AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Targeted Amendments to the Critical Medicines Act (CMA)

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €4 trillion in 2023, directly supports more than 4.6 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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AmCham EU suggested amendments and justifications

European Commission Proposal	Initial drafting of proposed Amendment	Justification
Chapter I-II Objectives, scope and definitions		
Article 1 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. 2. To achieve the objectives referred to in paragraph 1, the Regulation sets out a framework to: (b) lower the risk of supply disruptions and strengthen availability by incentivising supply chain	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 ***local*** 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 shall also support the Union's competitiveness and simplification objectives by fostering a more stable and predictable market environment supporting innovation in the research-based pharmaceutical and consumer health sectors as strategic assets for the Union's economy, and promoting targeted, evidence-based and proportionate measures that avoid unintended consequences on the security of supply of critical***	- As defined in article 3(5), medicinal products of common interest do not suffer from availability or shortages, but rather from broader market access challenges. Would also propose to directly reference the competitiveness and simplification objectives of the Draghi Report and EC Competitiveness Compass.

diversification and resilience in the public procurement procedures of critical medicinal products and other medicinal products of common interest;	***medicinal products and accessibility of those other medicinal products referred to above.*** 2. To achieve the objectives referred to in paragraph 1, the Regulation sets out a framework to: (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***~~;	
Article 2 Scope		
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.	2. Chapter IV ***- with the exemption of Articles 18, 19, ~~and~~ 20, 21, 22 and 23 -*** 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.***~~	- Medicinal Products of Common Interest do not suffer from supply chain disruptions or shortages but rather from broader market access challenges. Applying procurement requirements, national programs and other measures such as contingency stock requirements related to supporting supply chain

		resilience within the meaning of article 18, 19, 20, 21, 22 and 23 is not appropriate in this context, as these products are not at risk of security of supply.
	Article 3 Definitions	
(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;	**Proposed concept and definition of medicinal products of common interest to be removed** (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 ***available*** 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 ***taking in consideration shortages in the past 2 years, the products' complexities, specific characteristics and respecting***	- The dual focus on access and supply chain risks dilutes the emphasis on the original objective of the proposed Act and undermines the considerable work by the Critical Medicines Alliance in shaping the security of supply for critical medicines. - 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.

(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 Council14 [reference to be added after adoption cf. COM(2023) 193 final];	***EU international commitments, as*** performed by the MSSG in ***consultation with the respective marketing authorisation holders and in*** accordance with Regulation (EU) …/… of the European Parliament and of the Council14 [reference to be added after adoption cf. COM(2023) 193 final]; ***(x) 'contingency stock' means an obligation imposed on supply chain actors to establish buffer stocks of certain medicines to mitigate the risk of supply disruption.*** ***(x) 'stockpiling' by a (public) health institution in order to anticipate and manage a specific crisis.***	- Manufacturing outside of the EU/EEA should not automatically be considered a higher risk and therefore a vulnerability of the supply chains. - Definitions provided by the European Commission during the information session on the CMA in May 2025 (Link to slides with definition here).
Article 4 Strategic objective of the Union		
1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union. 2. The Member States and the Commission shall work together to strengthen the security of supply	3. The Commission shall support the coordinated efforts of the Members States. ***4. The Commission shall ensure that the potential impact on the security of supply and availability of critical medicinal products is assessed and taken***	- To support the security of supply objectives of the proposal, it is essential to ensure policy coherence across Union initiatives that may affect the supply and availability of critical medicinal products. The Commission should systematically assess such impacts when preparing legislative or

and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. 3. The Commission shall support the coordinated efforts of the Members States.	***into account when preparing any legislative proposals, delegated acts, or implementing acts, including under horizontal Union legislation, that may affect such supply and availability.***	implementing measures, including under horizontal Union legislation. An example is the recent adoption of the Urban Wastewater Treatment Directive (UWWTD), which places a disproportionate and unsustainable burden on the generic medicines sector accounting for 70% of dispensed medicines in Europe, while representing only 19% of the market value, highlights the need for such assessments to prevent unintended disruptions to the supply of essential and critical medicines and to safeguard patient access.
Chapter IV Public procurement		
Article 18.1 Incentivising resilience, sustainability and positive social impacts in public procurement procedures		
- For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those	- For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements ***in accordance with WTO Agreement on Government Procurement (GPA) non-discrimination principle*** other than price-only award criteria such as	- The proposal rightly includes the mandatory use of award criteria other than price. It is essential to ensure non-price award criteria include additional considerations, such as environmental and sustainable manufacturing criteria, to promote sustainable manufacturing practices and ensure fair competition.

procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery.	~~***procurement requirements that promote the resilience of supply in the Union***~~ ***supply diversity, environmental, corporate sustainability, sustainable manufacturing criteria. Contracting authorities shall make use where appropriate of multi-slot tendering procedures, with clearly defined and predictable volumes, quantities, and lead times, for the procurement of medicinal products. Multi-slot tendering shall be used in conjunction with non-price award criteria.*** Those procurement requirements shall be defined in accordance with Directive 2014/24/EU ***in consultation with the economic operators, including marketing authorisation holders and clinical experts*** *and* ***should include an appropriate and predictable mix and weighting of qualitative criteria that reward quality and promote innovation recognizing the value that innovative medicinal products bring to patients, the economy and society in general. These shall include patient impact and clinical value, environmental sustainability, supply chain robustness and agility,*** ~~***may relate to stockholding obligations,***~~ the number of diversified suppliers, ~~***monitoring of supply***~~	- As the majority of medicine tenders result in single-winner contracts, accounting for up to 84% of all contracts awarded in some cases (according to the European Commission Study on medicines shortages), such practices hamper competition and jeopardise supply security, given that other suppliers do not have any incentive to maintain active multiple production sources to mitigate shortages failing to win the tender. Multi-slot tenders for medicines should be introduced to promote supply diversity and resilience. - Stockpiling obligations in this provision directly undermines the overarching supply security objective, given that fragmented and disproportionate stockpiling requirements create artificial barriers within the market, impose rigid costs to manufacturers and consequently limit their flexibility to mitigate shortages.

	~~chains, their transparency to the contracting authority~~ upon request and subject to safeguarding the confidentiality of trade secrets, ~~and~~ contract performance clauses on timely delivery***, maintenance of minimum stock levels inside the company, availability of safety stocks at national or regional levels, and compliance with Good Manufacturing Practices (GMP) and regulatory standards.*** - ***In duly justified cases, marketing authorisation holders may be permitted to adjust pricing to support the continued and secure supply of such critical medicinal products.*** - ***A dedicated framework governing the public procurement of medicinal products shall be detailed in a delegated act to Directive 2014/24/EU.***	- Adjusting pricing during the duration of tender (e.g. sometimes over 1 or 2 year) becomes increasingly significant in scenarios with economic fluctuations—such as inflation and rising costs of goods—which lead to substantial increases in production and distribution costs, potentially undermining the viability of procured medicines. The long-term viability of production is the most effective way to safeguard the supply security of critical medicines, enabling sustained investment in diverse and resilient supply sources. Introducing the ability to adjust prices upwards in justified cases enables suppliers to mitigate these economic challenges while ensuring a consistent supply of medicines. This flexibility ultimately fosters an environment that is both resilient and sustainable, ultimately safeguarding patient access to essential medicines.
Article 18.2 Incentivising resilience, sustainability and positive social impacts in public procurement procedures		
- With regard to critical medicinal products for which a vulnerability in the supply	- With regard to critical medicinal products for which a vulnerability in the supply chains has	- Localisation in public procurement of medicines is a misguided approach that

chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments.	been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers ~~***that manufacture a significant proportion of these critical medicinal products***~~ ***with a significant footprint in the Union. The contracting authorities shall, where possible, introduce the division of tenders into multiple slots for EU and non-EU manufacturers. Each slot shall be awarded to multiple suppliers to promote diversity and resilience of supply.*** These requirements shall be applied in compliance with the Union's international commitments.	could weaken, rather than strengthen, the resilience of pharmaceutical supply chains. It is essential that the provision is framed to uphold free trade principles (e.g. WTO Government Procurement Agreement, Free Trade Agreements, and International Procurement Instrument) if incorporated into the final Regulation. - Furthermore, legal clarity is required to define what constitutes a 'significant proportion' of manufacturing in the EU. Instead, the proposal should support companies that invest in Europe, as well as facilitating and harmonising assessment of procurement bodies of companies' compliance with these requirements.

Article 18.3 Incentivising resilience, sustainability and positive social impacts in public procurement procedures		
- With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities may apply procurement requirements that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments.	- With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities may apply procurement requirements that favour suppliers ***~~that manufacture at least a significant proportion of these medicinal products in the Union~~*** ***~~.~~*** ***with a significant footprint in the Union. The contracting authorities shall, where possible, introduce the division of tenders into multiple slots for EU and non-EU manufacturers. Each slot shall be awarded to multiple suppliers to promote diversity and resilience of supply.*** These requirements shall be applied in compliance with the Union's international commitments.	- To safeguard competitive tendering processes of products of common interest, multiple slots should be foreseen and allocated between EU and non-EU manufacturers to support EU production while also ensuring supply diversity and safeguarding competition.

