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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 additional comments from the delegations 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: DE, IE, LT, RO **Updated: 11/08/2025 11:39**

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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	
Chapter I **General provisions**	
Article 1	
Objectives and subject matter	RO (Comments): RO appreciates and aims to ensure a high level of public health protection, thus clearly supports the CMA objective of strengthening the security of supply and availability of critical medicines, which is essential for protecting public health throughout the Union.

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Commission proposal	Drafting suggestions and Comments
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.	IE (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 **of common interest**, 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. IE (Comments): IE supports the reference to 'affordability'. Suggested edit to include 'of common interest' to ensure alignment with other articles that follow. RO (Drafting suggestions): 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. **This regulation also aims to establish a**

Commission proposal	Drafting suggestions and Comments
	coordinated EU approach to national policies aimed at preventing shortages of critical medicines and avoid disruptive measures across the EU. 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. **The regulation shall also support the Union's competitiveness in the area of critical medicines and promote targeted, evidence-based industrial and access policies which contribute to an effective ecosystem for steady and resilient supply of critical medicines.** RO (Comments): This links the Regulation to supporting a strong, competitive pharmaceutical sector-essential for innovation, investment, and supply resilience – while promoting targeted, evidence-based policies that avoid harming patient access or disrupting medicine availability.
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;	RO (Comments): As regards the mechanisms to facilitate investment in manufacturing capacity, including the provision of financing sources or incentives to manufacturers, RO considers it important that they are clarified and

Commission proposal	Drafting suggestions and Comments
	transparent, so that their implementation can be carried out without difficulties, taking into account that Union mechanisms will be combined with national mechanisms
(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;	
(c) leverage the aggregated demand of participating Member States through collaborative procurement procedures, and	RO (Comments): RO believes that joint procurement procedures need to be clarified and the ACM needs to ensure that accessibility remains a priority while increasing availability, with specific measures to balance these two objectives.
(d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.	RO (Comments): RO considers it important to define clear and firm criteria for identifying and establishing strategic partnerships, ensuring that these collaborations are effective in improving supply chain security.
Article 2	

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Commission proposal	Drafting suggestions and Comments
Scope	LT (Comments): LT: We support the inclusion of common interest medicinal products within the scope of the CMA. However, to ensure consistent implementation and legal clarity, we believe it necessary to clearly specify which provisions of the CMA would apply to these products and which would be exempt.
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].	
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.	
Article 3	
Definitions	IE

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Commission proposal	Drafting suggestions and Comments
	(Comments): Overall, IE notes the requirement to align definitions across the regulations and between the CMA and the Pharma Package LT (Comments): LT: To ensure legal clarity and avoid any confusion with the "emergency stock", we support the proposal to define the term "contingency stocks", taking into account Article 20 of the CMA, where such stocks are mentioned. RO (Comments): The inclusion of clear definitions of terms is essential to ensure a common understanding among all stakeholders involved in the implementation of the Regulation. The definitions provided serve as a fundamental aspect of the Regulation, establishing a common language that all stakeholders need to understand and respect for effective and rapid implementation. The CMA should clarify that all definitions will be aligned with existing EU directives (normative acts) to ensure consistency of interpretation.
	RO (Comments): RO supports the introduction of a clear definition for the concept of "list of vulnerable medicines", as follows from the vulnerability assessment methodology defined in the CMA Strategic Report, this list will include medicines with specific fragilities in the supply chain, by harmonizing the national critical lists with the EU critical list.

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Commission proposal	Drafting suggestions and Comments
For the purpose of this Regulation, the following definitions shall apply:	
(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;	DE (Drafting suggestions): 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including **starting materials for production of active ingredients or excipients,** primary packaging materials, excipients, solvents and reagents DE (Comments): For completeness IE (Comments): IE considers the proposed definition 'key input' to be very broad and would include any raw material used in the manufacture of a medicinal product. IE therefore suggests a more targeted approach focussing primarily on critical raw materials used in medicinal products that are specialised or not widely available.

