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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 recitals of the Critical Medicines Act (ST 6872/25).

Critical Medicines Act - Recitals Deadline: ***12 September 2025***

From: AT, BG, CZ, EE, ES, FI, FR, IE, IT, LT, LU, RO, SE **Updated: 17/09/2025 14:23**

PUBLIC

Guidelines to be followed

Please kindly provide your contributions in the table below.

Drafting suggestions: you may use '**track changes**' or formatting (for example **bold-underline** for additions and ~~strike-through~~ for deletions, **where necessary, in a different colour**).

Name of document: please add the **two initials** of your delegation's country followed by a space (to the MS Word document name), followed by any optional text, for example, for Austria: **AT comments on … .docx**

Thank you for your cooperation!

Commission proposal	Drafting suggestions and Comments
	General comments DE, FI, SE (with FR support) (Comments): DE, FI, and SE propose an exception in case of national security and defence, including the extension to article 20 of the CMA: ‘“Member States may waive the application of articles 5-6, articles 15-17 and article 20 insofar as the application of such requirements imply a risk to national security and defence.” In addition, two proposals for recitals regarding defense/national security in the CMA: 1. The same as in the Pharma package (8a) regarding sharing of information, here as a new (28 a).

PUBLIC

(28 a new) Without affecting the rules laid down in this Regulation, Member States remain the sole responsible for their own national security. They are responsible in defending their essential state functions, including ensuring their territorial integrity and safeguarding national security. In particular, under Article 346 TFEU, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security. For this reason, Member States should be able to waive some of the information obligations related to the marketing of medicinal products when these medicinal products are supplied for military or defence purposes or insofar as the application of such requirements imply a risk to national security and defence.

2. A short new one to explain that strategic projects that have common interests between the civil and defence mechanisms are still eligible under the CMA. This was confirmed by the Commission. FR thought it might be necessary to add something about this.

(28 b new) The rules laid down in this Regulation may also be applicable for strategic projects coinciding with strategic military or defence objectives in strengthening the security of supply of critical medicines.

AT
(Comments):

AT: General scrutiny reservation on the recitals. AT wishes to refer to its corresponding suggestions for various articles, these apply for their

PUBLIC

Commission proposal	Drafting suggestions and Comments
	respective recitals as well. Any additional comments will be brought forth when the first compromise text is available. CZ (Comments): In general, CZ has similar comments on individual recitals as on the related Articles of the draft Regulation to which the recitals relate. Therefore, CZ considers it necessary first to find an agreement on the wording of individual Articles, and then to adjust the recitals to correspond to the given Articles, as well as to add the new recitals to cover parts of the legislative text that will be supplemented by new Articles based on the comments of Member States and the discussion of the draft Regulation at the WPMMD level. FI (Comments): FI has a scrutiny reservation on all of the recitals LT (Comments): LT: We maintain a scrutiny reservation on all recitals, considering that recitals should be discussed once agreement on the provisions of the articles has been reached.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	SE (Comments): General comments from SE: We maintain a scrutiny reservation in the absence of an impact assessment. The recitals need to be revisited after an agreed compromise.
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	BG (Drafting suggestions): Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 **and Art. 168** thereof, BG (Comments): We reiterate our general comments on the legal basis made on previous occasions.
Having regard to the proposal from the European Commission,	

PUBLIC

Commission proposal	Drafting suggestions and Comments
After transmission of the draft legislative act to the national parliaments,	
Having regard to the opinion of the European Economic and Social Committee[1],	
Acting in accordance with the ordinary legislative procedure,	
Whereas:	
(1) Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and activities. The availability of safe, efficacious and high-quality medicinal products is vital to achieving this objective and to safeguarding public health across the Union.	BG (Drafting suggestions): Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and activities. The availability of safe, ~~efficacious~~ **effective** and high-quality medicinal products is vital to achieving this objective and to safeguarding public health across the Union. BG

[1] OJ C , , p. .

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(Comments): For a medicinal product, being efficacious means that the product can produce the desired beneficial effect in a controlled setting, such as during clinical trials. We propose to change the word with "effective", which is related to the intended therapeutic actions after the medicinal product has received MA. IE (Drafting suggestions): Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and activities. The availability of safe, efficacious, **affordable** and high-quality medicinal products is vital to achieving this objective and to safeguarding public health across the Union. IE (Comments): Ireland is supportive of the overall objectives of the provisions, would support a reference to affordability in line with obs submitted on Article 1 IT (Drafting suggestions): (1) Pursuant to **Articles** 9 **and 168** of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and

PUBLIC

Commission proposal	Drafting suggestions and Comments
	activities. The availability of safe, efficacious and high-quality medicinal products is vital to achieving this objective and to safeguarding public health across the Union IT (Comments): IT Comment: It would be appropriate to refer in the present recital, in addition to Article 9 TFEU and Article 35 of the Charter, also to Article 168 TFEU, concerning measures aimed at addressing common safety issues by establishing high standards of quality and safety for medicines and medical devices. LU (Drafting suggestions): (1) Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and activities. The availability **and the free movement within the internal market** of safe, efficacious and high-quality medicinal products is vital to achieving this objective and to safeguarding public health across the Union. LU (Comments): In relation to the comments made by Luxembourg on Article 1 (see comments shared on 27/07/2025), we would like to add the free movement of medicinal products as one of the main objectives. This addition is necessary to reflect the legal basis of the proposal, i.e. Article 114 TFEU.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	« *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 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) In recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages of medicinal products for which insufficient supply results in serious harm or risk of serious harm to patients.	BG (Drafting suggestions): In recent years, the Union has experienced an increasing number of shortages of **critical** medicinal products, including shortages of medicinal products for which insufficient supply results in serious harm or risk of serious harm to patients. BG (Comments): We note that the data from the SWD do not support many of the statements in the preamble. Some of the data refer to lack of or varying amounts of medicines available, such as for rare diseases, but medicines are needed in accordance with morbidity and prevalence, not per capita. Also, therapeutic alternatives and budgetary context matter. All these nuances and causalities that are part of the national pharmaceutical policies are not captured by the SWD. Hence, we request

PUBLIC

Commission proposal	Drafting suggestions and Comments
	horizontally the use of a more moderate language and exclusion of generalisations. RO (Drafting suggestions): In recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages of medicinal products for which insufficient supply results in serious harm or risk of serious harm to patients ***and health systems*** RO (Comments): Our proposal is based on the fact that medicinal product shortages impact not only patients, but also the healthcare system as a whole.
(3) Shortages of medicinal products can have very different and complex root causes, with challenges identified along the entire pharmaceutical value chain. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. These include existing dependencies on a limited number of suppliers globally and lack of Union capacities to produce certain medicinal products, their active substances or key raw pharmaceutical materials. Through diversification of supply sources and investment in local production, the Union can reduce its risk of exposure to shortages of medicinal products.	RO (Drafting suggestions): Shortages of medicinal products can have very different and complex root causes, with challenges identified along the entire pharmaceutical value chain. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. These include existing dependencies on a limited number of suppliers globally and lack of Union capacities to produce certain medicinal products, their active substances or key raw pharmaceutical materials. Through diversification of supply sources**,** ~~and~~ investment in local production~~,~~ **and competitivenesspolices that protect**

PUBLIC

Commission proposal	Drafting suggestions and Comments
	the economic viability of critical medicines, the Union can reduce its risk of exposure to shortages of medicinal products. RO (Comments): According to recital 12, one of the objectives of the proposal is to support the competitiveness of the Union by promoting a more stable and predictable market environment. The Critical Medicines Alliance should therefore refer to EU and national policies on competitiveness and economic viability in order to find their specific solutions for the identified critical medicines.
(4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in particular, for key raw pharmaceutical materials and active substances. Setting up new, or modernising existing manufacturing capacities in the Union for critical medicinal products, their key inputs and active substances, which have often been on the market for a long time and are considered to be relatively inexpensive, is currently not seen as a sufficiently attractive option for private investment, also in view of lower energy costs, lesser environmental and other legal requirements elsewhere in the world. Workforce shortages and the need for specialised skills in pharmaceutical manufacturing further add to the industrial challenges to manufacturing in the Union. Targeted financial incentives, simplified administrative processes, and better Union-level coordination can contribute to supporting efforts to increase manufacturing capacities in the Union and strengthen the supply chains for critical medicines.	AT (Drafting suggestions): AT: (4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in particular, for key raw pharmaceutical materials and active substances. Setting up new, or modernising existing **as well as the preservation of** manufacturing capacities in the Union for critical medicinal products, their key inputs and active substances, which have often been on the market for a long time and are considered to be relatively inexpensive, is currently not seen as a sufficiently attractive option for private investment, also in view of lower energy costs, lesser environmental and other legal requirements elsewhere in the world. […] AT

