and national, regional and or local 'stockpiling' of medicines by a (public) health institution in order to anticipate and manage a specific crisis. Maybe explore the possibility of including definition on shortages included of the GPL?
Chapter II **Strengthening the Union's security of supply**	
Article 4	BG

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Commission proposal	Drafting suggestions and Comments
	(Drafting suggestions): ~~*Article 4*~~ BG (Comments): The aim of this article is unclear. We suggest to move it in the preamble, with clear reference to the division of competences between the Union and the Member States when it comes to healthcare policy.
Strategic objective of the Union	BG (Drafting suggestions): ~~*Strategic objective of the Union*~~ CZ (Comments): In general, CZ supports ensuring the security of supply and availability of medicinal products for all EU patients, not only within the framework of the draft Regulation. Therefore, it is needed to properly link it to the Pharmaceutical Package.
1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.	BG (Drafting suggestions): ~~1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.~~ EE (Drafting suggestions):

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Commission proposal	Drafting suggestions and Comments
	The security of supply, accessibility and availability of critical medicinal products for patients is a strategic objective of the Union. EE (Comments): We support adding improving access to medicines as a strategic objective of the Union. ES (Drafting suggestions): 1. The security of supply, **access** and availability of critical medicinal products for patients is a strategic objective of the Union. ES (Comments): We propose a reference to access. LV (Comments): We would like to express our support for the Maltese delegation's proposal to include equal access to medicinal products across the Union as part of the Union's strategic objectives. MT (Drafting suggestions): 1. **Access, availability, affordability and** the security of supply and ~~availability~~ of critical medicinal products ~~**for**~~ ***serving the needs of*** patients ***within all Member States*** is a strategic objective of the Union MT (Comments):

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Commission proposal	Drafting suggestions and Comments
	These principles reflect objectives set by the Member State in several council conclusions and should be reflected within this article.
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.	BG (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.~~ EE (Drafting suggestions): 2. The Member States and the Commission shall work together to strengthen the security of supply, accessibility and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. ES (Comments): It is necessary to respect the division of competemcies between Member States and the Commission. FR (Drafting suggestions): NEW: The Commission shall support the coordinated efforts of the Members States to strengthen the security of supply and continuous availability of

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Commission proposal	Drafting suggestions and Comments
	critical medicinal products in the Union through measures that take full advantage of the potential of the internal market FR (Comments): The French authorities support a clear wording regarding the respective competences of the European Union and the Member States. Frances recalls that the Commission acts in support of the coordinated efforts of the Member States.
3. The Commission shall support the coordinated efforts of the Members States.	BG (Drafting suggestions): ~~3. The Commission shall support the coordinated efforts of the Members States.~~ FR (Drafting suggestions): DELETED
	BE (Drafting suggestions): **Article 17** BE (Comments): Was discussed on the 23/07 but concerns chapter III.
	BE (Drafting suggestions):

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Commission proposal	Drafting suggestions and Comments
	1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article 24 of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article 25. 2. The Commission shall inform periodically the Critical Medicines Group of the strategic projects that benefited from financial support from the Union. The Commission **shall proactively and in a timely manner** inform the Critical Medicines Group of the intention to propose the establishment of funding possibilities specifically designed to address vulnerabilities in the supply chains as well as inform of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes. BE (Comments): . The Commission should not limit itself to periodic or retrospective updates to the Critical Medicines Group on which strategic projects have received Union funding (as outlined in Article 17), but should also communicate its funding intentions proactively and in a timely manner. This only concerns an intention, there is no commitment here, there is no problem to share it with the Critical medicines groups. Also, this is an obligation for the MS, so there is logic to align the wording between §1 and §2.