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Commission proposal	Drafting suggestions and Comments
(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];	DE (Drafting suggestions): 'critical medicinal product' means a medicinal product **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]~~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]~~**; DE (Comments): We prefer an unambiguous definition related to "the list" in the Pharma package. This should be used consistently throughout the text. LT (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]; LT

Commission proposal	Drafting suggestions and Comments
	(Comments): LT: To ensure legal clarity regarding the reference to critical medicinal products, as defined in Article 4(13) of the Regulation under the EU pharmaceutical legislation revision (Pharmaceutical Package), we propose to delete the highlighted insertion and retain only the reference to that Regulation.
(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;	
(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;	DE (Drafting suggestions): '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 **or similar** route of administration and formulation, that compromise the continuous supply of such medicinal products to patients in the Union; DE (Comments):

Commission proposal	Drafting suggestions and Comments
	In our view, the vulnerability analysis should be limited to critical medicinal products for which there are no alternatives. Therefore, medicinal products with comparable routes of administration and formulations should also be included if there are no clinically relevant differences. This prevents irrelevant vulnerability analyses from being conducted. RO (Comments): The definition of "vulnerability in supply chains" emphasizes the need for a proactive assessment of potential risks, which is essential for maintaining a steady supply of medicines. The process for conducting a "vulnerability assessment" should be clearly defined, detailing how the MSSG will assess risks and deficiencies in critical medicines supply chains.
(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 European Parliament and of the Council1 [reference to be added after adoption cf. COM(2023) 193 final];	RO (Drafting suggestions): vulnerability evaluation' means the evaluation of the supply chains of critical medicinal products to identify their vulnerabilities **taking in consideration shortages in the past 2 years, the products' complexities, specific characteristics and respecting EU international commitments** performed by the MSSG in **consultation with the respective marketing authorisation holders and** in accordance with

[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
	Regulation (EU) …/… of the European Parliament and of the Council2 [reference to be added after adoption cf. COM(2023) 193 final. RO (Comments): This addition ensures the vulnerability evaluation is timely, focused and globally compliant. Considering recent shortages and product complexities highlights real-world risks and identifies fragile supply chains. Factoring in specific characteristics ensures critical medicines are prioritized while respecting international commitments safeguards the EU's legal obligations.
(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;	

[2] 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
(10) 'strategic project' means an industrial project identified pursuant to the criteria set out in Article 5;	
(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;	
(13) '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;	

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Commission proposal	Drafting suggestions and Comments
(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;	
(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;	
(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	

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Commission proposal	Drafting suggestions and Comments
to increase cooperation related to one or more critical medicinal products 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.	
	RO (Comments): RO reiterates the importance of having a unified framework for managing stocks (derived from the storage obligation provided for in Art 18 - Stimulating resilience, sustainability and positive social impact in public procurement procedures paragraph 1) to ensure fair distribution and prevent waste.
	RO (Comments): In addition, RO supports the introduction of a clear, separate definition for "emergency stocks" (referred to in Art 20). According to the Strategic Report of the Alliance for Critical Medicines, there is the mandatory emergency stock of the supplier, when there is a requirement imposed by an authority - government or a regulatory body, but the responsibility for maintaining and holding the stock remains with the supplier; a "buffer stock" at the supplier level, through which it practically ensures that it complies with the supply requirements at the level of each MS; emergency stocks made, managed and controlled by Member States or the EU related to supply chain disruptions and the prevention of shortages of medicines, practically a "buffer stock" at local/regional/EU level; and strategic reserves of Member States or the EU intended for use in emergency situations, e.g. health threats, natural disasters, economic crises.