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(Comments): AT: CMA should not only focus on the expansion of capacities, but also explicitly mention the preservation of manufacturing capacities within the EU. This creates clarity and strengthens security of supply. AT suggests adding the phrase “as well as the preservation of” to recital (4). FR (Comments): In its strategic report, the Alliance for Critical Medicines recommended launching a study to analyse the regulatory asymmetry between the European Union and Asia (in particular India and China, the main exporters of APIs and critical inputs) the observation made in this recital reaffirms the need to carry out this study, in order to have a solid basis on the environmental and social asymmetries between the EU and third countries, particularly in Asia. The SWD justifies the absence of level playing field measures in the text notably because of concerns about their potential unintended consequences on availability and affordability of medicines and lack of strong evidence that this would contribute to attain the objectives of the proposed Act. However, the French authorities believe that the EU should always strive for a level playing field and that, through the study, it could be possible to find ways to bridge this asymmetry while creating measures to preserve the affordability and availability of critical medicines.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	Moreover, the study will inform on mitigating measures to restore a level-playing field which is a key enabler of investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union (article 1 2(a)). Levelling the playing field will enable investments that, in the long term could contribute to strengthening the sovereignty of the manufacturing of critical medicines and their availability. France thus reaffirms the need to launch the study in that it contributes significantly to the objective of this regulation. IE (Comments): IE support the reference to the maintenance of existing manufacturing capacity alongside projects to expand capabilities for critical medicinal products and medicinal products of common interest. IT (Comments): IT Comment: The proposal does not appear to directly address the issue of workforce qualification through specific measures. Workforce qualification is an essential factor for the relocation of the production of innovative and critical medicines in Europe. This gap could create a significant risk of failing to achieve the general and specific objectives set by the Critical Medicines Act.

PUBLIC

Commission proposal	Drafting suggestions and Comments
(5) To enhance the security of supply for medicinal products and thereby contribute to a high level of public health protection, the Union has implemented a range of measures that contribute to building a European Health Union. In particular, Regulation (EU) 2022/123 of the European Parliament and of the Council[2] has reinforced the European Medicines Agency's ('the Agency') mandate by enhancing monitoring, coordination, and reporting mechanisms to prevent and mitigate supply disruptions of critical medicinal products across Member States. That Regulation also established the Agency's Executive Steering Group on Shortages and Safety of Medicinal Products ('the MSSG'), which brings together representatives from the Agency and Member States, to coordinate urgent actions within the Union to manage existing shortages and issues related to the quality, safety, and efficacy of medicinal products.	
(6) In addition, Regulation (EU) …/… of the European Parliament and of the Council[3] No *[reference to be added after adoption cf. COM(2023) 193 final*] further strengthens the continuity of supply and availability of medicinal products through developing the core tasks already granted to the Agency by Regulation (EU) 2022/123 and setting	SE (Drafting suggestions): (6) In addition, Regulation (EU) …/… of the European Parliament and of the Council[4] No *[reference to be added after adoption cf.*

[2] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.2.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj)

[3] 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 … *[OP: Please complete publication references]*).

[4] 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 … *[OP: Please complete publication references]*).

PUBLIC

Commission proposal	Drafting suggestions and Comments
out a framework for the activities to be deployed by the Member States and the Agency to improve the Union capacity to react efficiently and in coordinated manner to support the shortages management and security of supply of medicinal products, including by strengthening the obligations of marketing authorisation holders as it regards the shortages prevention and reporting.	*COM(2023) 193 final*] further **aims at** strengthen**ings** ~~s~~ the continuity of supply and availability of medicinal products **and to identify failed supply mechanisms where preventive measures are necessary**, through developing the core tasks already granted to the Agency by Regulation (EU) 2022/123 and setting out a framework for the activities to be deployed by the Member States and the Agency to improve the Union capacity to react efficiently and in coordinated manner to support the shortages management and security of supply of medicinal products, including by strengthening the obligations of marketing authorisation holders as it regards the shortages prevention and reporting. SE (Comments): We propose an addition here to clarify that the proposed pharmaceutical Regulation also contains tools to identify vulnerabilities and preventive measures.
(7) However, despite regulatory obligations on marketing authorisation holders to ensure the continuous supply of medicinal products to meet patients' demand and the additional regulatory mechanism introduced by Regulation of the European Parliament and of the Council (EU) 2022/123 and Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023)193 final*] to mitigate and respond to shortages, the functioning of markets alone does not always guarantee the availability of medicinal products. This risk is particularly evident in cases of supply chain disruptions, especially when the supply of a given medicinal product relies on a limited number of global suppliers and	

PUBLIC

Commission proposal	Drafting suggestions and Comments
production facilities or where there is a high dependency on a single or a limited number of third countries.	
(8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. Uncoordinated national measures risk disrupting the internal market, fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for further harmonisation.	BG (Drafting suggestions): As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. ~~Uncoordinated national measures risk disrupting the internal market, fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for further harmonisation.~~ BG (Comments): We believe that the current wording may unintentionally suggest that Member States are to blame for market disruptions. To avoid such implications and given the lack of proven causality, we propose deleting the sentence. FI (Drafting suggestions): (8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage

PUBLIC

Commission proposal	Drafting suggestions and Comments
	in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. Uncoordinated national measures ~~risk disrupting the internal market,~~ fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for further harmonisation. FI (Comments): FI proposes deleting "risk disrupting the internal market". Just from the fact that national measures differ from each other, you cannot draw the conclusion that the measures risk disrupting the internal market. This is a vague assumption. Also, because of the national competence in health services and medical care and the national competence in preparedness, it is vital, that EU-level coordination does not weaken the national systems but helps to strengthen them. LU (Drafting suggestions): (8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. Uncoordinated national measures risk disrupting the

PUBLIC

Commission proposal	Drafting suggestions and Comments
	internal market, fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for ~~**further**~~ **maximum** harmonisation. LU (Comments): Taking into account the legal basis of the proposal, i.e. Article 114 of the TFEU, the proposal should aim at maximum harmonisation. RO (Drafting suggestions): As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care ***and fair and equal access of patients to the medicinal products they need***. Uncoordinated national measures risk disrupting the internal market, fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for further harmonisation. RO (Comments):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	Our proposal is based on one of the key objectives of this Regulation—ensuring the availability of and equitable access to medicinal products for patients, in order to prevent inequalities between Member States.
(9) Some medicinal products of common interest which are key for the provision of adapted care to patients, while not affected by supply security issues, may still not be available to patients in some Member States. This may be caused by a variety of factors, including product or geographical demand market size, which can impact the timely availability of medicinal products in certain Member States.	BG (Drafting suggestions): ~~Some medicinal products of common interest which are key for the provision of adapted care to patients, while not affected by supply security issues, may still not be available to patients in some Member States. This may be caused by a variety of factors, including product or geographical demand market size, which can impact the timely availability of medicinal products in certain Member States.~~ BG (Comments): Our national position is that medicines of common interest should be out of the scope of the Regulation. The SWD does not demonstrate a clear link between the problems identified and the positive effect of the solutions proposed. Potential economies of scale are per se not a justification for circumvention of competence division or substitution of national rules, adapted to the national context. Furthermore, there is no successful practice to be scaled up: successes of regional initiatives do not stem from Union action, and the limited experiences beyond MCM during Covid-19, e.g. HERA pilot, are not positive. We also note the lack of safeguards that would prevent the negative consequences when joint procurement becomes a default for such a broad range of medicines: the impact on price convergence, the effects on non-