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Commission proposal	Drafting suggestions and Comments
Chapter V **Critical Medicines Coordination Group**	SI (Comments): SI supports the establishment of the Critical Medicines Coordination group as we believe that the group can make an important contribution to better coordinate between MS and EC in implementing measures to ensure the uninterrupted supply of critical medicines. Nevertheless, SI still believes that the role of CMCG members should be more clearly defined. As it currently stands the role of MS is described as consultative without clearly defined decision-making or voting mechanisms. SI would propose greater formalisation of the role of MS, particularly in the formulation of common positions and decisions that influence strategic orientations.
Article 25	
Establishment of Critical Medicines Coordination Group	BG (Comments): We are expecting an in-depth analysis of the need and the concrete mandate of this new expert group, given the potential of duplications and overlaps with existing new fora created in the recent years. National administrations are under pressure to remain limited in number; the

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	similar tasks performed by different Commission fora result in pressure on same experts, and demotivation. IT (Comments): IT COMMENT: IT has a scrutiny reservation on Articles 25 and 26 related to the establishment and tasks of the Critical Medicines Coordination Group. In particular, IT sees the potential for duplication and overlapping of competences as well as for adding complexity, given the existence of entities that are already vested with similar tasks. There could also be the risk of potential misalignments in the evaluation and management of identical/similar cases. IT would like to point out that the experts that make up MSSG, SPOC and potentially the Critical Medicines Coordination Group are often the same. As an alternative to the establishment of a new group, it is suggested to set up a sub-group, with the proposed composition, within one of the existing coordination groups. LV (Comments): We remain cautious regarding the establishment of a new coordination platform, as there is a risk of overlapping competencies and duplicating existing efforts. As a small Member State, we face challenges in allocating resources across numerous platforms. Should a new structure be deemed necessary, we would call for a thorough review and mapping of existing groups and their mandates, with a view to streamlining and potentially reducing the overall number of coordination platforms/ groups.

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Commission proposal	Drafting suggestions and Comments
1. A Critical Medicines Coordination Group ('Critical Medicines Group') is hereby established.	
2. The Member States and the Commission are Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status.	CZ (Comments): CZ welcomes the establishment of a Critical Medicines Coordination Group and the possibility to appoint different representatives to cover different tasks of such platform. ES (Drafting suggestions): The Member States and the Commission are Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the ~~expertise relevant~~ **capacity** for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status. ES (Comments): It would be essential that the members of the group have the capacity to make decisions regarding the proposed measures. Additionally, a cross-cutting perspective is necessary to enable them to identify the impact that any measure may have on access to medicines.

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Commission proposal	Drafting suggestions and Comments
	FI (Comments): The sentence "Appointed permanent representatives shall ensure the necessary coordination within their respective Member State" seems superfluous since it is up to the Member States to decide what the internal responsibilities of the representatives are. LU (Comments): The second sentence of paragraph 2 provides for the appointment of two high-level permanent representatives per Member State. The following sentence then states that several other representatives may be appointed according to their function or expertise. It is difficult to distinguish the role of the high-level permanent representatives from that of the other representatives. The respective roles should be clarified, or a broader provision should be included allowing each permanent representative to be assisted by experts appointed by the Member States. SI (Comments): SI believes that given the broad scope of the group's tasks – covering various aspects of health-related policies – it could be difficult for smaller MS, like SI, to provide permanent representatives with the appropriate multidisciplinary expertise. SI proposes the possibility of systematically involving additional experts depending on the topic under discussion, while ensuring the effectiveness of CMCGs work.

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Commission proposal	Drafting suggestions and Comments
3. The Critical Medicines Group shall work closely with the MSSG, the Agency, and national authorities responsible for medicinal products. For discussions where input from the medicines regulatory authorities' perspective is necessary, the Critical Medicines Group may organise joint meetings with the MSSG.	HU (Comments): Hungary supports the provisions of Section (3) of Article 25. We consider it important to involve the pharmaceutical authorities in the work of the Critical Medicines Group.
4. The Commission shall organise and coordinate the work of the Critical Medicines Group by means of the Secretariat.	ES (Comments): We consider necessary to define the functions of the Commission as a secretariat and ensure that it will have the necessary resources to carry them out. FR (Drafting suggestions): NEW: The Commission shall define, along with the Member States, the group's rules of procedure. FR (Comments): This addition echoes a proposal made during the WPPMD. The French authorities further stress that these rules should also build on existing procedures (where relevant) to ensure that there are no specific conflicts of interest for members sitting on this committee.