Commission proposal	Drafting suggestions and Comments
	Thus, these "emergency stocks" should be clearly defined and taken into account without limiting the phase of the product (unfinished or finished medicine) that is stored, the ownership of the stored product or the existence of financial compensation for holding and managing the emergency stock (unfinished or primary packaged medicine allows for high reallocation flexibility and supports the prevention of waste, while maintaining patient safety). RO supports the introduction of the definition of "insufficient availability" expressed in a period of time, according to this Regulation for the clear and correct understanding of the term critical medicine and the replacement of the phrase in the definition of medicine of common interest from "in three or more Member States" with "in at least three Member States".
Chapter II **Strengthening the Union's security of supply**	
Article 4	DE (Comments): We would like to add the reduction of supply dependencies from outside the EU concerning the production of critical medicinal products as additional strategic objective. The article should specify the role of the COM and the Member States respecting the responsibilities.

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Commission proposal	Drafting suggestions and Comments
	In addition: we would like to add an article targeting exemptions related to national security and defense, as indicated in the template for Chapters III & VII
Strategic objective of the Union	
1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.	IE (Drafting suggestions): The security of supply**, ~~and~~** availability **and affordability** of critical medicinal products for patients is a strategic objective of the Union. IE (Comments): IE supports referencing 'affordability' here.
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.	RO (Comments): The commitment to collaboration between Member States and the Commission signifies the desire for a unified approach to supply chain challenges, which is essential to achieve the objectives of the Regulation. RO considers collaboration between MS essential to maximise the effect of measures and to avoid unwanted effects on internal markets, but the fragmented national legislative framework needs to be harmonised to streamline processes.

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Commission proposal	Drafting suggestions and Comments
	RO believes that the ACM should detail how the potential of the internal market will be fully exploited, including any proposed frameworks or incentives that will facilitate this process.
3. The Commission shall support the coordinated efforts of the Members States.	RO (Comments): The Commission's role in supporting coordinated efforts between Member States is essential to ensure that initiatives are implemented effectively and aligned with the objectives of the Regulation, and the mechanisms through which the Commission will support coordinated efforts of Member States should be explicitly defined to ensure clarity of roles and responsibilities.
Chapter V **Critical Medicines Coordination Group**	
Article 25	

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Commission proposal	Drafting suggestions and Comments
Establishment of Critical Medicines Coordination Group	
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.	IE (Drafting suggestions): 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,~~ As necessary,** Member States may appoint **additional expert representatives in order to support the ~~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 IE (Comments):

Commission proposal	Drafting suggestions and Comments
	In establishing membership of the CMG, IE notes the appointment of a maximum of two permanent representatives by each MS. In order to allow for the most appropriate expert input, we welcome local coordination of additional expert input and suggest that this is more explicitly referenced in Article 25 (2). RO (Comments): The appointment of high-level permanent representatives from Member States to the Critical Medicines Coordination Group ensures a broad range of expertise, allowing for informed decisions that take into account different perspectives in the management of critical medicines.
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.	RO (Comments): The role of the Critical Medicines Coordination Group in facilitating strategic financial support and cooperative procurement policies is vital to strengthening the EU's overall capacity to manage critical medicines, with an impact on security of supply. The emphasis on consensus within the Critical Medicines Coordination Group promotes a collaborative environment, encouraging diverse perspectives to be taken into account while working towards common goals in the management of critical medicines.
4. The Commission shall organise and coordinate the work of the Critical Medicines Group by means of the Secretariat.	

Commission proposal	Drafting suggestions and Comments
5. A representative of the Commission shall chair the meetings of the Critical Medicines Group.	DE (Drafting suggestions): A representative of the Commission **and a representative of the Member States** shall **co-**chair the meetings of the Critical Medicines Group. DE (Comments): This reflects better, in our opinion, the remit of the coordination group's tasks IE (Comments): IE notes concerns raised by other MS that the chair role should be shared between MS and the Commission. IE is open to considering the rationale for both proposals.
6. The Critical Medicines Group, at the proposal of the Chair or any its members, may decide to establish a working group.	
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.	IE (Comments): It remains unclear what circumstances might arise which would require voting within the CMG. Further clarity is required in circumstances where a majority vote within the CMG is not supported at national level, taking into consideration that various elements of the CMA relate to some distinct areas of national competence.