PUBLIC

Commission proposal	Drafting suggestions and Comments
	participating MS, the concentration of market power detrimental for smaller manufacturers. SE (Comments): Article 56a in the pharma package (Directive) also deals with access, but by use of other regulatory tools. Q: How do the rules on joint MS procurement in the CMA and 56 a interact? Should a joint procurement fail before a MS applies 56a (= market protection not valid in a MS)?
(10) The smooth functioning of the internal market and a high level of protection of human health should be ensured as regards medicinal products and it should be aimed to complementing other Union pharmaceutical legislation by providing for a harmonised framework supporting Member States' coordinated efforts to encourage investments in new and existing manufacturing capacities for critical medicinal products, encouraging the strategic use of public procurement instruments by the Member States as well as the coordination of the Member States' approaches, including through leveraging aggregated demand through Commission facilitated collaborative procurement procedures of critical medicinal products and medicinal products of common interest. Due to the international dimension of the security of supply, in particular taking into account that diversification of supply chains and an overall increase	BG (Drafting suggestions): (10) The smooth functioning of the internal market and a high level of protection of human health should be ensured as regards medicinal products and it should be aimed to complementing other Union pharmaceutical legislation by providing for a harmonised framework supporting Member States' coordinated efforts to encourage investments in new and existing manufacturing capacities for critical medicinal products, encouraging the strategic use of public procurement instruments by the Member States as well as the coordination of the Member States' approaches, including through leveraging aggregated demand through Commission facilitated collaborative procurement procedures of critical medicinal products and medicinal products of common interest. Due to

PUBLIC

Commission proposal	Drafting suggestions and Comments
of supply are elements of a solution for ensuring the security of supply, international cooperation should be encouraged.	the international dimension of the security of supply, in particular taking into 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 be encouraged. BG (Comments): Boosting increase of supply per se in the area of health policy is a politically sensitive message. One should bear in mind that this in practice means that increase of morbidity is desirable: that may be positive from industrial perspective but is against the essence of health policies. CZ (Drafting suggestions): (10) The smooth functioning of the internal market and a high level of protection of human health should be ensured as regards medicinal products and it should be aimed to complementing other Union pharmaceutical legislation by providing for a harmonised framework supporting Member States' coordinated efforts to encourage investments in new and existing manufacturing capacities for critical medicinal products, encouraging the strategic use of public procurement instruments by the Member States as well as the coordination of the Member States' approaches, including through **harmonising the principles related to contingency stock of medicinal products and other security supply measures or through** leveraging aggregated demand through Commission facilitated collaborative procurement procedures of critical medicinal

PUBLIC

Commission proposal	Drafting suggestions and Comments
	products and medicinal products of common interest. Due to the international dimension of the security of supply, in particular taking into 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 be encouraged. CZ (Comments): CZ is of the opinion that it is essential to include contingency stocks and related measures into Recital 10 which sets out ways of achieving the Critical Medicines Act objectives. CZ believes that the harmonization of the contingency stocks requirements is key to ensuring the smooth functioning of the EU internal market and a high level of public health protection across the EU. Please see the changes in wording proposed. IT (Comments): IT Comment: With reference to collaborative procurement, although these instruments can be useful for improving the supply of medicines in certain situations - such as during emergencies -, or for specific categories of products - such as essential medicines or those used to treat ultra-rare diseases -, their use as standard procurement channels for a very wide range of medicines could negatively affect national price negotiations.

PUBLIC

Commission proposal	Drafting suggestions and Comments
(11) The measures introduced by this Regulation are without prejudice to marketing authorisation holders' obligations, in particular under 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*], Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023) 193 final*] and Regulation (EU) 2022/123, including the obligation to ensure sufficient supplies of medicinal products, within the limits of their responsibility. These measures are aligned with the principles of the internal market. This Regulation is without prejudice to Union competition law, including antitrust, merger and State aid rules.	BG (Drafting suggestions): (11) The measures introduced by this Regulation are without prejudice to marketing authorisation holders' obligations, in particular under 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], Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) 2022/123, including the obligation to ensure sufficient supplies of medicinal products, within the limits of their responsibility. ~~**These measures are aligned with the principles of the internal market.**~~ This Regulation is without prejudice **to 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.** This Regulation is **also** without prejudice Union competition law, including antitrust, merger and State aid rules. SE (Drafting suggestions): (11) The measures introduced by this Regulation are without prejudice to marketing authorisation holders' obligations, in particular under 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*], Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023) 193 final*] and Regulation (EU) 2022/123, including the obligation to ensure sufficient supplies of medicinal products, within the limits of their responsibility. These measures are aligned with the principles of the internal market. This Regulation is

PUBLIC

Commission proposal	Drafting suggestions and Comments
	without prejudice to Union competition law, including antitrust, merger and State aid rules. **This Regulation is without prejudice to Union and national legal Acts providing for the protection of intellectual property rights and trade secrets.** SE (Comments): We propose to add a sentence at the end regarding protection of IP and trade secrets.
(12) While the primary objective of this Regulation should be to strengthen the security of supply and ensure the availability of critical medicinal products and of medicinal products of common interest, given a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation should also support the Union's competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector. Ensuring the security of supply and availability of critical medicinal products and the availability and accessibility of other medicinal products of common interest should moreover contribute to the Union's preparedness, resilience, and economic and overall security, including when cross-border supply chains risk being disrupted.	BG (Drafting suggestions): (12) While the primary objective of this Regulation should be to strengthen the security of supply and ensure the availability of critical medicinal products and of medicinal products of common interest, given a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation should also support the Union's competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector. Ensuring the security of supply and availability of critical medicinal products ~~and the availability and accessibility of other medicinal products of common interest~~ should moreover contribute to the Union's EE (Drafting suggestions):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(12) While the primary objective of this Regulation should be to strengthen the security of supply and ensure the availability and accessibility of critical medicinal products and of medicinal products of common interest, given a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation should also support the Union's competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector. Ensuring the security of supply and availability and accessibility of critical medicinal products and the availability and accessibility of other medicinal products of common interest should moreover contribute to the Union's preparedness, resilience, and economic and overall security, including when cross-border supply chains risk being disrupted. EE (Comments): We suggest adding improving access to medicines as a primary objective of this regulation. IE (Drafting suggestions): While the primary objective of this Regulation should be to strengthen the security of supply and ensure the availability of critical medicinal products and of medicinal products of common interest, given a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation should also support the Union's competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector. Ensuring the security of supply, **affordability,** and availability of