Article 18.4 Incentivising resilience, sustainability and positive social impacts in public procurement procedures		
- This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights.	- This Article shall ~~***not preclude***~~ ***ensure*** contracting authorities ~~***from***~~ ***are*** using additional qualitative requirements, including in relation to environmental sustainability and social rights. ***This Article shall encourage the Commission to ensure a well-informed and inclusive process to harmonise the social and environmental MEAT criteria applied across the Internal Market.*** - ***In considering environmental MEAT criteria, the Commission shall consider well-established international and sector-specific frameworks and standards, applicable to company-level processes to more efficiently help scale good practices across the global supply chains, benefiting citizens in the EU and beyond. Relevant standards and frameworks for climate change mitigation and adaptation include company-level greenhouse gas reduction targets in scope 1&2 and scope 3 – approved and validated by the Science Based Targets initiative (SBTi), to ensure relevance to the Paris Agreement and associated public reporting***	- Allowing discretionary application of environmental criteria, as suggested in Article 18(4), risks creating a fragmented procurement environment, which could impose additional burdens on suppliers operating across multiple EU countries. Such fragmentation may lead to increased complexity and costs, as suppliers would need to navigate and comply with a patchwork of divergent requirements, potentially undermining the efficiency and effectiveness of the procurement process. - The Commission should ensure that non-price award criteria for the public procurement of critical medicines also mandatorily include environment, corporate sustainability and sustainable manufacturing criteria to streamline procurement processes across EU Member States.

	on those targets, actions for progress, and performance to promote transparency and accountability. Further, to help curb antimicrobial resistance, the Commission can encourage adherence to the AMR Industry Alliance's Standards for Responsible Antibiotic Manufacturing. Further, to encourage good practices in the global supply chain, the Commission shall recognize and promote global sector-specific initiatives such as the Pharmaceutical Supply Chain Initiative.	

Article 19.1 Programmes supporting sustainability and resilience in public procurement procedures		
- By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures.	- By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes ~~***may***~~ ***shall*** also include measures for pricing and reimbursement supporting security of supply ***and diversity of suppliers*** of those critical medicinal products that are not purchased through public procurement procedures. - ***Such programmes shall be empowered to provide "viability safety nets" to review price freezes as well as the impact of cost-containment measures such as clawbacks on market concentration and security of supply. These measures shall be assessed and reported to the European Commission in line with the Transparency Directive (89/105/EEC).***	- To ensure comprehensive oversight and coordination, P&R considerations should be a mandatory component of these national programmes, alongside public procurement procedures. This approach would enable the Critical Medicines Coordination Group to effectively monitor and assess the impact of P&R policies on the availability of critical medicines across the EU. - To enhance transparency on national P&R measures applicable to critical medicines, such programmes should also be empowered to review any potential price freezes which may be imposed on critical medicines to determine whether these are justified by economic conditions and in line with overall supply security recommendations. This would be in line with the objectives of the Transparency Directive (89/105/EEC).

Contingency stocks		
Article 20 Safeguards related to Member States' contingency stocks requirements and other security of supply measures		
- Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. - Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity.	- Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. - ***Member States shall, prior to the implementation of such measures, notify them to the European Commission who shall assess the proportionality of the national contingency stock measure in line with the objectives of this Regulation. They shall be adopted after consultation with relevant marketing authorisation holders and other relevant supply stakeholders.*** - ***Stockpiling obligations shall be limited to a clearly defined and harmonized list of vulnerable critical medicinal products. The scale and scope of such obligations shall be based on scientific vulnerability assessments. The duration of any***	- The Commission's proposal usefully highlights that contingency stock requirements must be proportionate and respectful of transparency and solidarity principles. However, the implementation of Article 20 requires targeted improvements to address growing structural risks and fragmentation resulting from national stockpiling mandates, particularly in the off-patent sector. - National stockpiling policies impose additional costs and create artificial increases in demand of critical medicines, impacting companies' capacity to supply other countries. It is important to recognize the shortfalls of stockpiling and to promote alternative, structural solutions that can effectively reduce the risk of shortages in Europe.