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Commission proposal	Drafting suggestions and Comments
Article 26	
Tasks of the Critical Medicines Coordination Group	RO (Comments): Although there are overlapping objectives, the MSSG and the Critical Medicines Coordination Group have distinct roles. The MSSG focuses on the operational aspects of monitoring medicine shortages and ensuring safety, while the Medicines Coordination Group operates at the strategic level, overseeing long-term initiatives and financial planning. The role of the Medicines Coordination Group in advising the MSSG on the prioritization of critical medicines for vulnerability assessments highlights a structured relationship in which both groups contribute their strengths, rather than a hierarchical dependency. The MSSG is responsible for immediate responses to public health emergencies related to medicine shortages, while the Medicines Coordination Group is tasked with long-term strategic planning, ensuring a balanced approach to both immediate and future challenges. A clear framework for collaboration between the MSSG and the Critical Medicines Coordination Group is essential to prevent overlaps in activities and to ensure that both groups effectively leverage their strengths, contributing to a coherent strategy for the management of critical medicines. RO supports coordination between initiatives to avoid duplication of efforts between the existing Coordination Group on Medicines Shortages and Medicines Safety (established by Regulation (EU) 2022/123 of the European Parliament and of the Council) - MSSG and the newly established group. A clearer definition of the objectives and roles of the

Commission proposal	Drafting suggestions and Comments
	Critical Medicines Coordination Group versus the objectives and roles of the MSSG is required. RO considers it important to underline that the MSSG maintains its operational independence in monitoring and responding to shortages, allowing it to act quickly without being overshadowed by the broader strategic discussions led by the Medicines Coordination Group.
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.	LT (Comments): LT: It is unclear how the coordination of financial support will be ensured in practice, as the Member States and the Commission will have already made decisions and informed the CMC group about the planned financial support. At what stage will discussions among Member States be organized regarding the manufacturing capacities for medicines needed by the Union? It would be appropriate to specify the implementation of tasks in more detail, so that coordination actions are carried out prior to the final decisions on recognizing projects as strategic and their financing. That is, to ensure that manufacturing capacities are strengthened or developed to produce medicinal products in quantities sufficient to meet the needs of the entire EU market. It is also unclear whether, under Article 26(3), upon receiving information, Member States will be able (or perhaps required) to amend the planned financial support.

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Commission proposal	Drafting suggestions and Comments
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;	IE (Drafting suggestions): (a) facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information**, where available,** 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; IE (Comments): IE endorses coordination and information exchange however notes that MS would not necessarily have information on manufacturing capacities which may be considered confidential or trade secret.
(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;	IE (Drafting suggestions):

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Commission proposal	Drafting suggestions and Comments
	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 other medicinal products of common interest;** IE (Comments): IE supports the inclusion of medicinal products of common interest in line with other articles. RO (Comments): With regard to the involvement of the Critical Medicines Coordination Group in exchanges on national programmes referred to in Article 19, as well as cooperation on public procurement policies of the Member States, it is important that these programmes are developed within a unified framework, and that the designated members are involved in such policies at national level.
(c) facilitate discussion of the need for a collaborative procurement initiative for a given medicinal product;	
(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.	DE (Drafting suggestions): **(NEW): e)work together with environmental fora in order to promote the ecologically sound production of pharmaceuticals**

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Commission proposal	Drafting suggestions and Comments
	IE (Comments): IE supports the need for a clear framework for engagement between MSSG and CMG in order to leverage expertise and avoid duplication. The difference in roles of the MSSG and CMG needs to be explicit and consideration should be given to documenting same as a recital.
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.	
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.	
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.	IE (Drafting suggestions):