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Commission proposal	Drafting suggestions and Comments
5. A representative of the Commission shall chair the meetings of the Critical Medicines Group.	BG (Comments): We note that the chairmanship by the Commission does not support the claim that this is Member States driven group. CZ (Drafting suggestions): 5. A representative of the Member States and a representative of the Commission shall co-chair the meetings of the Critical Medicines Group. CZ (Comments): CZ would like to include a Member States´ representative as a co-chair. The position of chair of coordination groups in other areas is also divided between the European Commission and the Member States. Please see the proposed text. ES (Drafting suggestions): A representative of ~~the Commission~~ **a Member State, nominated by the members of the Critical Medicines Group**, shall chair the meetings of the Critical Medicines Group. **In addition, a vice-chair shall be nominated by the Member States to support the chair in the performance of their duties.** ES (Comments): The leadership of the group should lie with the Member States, given that most of the proposed measures must be implemented at the national level

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Commission proposal	Drafting suggestions and Comments
	and have a direct impact on access to medicines, a responsibility that primarily falls within the competence of the Member States. FI (Comments): FI would also be in favour of a shared chair, since the task of the Critical Medicines Group is to facilitate exchange and coordination between the Member States. HU (Comments): We recommend considering having the group chaired by a Member State, possibly co-chaired with the Commission.
6. The Critical Medicines Group, at the proposal of the Chair or any its members, may decide to establish a working group.	CZ (Drafting suggestions): 6. The Critical Medicines Group, at the proposal of the co-chair or any its members, may decide to establish a working group. CZ (Comments): Related to the CZ comment on Article 25 para 5 above. Please see the proposed text.
7. The Critical Medicines Group shall use its best endeavours to reach consensus, where possible. Members with diverging positions may	BG (Comments): In order to determine the appropriate procedure, it is necessary to agree on the mandate and the tasks of the group. i.e. discussions and exchanges

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Commission proposal	Drafting suggestions and Comments
request that their positions and the grounds on which they are based be recorded in the Critical Medicines Group's position.	or opinions and recommendations. We note that the group, if created, is supposed to support Member States, not only the Commission. CZ (Drafting suggestions): 7. The Critical Medicines Group shall use its best endeavours to reach consensus. ~~, where possible. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the Critical Medicines Group's position.~~ CZ (Comments): CZ is of the opinion that the Member States should focus on reaching consensus. Therefore, CZ does not support the proposed wording. Please see the proposed amendment that also corresponds with other sectoral EU legislation. FI (Comments): The task of the Critical Medicines Group is to facilitate exchange and coordination between the Member States. It should be specified in what situations there is a need to reach consensus. The current wording of the tasks does not make it clear and there is no need for decision making. HU (Comments): We believe that the role of the group needs to be better defined, primarily on what issues it can make decisions.

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Commission proposal	Drafting suggestions and Comments
Article 26	
Tasks of the Critical Medicines Coordination Group	IT (Comments): IT COMMENT: Please see comment to Art. 25. As indicated, IT maintains a scrutiny reservation to further examine the scope of the powers and tasks attributed to the Critical Medicines Coordination Group. SI (Comments): SI is of the opinion that some of the functions assumed by the group may overlap with existing structures and instruments (e.g. HERA, EMA, Steering Group on Medicines Shortages), and therefore proposed a more precise division of responsibilities to Article to avoid duplication and ensure effective cooperation.
1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission, so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market.	BG (Drafting suggestions): 1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission, so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market **or on national healthcare systems**. BG (Comments):

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	There are predictable effects on national healthcare (incl. pharmaceutical) policies and budgets.
2. In order to attain the objectives referred to in paragraph 1, the Critical Medicines Group shall perform the following tasks:	
(a) facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security and availability of critical medicinal products within the Union;	BG (Drafting suggestions): facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security and availability of critical medicinal products within the Union, **while ensuring that such financial support does not burden national healthcare budgets and is primarily sourced from common EU budget lines.** BG (Comments): This task is unclear: what does “facilitate coordination on strategic orientation of the financial support” mean? Funding in support of strategic projects should in our view be provided through common European funds, rather at the expense of national healthcare budgets, which are allocated for specific national healthcare needs. The benefit of the exchange could be from learning about funding possibilities at Union level and experiences shared by other Member States.