PUBLIC

Commission proposal	Drafting suggestions and Comments
	critical medicinal products and the **affordability,** availability and accessibility of other medicinal products of common interest should moreover contribute to the Union's preparedness, resilience, and economic and overall security, including when cross-border supply chains risk being disrupted IE (Comments): IE agree that the primary objective of this Regulation is to strengthen the security of supply and the availability of critical medicinal products within the Union, however, as previously, support a reference to affordability. IT (Comments): IT Comment: The European resources made available to support strategic projects do not appear to include provisions for long-term funding through separate resources or programs, and their amount seems insufficient to address the critical issues of the production sector. Moreover, in the relocation of production, competitiveness within Europe should still be promoted to avoid directing incentives in a single direction, thereby replacing dependence on third countries with dependence on a single Member State or a producer located in Europe. In this regard, it is necessary to include critical medicines in the EU industrial priorities within the framework of reshoring and technological security policies, also aiming to strengthen the EU technological leadership. LU (Drafting suggestions):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(12) While the primary objective of this Regulation should be to strengthen the security of supply and ensure the availability **and the free movement** of critical medicinal products and of medicinal products of common interest **within the internal market**, given a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation should also support the Union's competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector. Ensuring the security of supply and availability of critical medicinal products and the availability and accessibility of other medicinal products of common interest should moreover contribute to the Union's preparedness, resilience, and economic and overall security, including when cross-border supply chains risk being disrupted. LU (Comments): In line with the comment made on recital 1, Luxembourg would like to add the free movement within the internal market as a primary objective of the proposal in order to better reflect the link with the proposal's legal basis (Article 114 TFEU).
(13) Taking into account the different root causes of the availability issues affecting critical medicinal products and medicinal products of common interest, some measures should apply to critical medicinal products only.	AT (Comments): (AT: Referring to Article 2, the proposal needs more clarity concerning its scope. We strongly suggest clear definitions of medicines of common interest as well as additional options for strategic projects, which are currently limited to critical medicines only.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	IE (Comments): As per previous discussions at WP meetings, the applicability of such measures need to be explicit in the Regulation.
(14) The availability and the security of supply of critical medicinal products are essential to safeguard public health and the economic and overall security of the Union and therefore should be considered strategic objectives of the Union.	EE (Drafting suggestions): (14) The availability, accessibility and the security of supply of critical medicinal products and other medicinal products of common interest are essential to safeguard public health and the economic and overall security of the Union and therefore should be considered strategic objectives of the Union. EE (Comments): We suggest adding improving access to both critical medicines and medicines of common interest as a strategic objective of the Union.
(15) A well-defined list of critical medicinal products is essential to ensure that the measures are targeted, effective, and proportionate. The critical medicinal products covered by this Regulation should be those for which insufficient supply results in serious harm or risk of serious harm to patients. For this reason this Regulation should apply to critical medicinal products on the Union list of critical medicinal products, as established by Regulation (EU) …/… [*reference to be added after*	IT (Comments): IT Comment: A thorough assessment of the present proposal - particularly with regard to its scope and extent - can only be carried out once the examination of Regulation Proposal COM(2023) 193 final has also been completed. Nevertheless, we reiterate the need for the definition of "critical

PUBLIC

Commission proposal	Drafting suggestions and Comments
adoption cf. COM(2023) 193 final]. That list builds upon the experiences of the European Medicines Agency and Member States' Agencies that in 2024, in anticipation of the reform of pharmaceutical legislation, identified a list of 276 critical medicinal products.	medicine" in the two measures to be identical, and for it to allow the generation of a more limited list than the current one, considering that the definition of critical medicine, which is still under discussion, may in some cases be considered too broad and could therefore negatively affect the effectiveness of countermeasures if their application were too extensive.
(16) To ensure that the measures are applied where justified and proportionate, it is necessary to demonstrate that some measures address a vulnerability in the supply chains of a given critical medicinal product. This Regulation should rely on the vulnerability evaluation performed for the purpose of the application of the general pharmaceutical legislation as per Regulation (EU) No …/… [*reference to be added after adoption cf. COM(2023) 193 final*]. To detect a vulnerability in the supply chains it is necessary to look at aggregated data across all medicinal products authorised in the Union and containing the same active substance, route of administration and formulation. Such an approach allows for the determination whether, for a critical medicinal product with a given active substance, the Union is highly dependent on a single or a limited number of third countries, or a limited number of sites, for active substances, key inputs, or finished dosage forms.	CZ (Comments): CZ finds the differences between Recital 16, which states "*data across all medicinal products authorised in the Union and containing the same active substance, route of administration and formulation*" and Article 3 para 6, which states "*taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation*." as confusing. CZ believes that the texts should be unified. RO (Drafting suggestions): 16a **In order to ensure legal clarity and effective coordination at Union level, it is essential to distinguish between 'contingency stock' and 'national stockpile'. Those two concepts refer to different types of reserves, governed by distinct legal and operational frameworks, and serving different purposes within the supply chain and public health preparedness. Thus, a clear differentiation is necessary to avoid**

PUBLIC

Commission proposal	Drafting suggestions and Comments
	confusion in reporting and management, and to support targeted and proportionate Union-level actions during supply disruptions or emergencies. RO (Comments): Our proposal is based on the necessity of establishing two distinct types of stocks, along with clear definitions for each, in order to highlight the importance of both contingency stock and the national stockpile during supply disruptions or emergencies.
(17) Certain projects can have a positive impact on security of supply as they increase the Union's manufacturing capacity for critical medicinal products and strengthen the resilience of the Union's supply chains. In order to encourage private investments in these projects, the concept of strategic projects should be introduced. Given their role in ensuring the Union's security of supply for critical medicinal products, the relevant permitting authority should consider strategic projects to be in the public interest. To ensure their expedient implementation, national authorities should ensure that the relevant permit granting processes are carried out in the fastest way possible making available, in particular any form of accelerated procedures that exists in applicable Union and national law. National authorities should consider, when possible, their streamlining as well as enable digital submission of required information.	AT (Drafting suggestions): AT: (17) Certain projects can have a positive impact on security of supply as they **preserve or** increase the Union's manufacturing capacity for critical medicinal products and strengthen the resilience of the Union's supply chains. […] AT (Comments): AT: As with recital 4, we suggest not only focusing on increasing but also on preserving the Union's manufacturing capacity. EE

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(Drafting suggestions): 17) Certain projects can have a positive impact on security of supply as they increase the Union's manufacturing capacity for critical medicinal products and strengthen the resilience of the Union's supply chains. In order to encourage private investments in these projects, the concept of strategic projects should be introduced. Given their role in ensuring the Union's security of supply for critical medicinal products, the relevant permitting authority should consider strategic projects verified by the designated authority to be in the public interest. To ensure their expedient implementation, national authorities should ensure that the relevant permit granting processes are carried out in the fastest way possible making available, in particular any form of accelerated procedures that exists in applicable Union and national law. National authorities should consider, when possible, their streamlining as well as enable digital submission of required information. EE (Comments): For clarity, we suggest adding that the accelerated processes are enabled to those projects that have been verified by the designated authority in accordance with Article 6. Not all projects that may, by their nature, meet the criteria of Article 5 can be treated as projects to which accelerated procedures apply. This would make it very difficult for the Member States' authorities to plan and organise their work effectively. IT (Comments):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	IT Comment: Given that the criteria for designating a strategic project are broad (as listed in Article 5), it is necessary to clarify how the uniform and consistent application of these criteria by the designated authorities in each Member State will be ensured. RO (Drafting suggestions): Certain projects **and technologies** can have a positive impact on security of supply as they increase the Union's manufacturing capacity **and improve efficiencies** for critical medicinal products and strengthen the resilience of the Union's supply chains. In order to encourage private investments in these projects, the concept of strategic projects should be introduced. Given their role in ensuring the Union's security of supply for critical medicinal products, the relevant permitting authority should consider strategic projects to be in the public interest. To ensure their expedient implementation, national authorities should ensure that the relevant permit granting processes are carried out in the fastest way possible making available, in particular any form of accelerated procedures that exists in applicable Union and national law. National authorities should consider, when possible, their streamlining **with a single point of contact for applicants**, as well as enable digital submission of required information. **The European Medicines Agency should have a clear mandate and framework to accelerate the assessment of new technologies that can improve the efficiency of the production of critical medicines.** RO (Comments):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	Our proposal is based on the fact that strategic projects should explicitly aim to accelerate the regulatory process for the implementation of new technologies that introduce efficiencies in terms of production, time, economy and environment in the existing manufacturing process for critical medicines.
(18) To avoid unnecessary delays and the creation of additional administrative layers, the verification of whether a project fulfils the strategic project criteria should be performed by any Member State authority requested to provide advantages offered in this Regulation. A designated authority should, when solicited, verify whether a given project is a strategic project. In order to accelerate and facilitate their deployment, strategic projects should benefit from streamlined administrative processes, priority status in the context of permit granting procedures and related dispute resolution procedures, as well as, be offered targeted regulatory support. In this context, the Member States should give particular attention to small and medium sized enterprises (SMEs) which should have a fair chance to initiate strategic projects.	AT (Drafting suggestions): AT: (18) To avoid unnecessary delays and the creation of additional administrative layers, the ~~verification~~ **assessment** of whether a project fulfils the strategic project criteria should be performed by any Member State authority requested to provide advantages offered in this Regulation. ~~A~~ **The** designated authority should, **however** ~~when solicited~~, **always** verify whether a given project is a strategic project. In order to accelerate and facilitate their deployment, strategic projects should benefit from streamlined administrative processes, priority status in the context of permit granting procedures and related dispute resolution procedures, as well as, be offered targeted regulatory support. In this context, the Member States should give particular attention to small and medium sized enterprises (SMEs) which should have a fair chance to initiate strategic projects. AT (Comments):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	AT: The competence regarding assessment and verification must be clear and should preferably be restricted to the designated authority. Alternatively, at least the final verification of a respective assessment performed by any Member State authority, other than the designated authority, should always be done by the designated authority. CZ (Comments): CZ considers it important to allow Member States to set the system of verification of the strategic projects so that the designated authority makes the decision, not any other Member States authority, or, where appropriate, a binding opinion is issued by the designated authority. Therefore, this part is proposed to be amended in line with the changes in the Article 6 of the draft Regulation which were proposed in our written comments after WPMMD on 15th July 2025. EE (Drafting suggestions): (18) ~~To avoid unnecessary delays and the creation of additional administrative layers, t~~The verification of whether a project fulfils the strategic project criteria should be performed by ~~any~~a Member State designated authority. ~~requested to provide advantages offered in this Regulation. A designated authority should, when solicited, verify whether a given project is a strategic project.~~ In order to accelerate and facilitate their deployment, strategic projects should benefit from streamlined administrative processes, priority status in the context of permit granting procedures and related dispute resolution procedures, as well as, be offered targeted regulatory support. In this context, the Member States