Commission proposal	Drafting suggestions and Comments
	5. The Critical Medicines Group, at **either** the Commission's **or Member State'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 IE (Comments): It should also be possible for a MS to request the views of the CMG on matters relating to the Regulation
Chapter VI **International cooperation**	
Article 27	
Strategic partnerships	RO (Comments): For legal clarity, we consider it necessary to define the phrase "explore possibilities of concluding strategic partnerships" by providing more information, namely: Is there a certain periodicity in the feasibility

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Commission proposal	Drafting suggestions and Comments
	analysis and the communication of the results to the MS? Will there be transparency regarding the conclusion of strategic partnerships? Will there be a platform for transparency of information with common access for the MS and the Commission? RO underlines that partnerships with third countries should be structured in such a way as to ensure quality standards equivalent to those in the EU, thus also supporting European manufacturers. In order to strengthen the resilience of pharmaceutical supply chains, the ACM should promote international trade and regulatory cooperation in strategic partnerships with third countries. The ACM should promote regulatory convergence and harmonisation through mutual recognition agreements and trust in regulatory authorities. The EMA should involve international regulatory cooperation initiatives, such as the International Coalition of Medicines Regulatory Authorities (ICMRA)/ Pharmaceutical Quality Knowledge Management System (PQ KMS) collaborative assessment and hybrid inspection pilots, with adequate resources at EMA and Member State level. The EMA should support improved coordination of international inspectorates through existing frameworks, such as PIC/S and mutual recognition processes, to streamline oversight and facilitate global market access. The EMA and many of the medicines regulatory authorities in the EU MSs are involved in the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation System (PIC/S), a close international cooperation between pharmaceutical inspection authorities in the field of GMP. The concept of hybrid inspection involves a combination of physical inspections and virtual assessments. It was developed in response to the need to maintain high quality standards and ensure compliance in conditions of increased efficiency, especially in the context of global challenges such as the COVID-19 pandemic.

Commission proposal	Drafting suggestions and Comments
	Based on the above, we emphasize the importance of involving industry representatives within the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), established in 1968.
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.	DE (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 **as well as starting materials for production of active ingredients or excipients,** and **other** 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. **Where possible, in order to facilitate logistics and import, regional partnerships in Europe shall be preferred over those targeting countries outside of Europe.** **The provisions laid down in this article shall not exclude Member States to form their own bilateral partnerships with targeted countries. When selecting strategic partners, emphasis should be placed on similar social and environmental standards** DE (Comments): Starting materials for active incredients production are important to achieve real independency from third countries. This is because if API production is still relying on raw materials from single suppliers, building strategic partnerships for buying API is still maintaining dependencies by proxy.

Commission proposal	Drafting suggestions and Comments
	Europe provides for a larger market than the EU, however still offers advantages of short and facilitated transport routes. Having partners on the European continent would be particularly valuable in times of travel and transport restrictions, such as during the pandemic (SARS-CoV-2). LT (Comments): LT: This Article empowers the Commission to explore the possibility of establishing strategic partnerships. We believe it should be indicated in the text that Commission shall inform Member States about the outcomes of such assessments. RO (Drafting suggestions): Without prejudice to the prerogatives of the Council, the Commission, shall **seek to conclude** ~~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~~ **aim to build** ~~of building~~ on existing forms of cooperation, **such as Free trade Agreements (FTA),** when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. RO (Comments): In light of global challenges and increasing geopolitical tensions, there is an even stronger rationale for the EU to pragmatically increase supply chain resilience collaboration with trusted partners. This is line with what is stated in Recital 10 and the suggested amendment:" Due to the international dimension of the security of supply, in particular taking into

Commission proposal	Drafting suggestions and Comments
	account that diversification of supply chains and an overall increase of supply are elements of a solution for ensuring the security of supply, international cooperation ~~should~~ shall be encouraged." Uninterrupted supply chains across borders are key not only to the EU's own resilience, but would also bolster the EU's international trade position in pharmaceuticals and contribute to health security globally (given Europe's role as the world largest exporter of medicines and vaccines).
Chapter VIII **Final provisions**	