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Commission proposal	Drafting suggestions and Comments
	CZ (Drafting suggestions): (a) facilitate coordination based on the Union investment strategy for critical medicinal products on strategic orientation of the financial support for strategic projects, including by exchanging information on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security and availability of critical medicinal products within the Union; CZ (Comments): CZ finds it important to clearly set the competence of Critical Medicines Group. The Critical Medicines Group should be able to coordinate the financial support of strategic projects to fulfil the Union investment strategy for critical medicinal products. Moreover, the Union investment strategy for critical medicinal products should among other include the fact that the financial support should be only approved if the manufacture in the EU does not cover the needs of the EU patients. Please see the text proposed. EE (Drafting suggestions): Add: providing guidance on the application of criteria as set out in Article 5 EE (Comments):

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Commission proposal	Drafting suggestions and Comments
	In addition to strategic orientation, we propose to add guidance on criteria set out in Art 5 for designation of strategic projects to ensure uniform application and to assist the national authorities. FI (Comments): According to para 2 (a) the Critical Medicines Group shall exchange information on the manufacturing capacity for a given critical medicinal product, existing or planned. This kind of information would typically be seen as trade secret. Are there enough safeguards in the Article to ensure that only absolutely necessary information is exchanged? FR (Drafting suggestions): Facilitate coordination on strategic orientation of the financial support for strategic projects, including by reporting on the deployment of national and European funding, exchanging information on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security, sustainability and availability of key inputs, active substances and critical medicinal products within the Union FR (Comments): The French authorities see it as coherent that the CMG plays a role in exchanging information on funding at both national (as per article 15) and European funding.

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Commission proposal	Drafting suggestions and Comments
(b) facilitate exchanges on the national programmes referred to in Article 19 and enable cooperation on and coordination of Member States public procurement policies with regard to critical medicinal products;	BG (Drafting suggestions): (b) facilitate exchanges on the national programmes referred to in Article 19 ~~and enable cooperation~~ on ~~and coordination of~~ Member States public procurement policies with regard to critical medicinal products, **without prejudice to national competences;** BG (Comments): We propose to limit the exchange to best practice solutions that may inspire national policies, rather than to create a burdensome reporting mechanism of no clear value, or attempt coordination of procurement policies. National procurements are adapted to national needs and budgets: the purpose of these procedures is not alignment with Union level goals but with patients' needs at national level. CZ (Drafting suggestions): (b) facilitate exchanges on the national programmes referred to in Article 19 and enable cooperation on and coordination of Member States public procurement policies with regard to critical medicinal products and medicinal products of common interest; CZ (Comments): Based on the current wording of Article 2 para 2, CZ is of the opinion that Article 19 (as part of Chapter IV) also applies to medicinal products of common interest. Therefore, CZ proposes to add medicinal products of common interest also in this para, unless they will not be covered by Article

Commission proposal	Drafting suggestions and Comments
	2 para 2 as proposed above (that would be the most preferred option). Please see the text proposed. As stated above, it is needed to clarify the Articles that apply to medicinal products of common interest. EE (Drafting suggestions): (b) facilitate exchanges on the national measures ~~referred to in Article 19~~ and enable cooperation on and coordination of Member States public procurement policies with regard to critical medicinal products; EE (Comments): We have doubts about the added value of stand-alone national programmes and propose to use a more general wording. ES (Drafting suggestions): facilitate exchanges on the national programmes referred to in Article 19 and enable **coherence** ~~cooperation on and coordination~~ of Member States public procurement policies **aiming to attain the objectives of this Regulation** ~~with regard to critical medicinal products~~ ES (Comments): The terms 'cooperation' and 'coordination' may suggest the need to reach joint agreements, whereas in reality, public procurement is a national competence. Therefore, it is more appropriate to refer to the need to promote coherence among national policies, while fully respecting the competences of the Member States.

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Commission proposal	Drafting suggestions and Comments
	Additionally, the last sentence is a minor change, but we believe it is more accurate.
(c) facilitate discussion of the need for a collaborative procurement initiative for a given medicinal product;	EE (Comments): What would be the delineation of responsibilities with the current structures under the Joint Procurement Agreement? Could JPA structures be used to carry out practical implementation of collaborative procurement? Since procurement related expertise already exists in the JPA Steering Committee, this could be used also for collaborative procurements under the CMA. It would ensure more efficient use of resources at the national level and avoid duplication between the two instruments. MT (Drafting suggestions): (c) facilitate discussion of the need for a collaborative procurement initiative **~~for a given medicinal product;~~** MT (Comments): This should not be restricted to a single product since this is intended to support initiatives such as BENELUXA which is intended for different purchases.