PUBLIC

Commission proposal	Drafting suggestions and Comments
	should give particular attention to small and medium sized enterprises (SMEs) which should have a fair chance to initiate strategic projects and fair access to funding. EE (Comments): To be aligned with our proposal in Article 6. We propose that it should always be the promoter who will request determination as strategic project by the designated authority. A single entry-point at the national level would be more efficient. The request from the promoter should always be submitted to the designated authority as a first step. Although it might be considered as an additional administrative step, it would ensure an overview of strategic projects at the national level, also for better strategic planning. Moreover, other permit granting authorities may not be well-placed to decide on whether the project meets the criteria for strategic projects. Additionally, special attention to SMEs should be included when it comes to access to Union funding. ES (Drafting suggestions): (18) To avoid unnecessary delays and the creation of additional administrative layers, the verification of whether a project fulfils the strategic project criteria should be performed by any Member State authority requested to provide advantages offered in this Regulation. A designated authority should, when solicited, verify whether a given project is a strategic project. In order to accelerate and facilitate their deployment, strategic projects should benefit from streamlined administrative processes, priority status in the context of permit granting procedures and

PUBLIC

Commission proposal	Drafting suggestions and Comments
	related dispute resolution procedures, as well as, be offered targeted regulatory support. In this context, the Member States should give particular attention to small and medium sized enterprises (SMEs) which should have a fair chance to initiate strategic projects. **The Commission intends to issue guidelines designed to support Member States in the application of harmonised criteria to name Strategic Project.** ES (Comments): The application of harmonised criteria is crucial. LT (Comments): LT: It follows from the provisions of Article 10 and Article 7 of the Proposal that urgency procedures apply only when they are provided for in national law. Nevertheless, recital 18 provides that strategic projects should benefit from streamlined procedures and given priority status but does not refer to national law. In the interests of legal clarity, it is appropriate to amend recital 18 by clearly indicating that this is left to the discretion of the Member States and regulated by national law. SE (Drafting suggestions):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(18) ~~**To avoid unnecessary delays and the creation of additional administrative layers, the verification of whether a project fulfils the strategic project criteria should be performed by any Member State authority requested to provide advantages offered in this Regulation. A designated authority should, when solicited, verify whether a given project is a strategic project.**~~ In order to accelerate and facilitate their deployment, strategic projects should benefit from streamlined administrative processes, priority status in the context of permit granting procedures and related dispute resolution procedures, as well as, be offered targeted regulatory support. In this context, the Member States should give particular attention to small and medium sized enterprises (SMEs) which should have a fair chance to initiate strategic projects. SE (Comments): We have a negative scrutiny reservation for (18) and wish to remove the two first sentences, and the corresponding Article 6.4 should be adjusted accordingly to one designated authority to check fulfilment of criteria. We believe the designated authority should be the coordinating authority, otherwise there is a risk for disparate views. We would like to know if several MS could be involved in the same strategic project, and how the permits then should be coordinated.
(19) The production of medicinal products has environmental implications and may negatively impact not only the environment itself but also human health. The environmental assessments and authorisations required under Union law are an integral part of the permit-granting	SE (Comments):

PUBLIC

Commission proposal	Drafting suggestions and Comments
process for strategic projects and an essential safeguard to ensure negative environmental impacts are prevented or minimised. However, to ensure that permit-granting processes for strategic projects are predictable and timely, it should be possible to streamline the required assessments and authorisations by the relevant authority, while not lowering the level of environmental protection.	This recital reflects national competence. A general reflection is that it may be problematic if decisions are made by different authorities in a MS, and if the timelines include decisions for specific or strategic environmental assessments in the planning stage.
(20) Land use conflicts can create barriers to the deployment of strategic projects. The relevant national, regional or local authority responsible for preparing zoning, spatial and land use plans should consider whether to introduce in these plans certain provisions related to strategic projects. Those plans have the potential to help balance the public interest and common good, decreasing the potential for conflict and accelerating the sustainable deployment of strategic projects in the Union.	SE (Drafting suggestions): (20) Land use conflicts can create barriers to the deployment of strategic projects. The relevant national, regional or local authority responsible for preparing zoning, spatial and land use plans should, **where appropriate**, consider whether to introduce in these plans certain provisions related to strategic projects. Those plans have the potential to help balance the public interest and common good, decreasing the potential for conflict and accelerating the sustainable deployment of strategic projects in the Union. SE (Comments): The corresponding Article 13.1. has incorporated “where appropriate”, it should be reflected in the recital as well.
(21) Given the capital-intensive nature of pharmaceutical production, including the establishment or expansion of manufacturing sites for critical medicinal products, active substances, and key inputs, targeted	AT (Comments):

PUBLIC

Commission proposal	Drafting suggestions and Comments
financial support can play a crucial role in incentivising production within the Union. To strengthen the security of supply of critical medicinal products, and where private investment alone is not sufficient, financial support of investments in manufacturing capacity within the Union may be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary.	AT: We would like to reiterate that we see it of utmost importance that sufficient financial resources are also made available at EU level. The support should not be left solely to the Member States as this would likely lead to significant discrepancies and be particularly problematic for small Member States. Promoting pharmaceutical production is cost-intensive and complex; for example, funds from the EU defence budget should be accessible for CMA funding. BG (Drafting suggestions): (21) Given the capital-intensive nature of pharmaceutical production, including the establishment or expansion **or modernisation** of manufacturing sites for critical medicinal products, active substances, and key inputs, targeted financial support can play a crucial role in incentivising production within the Union. To strengthen the security of supply of critical medicinal products, and where private investment alone is not sufficient, financial support of investments in manufacturing capacity within the Union may be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary. ES (Drafting suggestions): (…) To strengthen the security of supply of critical medicinal products, and where private investment alone is not sufficient, financial support of

PUBLIC

Commission proposal	Drafting suggestions and Comments
	investments in manufacturing capacity within the Union may be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, **including projects aimed at temporarily protecting existing manufacturing capacity that contributes to the production of critical medicinal products**, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary. ES (Comments): We consider it important to protect the preservation of existing manufacturing capacities, particularly when these are in a critical state and the continuity of production is at risk. LU (Comments): If "specific guidance to clarify the application of EU State aid rules to assist the Member States" has already been provided, it might be useful to insert a direct reference to it in the recital.
(22) Union-level funding may be leveraged to facilitate investments in strategic projects. Strategic projects may benefit from access to existing	EE (Comments): We would like to see more explicit wording on the obligation of the MAH to supply the Union market as a condition of receiving public funding.