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Commission proposal	Drafting suggestions and Comments
Article 29	RO (Comments): Article 29 highlights the importance of transparency in the supply chain of critical medicines, while emphasizing efficiency and the protection of confidentiality. However, further clarifications on specific obligations and coordination between authorities could contribute to a more efficient and equitable implementation of the regulations.
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.	DE (Comments): Para 1: suggest to name concrete information IE (Comments): IE supports the obligation in Article 29 for market actors to provide current and accurate information necessary on request. IE notes and supports the suggestion to use data in existing systems where possible to avoid duplication, but nevertheless considers it important to retain the obligation under the Article. RO (Comments):

Commission proposal	Drafting suggestions and Comments
	RO considers that establishing these obligations for market actors may require further clarification on the exact types of information to be provided. A detailed definition of this information could help to prevent confusion and ensure compliance. RO suggests expanding the ESMP operational platform by developing its applicability to both marketing authorisation holders and actors in the supply and distribution chains.
2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.	DE (Comments): Para 2: risk to increase bureaucratic burden LT (Comments): LT: It remains unclear how this provision will be implemented in practice, i. e. how duplication will be avoided. RO (Comments): RO supports the implementation of a platform managed by the Commission, which would centralise the information collected from MS and allow for transparency, in order to avoid duplication of information requested and transmitted.

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.	DE (Drafting suggestions): 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. DE (Comments): Criteria for the definition of "commercially confidential" need to be set somewhere for reasons of transparency. Does it relate to Art. 2 Nr. 1 RL (EU) Nr. 2016/943? "economic operator" should be defined in Art. 3; it should be clarified, that administrative bodies are not included IE (Comments): IE would welcome clear guidance on how confidentiality claims will be assessed and confidential information safeguarded. RO (Comments): RO considers that clarifying the criteria that will be used to assess these requests could reduce uncertainty for authorisation holders.

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Commission proposal	Drafting suggestions and Comments
	Although the article mentions both the Commission and the national authorities, it is important to clarify how this process will be coordinated. Detailing the specific responsibilities of each entity could facilitate more efficient implementation of the regulations. It is also important to consider how these reporting obligations may impact small producers or economic operators who may not have the resources to meet the administrative requirements. A clarification of the support available to them could be beneficial to ensure equitable compliance.
Article 30	
Evaluation	RO (Comments): RO supports the need for periodic assessments that analyse the impact on the security of supply and availability of critical medicines, however we believe that clear assessment criteria should be specified and clear parameters should be established for monitoring and defining major deficiencies in accordance with this Regulation for the aligned understanding of all MS and the European Commission.
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	DE (Drafting suggestions): 1. By *[OP please insert the date of:]* **at the latest** 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

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Commission proposal	Drafting suggestions and Comments
main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.	main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions. DE (Comments): In case of unforeseen geopolitical events, it should be possible to evaluate before 5 years are over. RO (Comments): RO supports the introduction in paragraph 1 of the fact that the report will be transmitted to the European Parliament after prior acceptance of the report issued by the European Commission.
2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1 have been achieved.	
3. The national authorities and the economic operators shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1.	DE (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**~~ **needs** for its assessment pursuant to in paragraph 1. DE (Comments):

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Commission proposal	Drafting suggestions and Comments
	In order to avoid additional bureaucratic burden for all parties involved, only those pieces of information that are really needed should be transmitted RO (Comments): For transparency of information, RO supports the establishment of a deadline for transmitting the necessary information to the Commission, prior to the date on which the assessment by the European Commission will take place, for a smooth process and the establishment of a flow of information transmission, for example: market actors -> national authorities -> Commission.
Article 31	
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*.	IE (Comments): IE understands that ideally the regulation would be enforced as soon as possible, however a reasonable timeframe for implementation is needed.

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Commission proposal	Drafting suggestions and Comments
It shall apply from [….].	
This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Done at Strasbourg,	
For the European Parliament *For the Council*	
The President *The President*	