	stockpiling requirement shall not exceed a period of two months. Marketing authorisation holders' self-adopted supply risk and resilience plans shall be taken into account. - ***Should the Commission decide to establish Union-level security of supply requirements such as contingency stock requirements, it must coordinate with national competent authorities to ensure alignment and avoid duplication with national equivalent contingency stock and stockpiling arrangements. Union-level contingency stock or other security of supply requirements shall supersede any similar national requirements.*** - Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks ***and minimise waste*** are proportionate and respect the principles of transparency and solidarity. - ***The reporting of such contingency stocks shall form an integral part of national programmes aimed at strengthening the***	

	<u>security of supply of critical medicines, as outlined in Article 19.</u> - ***Regulatory flexibilities such as multi-language or EU-based packs with harmonized labelling and electronic package leaflet shall be considered.*** - ***<u>Medicines subject to contingency stockholding obligations shall be exempt from parallel export activities.</u>*** - ***<u>Companies that respond to shortages in another Member States through solidarity stock transfers shall be exempt from any penalties for failure to comply with local contingency stock requirements. Such companies shall be entitled to predictable compensation to safeguard continued supply, duly reflecting actual costs incurred, including but not limited to storage, logistics, inflation adjustments, and losses due to product expiry.</u>***	

Chapter V Critical Medicines Coordination Group		
Article 25 Establishment of Critical Medicine 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. 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.	***6a. The Critical Medicines Group shall have biannual meetings to consult with the Critical Medicines Alliance and additional meetings when needed.*** ***7. The Critical Medicines Group may invite national authorities, experts and observers as well as Union institutions, bodies, offices, and agencies to those referred in paragraph 3, and research infrastructures and other similar infrastructures to attend its meetings. The Critical Medicines Group may cooperate with external experts where appropriate.***	- It is essential that its structure includes broad stakeholder representation, including industry. Involving industry representatives is critical to ensure that the Group can draw upon real-world expertise and lessons learned from all actors actively working to enhance supply chain resilience and security of critical medicines.

4. The Commission shall organise and coordinate the work of the Critical Medicines Group by means of the Secretariat. 5. A representative of the Commission shall chair the meetings of the Critical Medicines Group. 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.		

Article 26 Tasks of the Critical 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. 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; 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;	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 ~~***critically***~~ vulnerable ***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; 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; c. facilitate discussion of the need for a collaborative procurement initiative for a given medicinal product; ***d. promote alignment between Union legislation and national market incentives in relation to critical medicinal products;***	- The Critical Medicines Coordination Group should also focus on the alignment between EU regulations and national market incentives to safeguard patient access.

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.	e. 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. ***f. facilitate discussion on market failures and vulnerabilities that contribute to the discontinuation of supply or withdrawal by MAHs.***	

Chapter VI International cooperation		
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.	- 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.***~~ ***shall continue collaboration with key international partners that are integral to global pharmaceutical supply chains, as well as accession candidates, on the security of supply and solidarity-based responses to health crises.*** - ***The Commission shall include health security chapters in Free Trade Agreements (FTAs) with strategic partners to ensure***	- The EU should remain a strong advocate for open trade and multilateral cooperation by: (1) ensuring and facilitating robust, resilient and open global supply chains to safeguard patient access to medicines in Europe and beyond, and (2) continuing collaboration with key international partners playing crucial role in global medicinal supply chains, as well as accession candidates, on the security of supply and solidarity-based responses to crises. - The international partnerships under the CMA should prioritize the facilitation of trade for high-priority products. A key focus should be on enhancing and expanding Mutual Recognition Agreements (MRAs) for pharmaceutical Good Manufacturing Practice (GMP). MRAs are essential tools that can significantly support resource savings for regulators and reduce the timelines for delivering

	continued access to essential medical goods within the region and beyond. - ***The Commission shall facilitate the simplification of cross-border trade by supporting the implementation of green lanes, the use of digital documentation, and mutual recognition of regulatory standards. The Commission shall enhance and expand Mutual Recognition Agreements (MRAs), particularly those related to Pharmaceutical Good Manufacturing Practice (GMP) standards.***	imported medicines to patients. For example, current import testing requirements result in an average delay of 30 days in medicine delivery, which also reduces the product's shelf life. - In addition to exploring new MRAs with partners who meet appropriate standards (e.g., EU–India), it is crucial to consider expanding the scope of existing MRAs.
Article 29 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. 2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.	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.	- We propose that the information obligation in Article 29 is only applicable to manufacturers of critical medicines, not MPCIs. - In addition, the types of information that can be requested should be narrowed down, with reference to specific types of information. - Lastly, the point 3 should add detail on the standard that would apply to the

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.	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.	confidentiality process set out in Article 29 (3).