PUBLIC

Commission proposal	Drafting suggestions and Comments
EU funding instruments, such as the EU4Health Programme[5], Digital Europe Programme[6] and Horizon Europe[7] (relevant, for example, for active substances referred to in Article 5(d) of Regulation (EU)2021/695), as well as the Strategic Technologies for Europe Platform (STEP), when they fulfil the criteria established in these instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 of the European Parliament and of the Council[8] (STEP) should in particular consider supporting strategic projects addressing a vulnerability in the supply chains of critical medicinal products and therefore Regulation (EU) 2024/795 should be amended.	ES (Drafting suggestions): Union-level funding may be leveraged to facilitate investments in strategic projects, **including those focused on protecting existing manufacturing capacity where necessary**. (…) ES (Comments): In line with the previous comment (21). IT (Comments): IT Comment: It should be considered whether to provide incentive mechanisms accessible also for investments ranging between €5 and €20 million. Indeed, the regulation should foresee incentives not only for the construction of new facilities but also for increasing the production capacity of existing ones. This would ensure faster implementation times

5 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of Health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, (OJ L 107, 26.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/522/oj)

6 Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240(OJ L166, 11.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/694/2023-09-21)

7 Regulation (EU) 2021/695 of the European Parliament and of the council of 28 April 2021 establishing Horizon //Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L170, 12.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/695/oj)

8 Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, (OJL 2024/794, 29.2.2024, ELI: http://data.europa.eu/eli/reg/2024/795/oj)

PUBLIC

Commission proposal	Drafting suggestions and Comments
	and a more efficient use of resources. The investment target of €5–20 million is particularly suitable to support modernization and capacity-enhancement interventions in already operational plants. For this reason, it would be appropriate to consider adequate financial incentives for this investment range.
(23) To allow for a more coordinated approach to financial support, it is appropriate that Member States and the Commission exchange the information on financial support to strategic projects. As regards the strategic projects that have benefitted from EU funding, the beneficiaries should follow the relevant communication and visibility rules[9].	
(24) Given that public authorities or entities are the principal buyers of medicinal products for the inpatient sector and that the public procurement of medicinal products is a powerful tool to improve security of supply and the availability and accessibility of other medicinal products of common interest, it is necessary to establish rules that require the use of the procurement requirements referring to Most Economically Advantageous Tender (MEAT) that take into account the supply security and availability considerations. Procurement requirements based on such considerations should include stockholding obligations, a number of diversified suppliers, state of the art monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery and measures in case of non-timely delivery.	BG (Drafting suggestions): (24) Given that public authorities or entities are the principal buyers of medicinal products for the inpatient sector and that the public procurement of medicinal products is a powerful tool to improve security of supply and the availability and accessibility of ~~other~~ medicinal products ~~of common interest~~, it is necessary to establish rules that **allow for** ~~**require**~~ the use of the procurement requirements referring to Most Economically Advantageous Tender (MEAT) that take into account the supply security and availability considerations. Procurement requirements based on such considerations ~~should~~ could include stockholding

[9] Communication and visibility rules - Publications Office of the EU

Commission proposal	Drafting suggestions and Comments
	obligations, a number of diversified suppliers, state of the art monitoring of supply chains, their transparency BG (Comments): The MEAT criteria should be used on voluntary basis, where appropriate. We recognise the potential benefits of having at disposal a variety of options at Union level, but the assessment for their implementation should remain with the authorities at national or subnational level. CZ (Drafting suggestions): (24) Given that public authorities or entities are the principal buyers of medicinal products for the inpatient sector and that the public procurement of medicinal products is a powerful tool to improve security of supply and the availability and accessibility of other medicinal products of common interest, it is necessary to establish rules that ~~require the use of the procurement requirements referring to Most Economically Advantageous Tender (MEAT) that take into account the supply security and availability considerations~~ **ensure that procurement requirements duly take into account supply security and availability considerations**. ~~Procurement~~ **Such** requirements ~~based on such considerations~~ ~~should~~ **may** include stockholding obligations, a number of diversified suppliers, state of the art monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery and measures in case

PUBLIC

PUBLIC

Commission proposal	Drafting suggestions and Comments
	of non-timely delivery. **Compliance with such requirements should be demonstrated in an appropriate and proportionate manner.** CZ (Comments): CZ considers automatic rejection of the price only evaluation as problematic and outdated in cases where the procurement requirements for quality, sustainability, and resilience are required and measured in other ways (as is stipulated in the last sentence, for that matter). Moreover, it should be ensured that requirements relating to supply security and availability are applied and enforceable, while allowing compliance to be demonstrated in an appropriate and proportionate manner. The objective is to prevent complicated or vaguely defined verification obligations from leading to obstruction, delays or blocking of procurement procedures, which would ultimately undermine the very availability of medicinal products that this legislation aims to safeguard. FR (Drafting suggestions): NEW: Manufacturing in the European Union complies with strict environmental and social standards, while certain third countries are not necessarily subject to the same requirements. This situation leads indirectly to the outsourcing of some of the environmental and social costs of drug production to Europe. Similarly, manufacturers established in the EU

PUBLIC

Commission proposal	Drafting suggestions and Comments
	incur compliance costs linked to these standards, which manufacturers located outside the EU may not have to face, thereby reducing their competitiveness. In order to gather further evidence on this situation, the Commission will launch a study to identify the sources of competitive disadvantage between European and non-European producers of critical medicines, their essential inputs and APIs. This study will compare the regulatory standards applicable to pharmaceutical manufacturing, its essential inputs and APIs between EU legislation (and its cumulative impact) and non-EU legislation, and quantify their impact on competitiveness, environmental risks and risks to public health. FR (Comments): As explained during the last group: The Critical Medicines Alliance indicated in its strategic report that a study should be launched to characterise potential regulatory asymmetry between Europe and Asia with regard to pharmaceutical production (in particular India and China, the main exporters of critical inputs and APIs) and to assess its impact on the competitiveness of European companies, environmental risks and risks to human health. It is essential to launch such a study in order to have a solid basis on the environmental and social asymmetries between the European Union and third countries, particularly in Asia. The study will quantify these effects, assess their impact on competitiveness, sustainability and human health,

PUBLIC

Commission proposal	Drafting suggestions and Comments
	and inform appropriate policy measures to re-establish a level playing field and support the EU's health sovereignty. Within this framework, following the study for example, it could be worthwhile to investigate potential mitigating measures and assess the impact of these measures on the continuity and affordability of supply. SE (Drafting suggestions): (24) Given that public authorities or **by them contracted private** entities are the principal buyers of medicinal products for the inpatient sector and that the public procurement of medicinal products is a powerful tool to improve security of supply and the availability and accessibility of other medicinal products of common interest, it is necessary to ~~establish~~ **promote the use of** rules **for** ~~**that require the use of the**~~ procurement requirements **that do not increase vulnerability of supply.** ~~**referring to Most Economically Advantageous Tender (MEAT) that take into account the supply security and availability considerations.**~~ Procurement requirements based on such considerations ~~should~~ **may** include stockholding obligations, a number of diversified suppliers, state of the art monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery and measures in case of non-timely delivery. SE (Comments):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	Please see proposed addition to cover all possible buyers, although public authorities are more common, at least in SE, and alterations to accommodate more flexibility to the recital.
(25) Inconsistent use of procurement requirements in public procurement procedures may have negative impact on the internal market as it creates obstacles to cross-border participation and a lack of predictability for bidders. In order to avoid such negative outcomes, the use of MEAT criteria should be mandatory.	AT (Comments): AT: (general comment): The recital addresses the negative effects of inconsistent application of procurement requirements. The mandatory use of MEAT is intended to remedy this situation. However, Article 18 of the proposed regulation does not provide for the mandatory application of specific, operationally applicable criteria. The mandatory use of MEAT has no effect on the inconsistent application of criteria addressed in the recital, nor does it have any effect on barriers to cross-border participation and the lack of predictability for bidders. With regard to Article 18 of the proposed regulation, this statement is therefore problematic. Subject to the upcoming compromise text and since the mandatory use of MEAT is already addressed in Recital 24, AT currently advocates for the deletion of Recital 25. BG (Drafting suggestions): ~~Inconsistent use of procurement requirements in public procurement procedures may have negative impact on the internal market as it creates obstacles to cross-border participation and a lack of predictability for~~