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Commission proposal	Drafting suggestions and Comments
(d) advise the MSSG to provide the order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of existing evaluations where necessary.	EE (Comments): Consistency and interplay with the general pharmaceutical legislation needs to be clarified. According to the Draft Regulation Art 130 (1) (b), the MSSG will decide on the priorities based on a common methodology to be developed by EMA.
3. The Critical Medicines Group shall enable the exchanges of information between the Member States and the Commission as referred to in Article 17 and shall enable, where necessary, a coordination of respective actions aiming to attain the objectives of this Regulation.	BG (Drafting suggestions): 3. The Critical Medicines Group shall enable the exchanges of information between the Member States and the Commission as referred to in Article 17 ~~and shall enable, where necessary, a coordination of respective actions aiming to attain the objectives of this Regulation.~~ BG (Comments): The goal of this coordination of "respective actions" is unclear.
4. The Critical Medicines Group shall periodically discuss the potential contribution of strategic partnerships to the objectives of this Regulation, prioritisation of third countries for this purpose, and the consistency and potential synergies between Member States' cooperation with relevant third countries and the actions carried out by the Union.	FR (Drafting suggestions): In accordance with the mandate set out in Article 27 of this Regulation, the Commission shall consult the Critical Medicines Group (CMG) on potential strategic partnerships. This consultation shall cover, but not be limited to, the following areas: the potential contribution of strategic partnerships to the objectives of this Regulation, the prioritisation of third countries for this purpose, and the consistency and potential synergies

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	between Member States' cooperation with relevant third countries and the actions carried out by the Union FR (Comments): The French authorities emphasize that the expertise of the Group's members regarding critical medicines is a valuable asset, and their consultation would help to increase transparency and the visibility of these initiatives in the eyes of the Member States.
5. The Critical Medicines Group, at the Commission's request, may provide an opinion on matters related to the application of this Regulation in the context of performing tasks as referred to in this Article.	BG (Drafting suggestions): ~~5. The Critical Medicines Group, at the Commission's request, may provide an opinion on matters related to the application of this Regulation in the context of performing tasks as referred to in this Article.~~ BG (Comments): We disagree with the proposal for "opinions" on Commission request on a file of such a broad scope and measures, including such that may have an impact on national competences. ES (Drafting suggestions): The Critical Medicines Group, at the Commission's request **or at the request of any Member State,** may provide an opinion on matters related to the application of this Regulation in the context of performing tasks as referred to in this Article.

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	ES (Comments): We would like to include that opinions be given not only at the request of the COM, but also at the request of one or more Member States. FI (Comments): It is a bit unclear, what the legal status or significance of the coordination group's opinion is? According to article 25 para 7 the coordination group should try to reach consensus, which refers to decision-making. However, the tasks in para 2 do not require legal decision-making. If the main tasks are exchanging information and coordination between MS, what is the opinion for? We think there is a need to clarify. If there is a need in specified cases for an opinion of the Critical Medicines Group it should be considered whether the Member States should also have the right to request for it.
Chapter VI **International cooperation**	

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Commission proposal	Drafting suggestions and Comments
Article 27	
Strategic partnerships	
Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union.	ES (Comments): Commission can act on its own initiative, and we would like to add that the Commission acts at the request of the Coordination Group or at the request of one or more Member States. In our opinion, the Commission's action should be carried out at least in communication with the Critical Medicines Group. DGCyF - We view this proposal positively. However, we believe it is necessary to clarify the mechanism of interaction and communication between the Commission and the Critical Medicines Group in relation to this article. In particular, it would be helpful to specify whether the Commission acts on its own initiative, at the request of the Group, or whether it is required to report to the Group. In our opinion, the Commission's actions should be carried out, at a minimum, in communication with the Critical Medicines Group. FR (Drafting suggestions): Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal

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	products in the Union. The Commission shall also consider building shall also explore the possibility of building on existing forms of cooperation, where appropriate, to enhance security of supply. LU (Comments): In the first sentence, the reference '*to increase the security of supply of critical medicinal products in the Union'* is redundant, as this is the general objective of the proposed regulation. Article 1 states that '*The objective of this Regulation is to strengthen the security of supply and availability of critical medicinal products within the Union*.'
	CZ (Drafting suggestions): 2. Third countries are allowed to participate in the collaborative procurement according to Articles 21, 22 and 23. Third countries shall not change the conditions of the collaborative procurement set by the Member States or Commission. CZ (Comments): Additionally, CZ supports the inclusion of the third countries into the collaborative procurement mechanism (similarly to the EP amendment in 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*). CZ is of the opinion that these third countries could join the collaborative procurement while not interfering with the set conditions. This approach

Commission proposal	Drafting suggestions and Comments
	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 third countries and it could strengthen bilateral relations as well. This comment was sent by CZ after WPPMD on July 3rd and 4th. Please see the text proposed.
Chapter VIII **Final provisions**	CZ (Comments): CZ is of the opinion that the draft Regulation should also include transitional provisions, for example in the area of public procurement (e.g. transitional provisions for the purposes of ongoing procurement procedures, in particular concluded framework agreements and dynamic purchasing systems).

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Commission proposal	Drafting suggestions and Comments
Article 29	HU (Comments): HU agrees with other MSs on that it needs to be better defined what information marketing authorisation holders need to provide and how the information will be provided. We also consider that the text need to stipulate how to handle market secrets, for example: on what basis Commission and national authorities will decide whether the confidentiality claims are merited or not. Also, which stakeholder will make the final decision on confidentiality claims? The Commission or the national authorities?
Obligation of the market actors to provide information	
1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation.	AT (Drafting suggestions): AT: 1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation, **unless this information can be obtained via existing databases.** AT (Comments):

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	AT: we strongly support more transparency in the supply chain, e.g. by reference to already established databases (ESMP). Usage of existing databases is strongly encouraged ("interoperability"), any additional bureaucracy or duplications should be avoided. BG (Drafting suggestions): 1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances ~~or medicinal products of common interest~~ shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation. CZ (Drafting suggestions): 1. Marketing authorisation holders and other ~~economic operators~~ actors in the supply and distribution chains of critical medicinal products or medicinal products of common interest including their key inputs and active substances ~~or medicinal products of common interest~~ shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation. CZ (Comments): CZ believes that marketing authorisation holders and other economic operators in the supply and distribution chains should provide information about key inputs and API also in relation to the medicinal products of

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Commission proposal	Drafting suggestions and Comments
	common interest, not only in a case of critical medicines. Please see the text proposed. Apart from that, CZ is of the opinion that the wording in the draft Regulation and the Pharmaceutical Package should be aligned. Therefore, we propose to change "other economic operators" to "other actors" as stated in Article 129 of draft Regulation in the Pharmaceutical Package. ES (Drafting suggestions): Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation. **In addition, they shall provide the Commission or the relevant national authorities, upon request, with comprehensive information on any financial support received pursuant to this Regulation.** ES (Comments): This information may be relevant for decision-making at the national level. In particular, it may have an impact on pricing and reimbursement decisions adopted at the national level. FI (Comments): The obligation to give information is very broad. There is need to clarify. In addition, it should be assessed whether such an extensive obligation could risk reducing the attractiveness of the EU market.

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Commission proposal	Drafting suggestions and Comments
	FR (Drafting suggestions): Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission, the Agency, the MSSG or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation FR (Comments): The Agency and the MSSG play a central role in the implementation of this Regulation. The Agency is responsible for maintaining the Union list of critical medicines and providing regulatory and scientific advice (as outlined in Article 11), while the MSSG conducts vulnerability evaluation. It is therefore appropriate to empower these bodies to request information from market operators when necessary. LU (Comments): The '*Other economic operators in the supply and distribution chains'* are not defined in Article 3. It is difficult to determine which economic operators are covered by this concept, given that the proposal does not provide individual definitions (importers, distributors). Furthermore, paragraph 18 of Article 3 provides the following definition of '*supplier'*: '*means the manufacturer or marketing authorisation holder of finished dosage forms, or manufacturer of key inputs or active substances*'. Are '*manufacturers of finished dosage forms*' and '*manufacturers of key inputs or active substances*' included in the concept of '*other economic operators in the supply and distribution chains"*? If so, why not simply