PUBLIC

Commission proposal	Drafting suggestions and Comments
	~~bidders. In order to avoid such negative outcomes, the use of MEAT criteria should be mandatory.~~ BG (Comments): We propose deleting the sentence making the use of MEAT criteria mandatory. It should be possible also in future to use the price as the leading criterium. Our objection to the mandatory introduction of the MEAT criteria is related to the comments on the legal basis, incl. Art. 168 (7) TFEU. CZ (Drafting suggestions): ~~(25) Inconsistent use of procurement requirements in public procurement procedures may have negative impact on the internal market as it creates obstacles to cross-border participation and a lack of predictability for bidders. In order to avoid such negative outcomes, the use of MEAT criteria should be mandatory.~~ CZ (Comments): Please see the comment on recital 24 above. EE (Drafting suggestions): (25) Inconsistent use of procurement requirements in public procurement procedures may have negative impact on the internal market as it creates obstacles to cross-border participation and a lack of predictability for bidders. In order to avoid such negative outcomes, the

PUBLIC

Commission proposal	Drafting suggestions and Comments
	use of MEAT criteria should be mandatory, unless justified by the considerations related to the market analysis or considerations related to financing of health services. EE (Comments): To better explain the full content of Article 18. We stress the importance of maintaining flexibility for Member States, particularly in smaller markets or low-competition contexts. The application of MEAT criteria should remain flexible and must not become mandatory where it risks undermining competition or procurement feasibility. ES (Comments): In line with other Member States such as BG, SE, HR, PL, LT or AT, we believe that is necessary to introduce a certain degree of flexibility regarding compliance with the MEAT criteria, avoiding terms such as “should” and “mandatory”. FR (Drafting suggestions): NEW: In order to promote the resilient, competitive and environmentally sustainable production of critical medicines, public procurement procedures can incorporate qualitative award criteria, including those related to environmental sustainability and social considerations. However, these efforts require a harmonised approach at EU level. The

PUBLIC

Commission proposal	Drafting suggestions and Comments
	European Commission, in close cooperation with the Critical Medicines Alliance, Member States and relevant stakeholders, should therefore support the development of common European public procurement standards related to sustainability requirements and socially responsible procurement. In particular, with regard to the environmental impact of medicinal products, the Commission shall work towards the development of harmonised methodologies for environmental impact assessment in public procurement procedures for medicinal products, encompassing the carbon footprint as well as other critical environmental indicators such as water consumption, use of natural resources and impact on biodiversity. The priority should be to establish a harmonised methodology for assessing the carbon footprint of medicinal products, in order to recognise the efforts of EU-based manufacturers, ensure a level playing field in tendering procedures and minimise the burden on bidders and purchasers. This should be accompanied by the creation of common platforms for the collection, exchange and use of comprehensive environmental data. FR (Comments): Reflecting the comments shared during the last group meeting, in order to highlight the environmental value of European production, based on compliance with strict standards, the use of public procurement will be an essential lever for strengthening the security of supply and resilience associated with models based on European production. Although the draft regulation already authorises the use of qualitative criteria (social, environmental, etc.) in calls for tender relating to critical medicinal products (article 18(4)), to guarantee a real impact it seems necessary to work on a common and harmonised definition of these standards, in order

PUBLIC

Commission proposal	Drafting suggestions and Comments
	to implement them progressively and ensure effective differentiation when contracts are allocated. SE (Drafting suggestions): ~~**(25) Inconsistent use of procurement requirements in public procurement procedures may have negative impact on the internal market as it creates obstacles to cross-border participation and a lack of predictability for bidders. In order to avoid such negative outcomes, the use of MEAT criteria should be mandatory.**~~ SE (Comments): We suggest this is deleted in its entirety. This recital precludes an ongoing discussion on public procurement at the EU level.
(26) To ensure a high level of health protection and security of supply, it is necessary to procure in a way that promotes diversification of suppliers where dependency on a single or a limited number of third countries, threatening the security of supply, has been established through a vulnerability evaluation. In such situations, contracting authorities in the Member States should introduce procurement requirements that favour suppliers of critical medicinal products that manufacture a significant portion of these products in the EU. Moreover, the contracting authorities in the Member States, when justified by market analysis and public health considerations, may apply procurement requirements that favour suppliers of medicinal products of common interest that manufacture a	BG (Drafting suggestions): (26) To ensure a high level of health protection and security of supply, it is necessary to procure in a way that promotes diversification of suppliers where dependency on a single or a limited number of third countries, threatening the security of supply, has been established through a vulnerability evaluation. In such situations, contracting authorities in the Member States **may** ~~should~~ introduce procurement requirements that favour suppliers of critical medicinal products that manufacture a significant portion of these products in the EU. ~~**Moreover, the**~~

PUBLIC

Commission proposal	Drafting suggestions and Comments
significant portion of these medicinal products in the EU. These measures should be designed and applied in line with the Union's international obligations including the principles of non-discrimination and proportionality.	~~**contracting authorities in the Member States, when justified by market analysis and public health considerations, may apply procurement requirements that favour suppliers of medicinal products of common interest that manufacture a significant portion of these medicinal products in the EU. These measures should be designed and applied in line with the Union's international obligations including the principles of non-discrimination and proportionality.**~~ CZ (Drafting suggestions): 26) To ensure a high level of health protection and security of supply, it is necessary to procure in a way that promotes diversification of suppliers where dependency on a single or a limited number of third countries, threatening the security of supply, has been established through a vulnerability evaluation. In such situations, contracting authorities in the Member States should introduce procurement requirements that favour suppliers of critical medicinal products that manufacture a significant portion of these products in the EU. **As established by the case-law of the *Court of Justice of the European Union*, notably in the *Kolin Inşaat Turizm* and *Quingdao* cases**, the contracting authorities in the Member States, when justified by market analysis and public health considerations, may apply procurement requirements that favour suppliers of medicinal products of common interest that manufacture a significant portion of these medicinal products in the EU. **These measures shall be framed and applied under this Regulation in a manner consistent with the Union's international obligations. The Commission shall provide the necessary**

PUBLIC

Commission proposal	Drafting suggestions and Comments
	guidance and assistance to Member States and contracting authorities in the application of such measures. CZ (Comments): CZ believes that the option to favour non third countries suppliers stems from the CJEU ruling in Case C-652/22 (Kolin Inşaat Turizm), allowing contracting authorities to exclude third county suppliers — without needing an explicit legal mandate to do so. CZ proposes the amendment to clarify that the Union, not individual contracting authorities or Member States, bears responsibility for compliance with international obligations. Contracting authorities should be able to take security of supply and EU production into account without fear of international dispute settlement risks. The Commission should therefore provide the necessary guidance and assistance to Member States to ensure coherent and practicable implementation. In any case, we believe the Kolin and Quingdao judgement was discussed in detail with GROW and TRADE. Moreover, CZ suggests that the draft Regulation or the recitals stipulates how to • handle long-term contracts where total volumes are not predetermined • how to deal with purchases not made directly from the manufacturer. EE (Comments):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	"A significant portion" needs more clarity, as it is not defined in main text either. LU (Drafting suggestions): (26) To ensure a high level of health protection and security of supply, it is necessary to procure in a way that promotes diversification of suppliers where dependency on a single or a limited number of third countries, threatening the security of supply, has been established through a vulnerability evaluation. ~~**In such situations, contracting authorities in the Member States should introduce procurement requirements that favour suppliers of critical medicinal products that manufacture a significant portion of these products in the EU.**~~ ~~**Moreover, the contracting authorities in the Member States, when justified by market analysis and public health considerations, may apply procurement requirements that favour suppliers of medicinal products of common interest that manufacture a significant portion of these medicinal products in the EU. These measures should be designed and applied in line with the Union's international obligations including the principles of non-discrimination and proportionality.**~~ LU (Comments): Luxembourg is reluctant to include an explicit reference to the principle of European preference in the provisions relating to public procurement.