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Commission proposal	Drafting suggestions and Comments
	refer to the '*suppliers*'? If this concept covers other economic operators, which ones are they and why are they not defined in Article 3? MT (Drafting suggestions): 1. **The European Medicines Verification Organisation (EMVO),** Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation. MT (Comments): We should avoid the duplication of efforts and make best use of available data. The EMVS collects reliable EU aggregated data which should also be made available for the purposes of this regulation. Furthermore, we should reduce administrative burdens on operators as much as possible and provide clear timeframes. We should also make it clear that this should not result in duplication of requests under different legislation since we have similar provisions in the pharmaceutical legislation.
2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.	BG (Drafting suggestions): 2. The Commission ~~and national authorities of the Member States~~ shall ~~aim to~~ avoid duplication of the information requested and submitted **at Union level**.

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Commission proposal	Drafting suggestions and Comments
3. The Commission and national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other economic operators, requested to provide information per paragraph 1, and shall protect any information that is commercially confidential against unjustified disclosure.	AT (Comments): . CZ (Drafting suggestions): 3. The Commission and national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other actors, ~~economic operators~~, requested to provide information per paragraph 1, and shall protect any information that is commercially confidential against unjustified disclosure. CZ (Comments): Please see the CZ comment related to Article 29, para 1 above and a text proposed. FI (Comments): What is meant by "unjustified disclosure"? Are there enough safeguards to protect confidential information.
	CZ (Drafting suggestions): *Article 29a* *Penalties*

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Commission proposal	Drafting suggestions and Comments
	Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. CZ (Comments): CZ is of the opinion that an article which states that the Member States are obligated to set penalties at national level should also be added. We believe that without establishment of penalties, for example in the case of an obligation stated in the Article 29, the negative impact on the market may occur. Please see the text proposed.
Article 30	
Evaluation	
1. By *[OP please insert the date of:]* five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.	

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Commission proposal	Drafting suggestions and Comments
2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1 have been achieved.	BG (Comments): Given our negative opinion on the very broad scope proposed (not backed by Impact Assessment, but with predictable impact on national competences) we are open to include a possibility for amendment of scope based on the evaluation of the implementation of the Regulation. At the current point of time however, practice (including with HERA pilots) does not suggest scaling-up of any successful joint procurement.
3. The national authorities and the economic operators shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1.	BG (Drafting suggestions): 3. The national authorities and the economic operators shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1. **The requests should be limited to what is necessary to evaluate the effect of the concrete measures, and should in any case not include information about national decision making within competences of Member States, such as pricing and reimbursement, national negotiations or sensitive pubic procurement information.** MT (Comments): Kindly refer to the previous comment.

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Commission proposal	Drafting suggestions and Comments
Article 31	CZ (Comments): In general, CZ would like to emphasize that the draft Regulation should state the applicability of the Regulation taking into account the interconnection with the Pharmaceutical Package.
Entry into force and application	
This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	AT (Drafting suggestions): AT: This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. It shall apply from [….]. **Articles 18 shall apply from [6/12 months after entry into force]**. This Regulation shall be binding in its entirety and directly applicable in all Member States AT (Comments): AT: Article 31 does not provide for a legislative vacancy concerning Article 18. In a procurement procedure, as a rule, the provisions in force at the time of the commencement of a procurement procedure are to be applied (cf. CJEU 14.1.2021, C-387/19, *RTS Infra and Aannemingsbedrijf Norree-Behaegel*). Without legislative vacancy

Commission proposal	Drafting suggestions and Comments
	established in the CMA or without a transitional provision, complex legal issues will arise or it could happen that ongoing procurement procedures would have to be discontinued (with the consequence of damages). It will be impossible to establish "*resilience templates*" if the CMA should be applicable within a short timeframe. Furthermore it will be essential to disseminate this information to all contracting authorities concerned. Accordingly, a legislative vacancy or a transitional provision must be included regarding Article 18 and enough time must be provided for the MS to prepare for the implementation of Art. 18. BG (Comments): We suggest to revise the timelines at the final stages of negotiations, given the need for a realistic timeframe for implementation and coherence with other legislative proposals.
It shall apply from [….].	
This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Done at Strasbourg,	

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Commission proposal	Drafting suggestions and Comments
For the European Parliament *For the Council*	
The President *The President*	