PUBLIC

Commission proposal	Drafting suggestions and Comments
(27) The application of procurement requirements should take into account the specific market conditions and public health needs of each procurement procedure, whilst bearing in mind the considerations related to affordability of medicinal products. Certain procurement requirements may not be justified if they result in disproportionate cost for procurers or discourage participation, leading to no bids.	CZ (Drafting suggestions): (27) The application of procurement requirements should take into account the specific market conditions and public health needs of each procurement procedure, whilst bearing in mind the considerations related to affordability of medicinal products. Certain procurement requirements may ~~not~~ be neither justified **nor mandatory** if they result in disproportionate cost for procurers or discourage participation, leading to no bids. CZ (Comments): CZ believes that for clarity of text this recital should not only state that certain procurement requirements may not be justified, but also that they may not be mandatory. LU (Comments): Luxembourg would kindly ask the COM to clarify what is meant by "disproportionate costs" in recital 27 so that the MS can assess this when drawing up their public tenders. The COM is also asked to clarify the link between this recital and Article 8, $5 and justify the use of different vocabulary. Furthermore, Luxembourg kindly asks the COM to clarify the implementation of this exception to the use of MEAT criteria, since the

PUBLIC

Commission proposal	Drafting suggestions and Comments
	"disproportionate costs" would only be known once the tender has been launched and the bids received.
(28) In accordance with Article 168(7) TFEU Member States' responsibilities for the definition of their health policy and for the organisation and delivery of health services and medical care, including the allocation of financial resources, are to be respected. The contracting authorities should therefore retain the ability, where justified by the considerations related to the market analysis or considerations related to financing of health services, to adopt procurement approaches that differ from those set out in this Regulation as long as they are in line with the Union's international obligations.	
	FI (Drafting suggestions): **28 a new) Without affecting the rules laid down in this Regulation, Member States remain the sole responsible for their own national security. They are responsible in defending their essential state functions, including ensuring their territorial integrity and safeguarding national security. In particular, under Article 346 TFEU, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security. For this reason, Member States should be able to waive some of the information obligations related to the marketing of medicinal products when these medicinal products are supplied for military or defence purposes or insofar as the application of such requirements imply a risk to national security and defence.**

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(28 b new) The rules laid down in this Regulation may also be applicable for strategic projects coinciding with strategic military or defence objectives in strengthening the security of supply of critical medicines. FI (Comments): DE, FI and SE proposal concerning a new recital that takes into account the Member States' responsibilities concerning security as well. SE (Drafting suggestions): **(28 a new) Without affecting the rules laid down in this Regulation, Member States remain the sole responsible for their own national security. They are responsible in defending their essential state functions, including ensuring their territorial integrity and safeguarding national security. In particular, under Article 346 TFEU, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security. For this reason, Member States should be able to waive some of the information obligations related to the marketing of medicinal products when these medicinal products are supplied for military or defence purposes or insofar as the application of such requirements imply a risk to national security and defence.**

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(28 b new) The rules laid down in this Regulation may also be applicable for strategic projects coinciding with strategic military or defence objectives in strengthening the security of supply of critical medicines. SE (Comments): In conjunction to recital 28 we would like to add two recitals (28a new, which is identical from Chapter X in the pharma package). 28 b new, to ensure that civil and defence may have coinciding objectives in a strategic project.
(29) The Commission intends to issue guidelines designed to support Member States in implementing their obligations to use procurement requirements including award criteria beyond price considerations with a view to strengthening the security of supply, building on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate.	BG (Drafting suggestions): The Commission intends to issue guidelines designed to support Member States ~~in~~ **if they decide to ~~implementing~~ ~~their obligations to~~** use procurement requirements including award criteria beyond price considerations with a view to strengthening the security of supply, building on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate. CZ (Drafting suggestions):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(29) The Commission **shall issue implementing act** ~~intends to issue guidelines~~ designed to support Member States in implementing their obligations to use procurement requirements including award criteria beyond price considerations with a view to strengthening the security of supply, building on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate. CZ (Comments): CZ considers guidelines mentioned only in Recital to be insufficient. Therefore, CZ believes it is necessary to include specific information in implementing act instead of guidelines, meaning to support Member States in implementing their obligations to use procurement requirements, as proposed by CZ in the Article 19 of the draft Regulation in our previous written comments. Please see the changes in wording proposed. IE (Comments): IE welcome the Commission's intention to publish guidelines LU (Comments): LU would kindly ask the COM to specify when it intends to publish these guidelines.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	RO (Drafting suggestions): The Commission ~~intends~~ **should** to issue guidelines designed to support Member States in implementing their obligations to use procurement requirements including award criteria beyond price considerations with a view to strengthening the security of supply, building on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate. RO (Comments): Our intention is based on the fact that guidance from the Commission is needed in the implementation of the obligations on the procurement component. Moreover, it is necessary to establish a deadline that is prior to the 6-month deadline imposed by the MS in art. 19, which is not feasible - as we mentioned in our previous comments.
(30) The procurement of medicinal products is organised differently across Member States, involving various actors. To strengthen the security of supply chains for critical medicinal products, Member States should establish national programmes that promote the consistent use of procurement criteria by contracting authorities within their territory, including the application of multi-winner approaches where beneficial, based on thorough market analysis. To ensure a comprehensive approach, and considering that critical medicinal products are also relevant for	BG (Drafting suggestions): ~~(30) The procurement of medicinal products is organised differently across Member States, involving various actors. To strengthen the security of supply chains for critical medicinal products, Member States should may establish national programmes that promote the consistent use of procurement criteria by contracting authorities within their~~

PUBLIC

Commission proposal	Drafting suggestions and Comments
outpatient sector where they are often not purchased through public procurement, these programmes may also encompass measures to strengthen supply chain resilience and sustainability through measures related to pricing and reimbursement, where appropriate. The programmes should be shared with the Commission and the Critical Medicines Coordination Group, established by this Regulation, to facilitate the exchange of best practices and coordination between the Member States. This cooperation should enhance the overall effectiveness of the various measures put forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality.	~~territory, including the application of multi-winner approaches where beneficial, based on thorough market analysis. To ensure a comprehensive approach, and considering that critical medicinal products are also relevant for outpatient sector where they are often not purchased through public procurement, these programmes may also encompass measures to strengthen supply chain resilience and sustainability through measures related to pricing and reimbursement, where appropriate. The programmes should be shared with the Commission and the Critical Medicines Coordination Group, established by this Regulation, to facilitate the exchange of best practices and coordination between the Member States. This cooperation should enhance the overall effectiveness of the various measures put forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality.~~ BG (Comments): Before introducing such a burdensome obligation for Member States, the expected benefits should be demonstrated. In any case, references to pricing and reimbursement policies are misplaced in this act. EE (Comments): Scres on national programmes until better understanding of added value of national programmes, incl. to voluntarily encompass measures to strengthen supply chain resilience and sustainability through measures related to pricing and reimbursement.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	IT (Drafting suggestions): (30) The procurement of medicinal products is organised differently across Member States, involving various actors. To strengthen the security of supply chains for critical medicinal products, Member States should establish national programmes that promote the consistent use of procurement criteria by contracting authorities within their territory, including the application of multi-winner approaches where beneficial, based on thorough market analysis. To ensure a comprehensive approach, and considering that critical medicinal products are also relevant for outpatient sector where they are often not purchased through public procurement, these programmes may also encompass measures to strengthen supply chain resilience and sustainability ~~through measures related to pricing and reimbursement, where appropriate.~~ The programmes should be shared with the Commission and the Critical Medicines Coordination Group, established by this Regulation, to facilitate the exchange of best practices and coordination between the Member States. This cooperation should enhance the overall effectiveness of the various measures put forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality. IT (Comments): IT Comment: Given that the programs mentioned could include pricing and reimbursement measures, which fall under exclusive national competence, we would like to revise this recital accordingly. RO

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(Drafting suggestions): The procurement of medicinal products is organised differently across Member States, involving various actors. To strengthen the security of supply chains for critical medicinal products, Member States should establish national programmes that promote the consistent use of procurement criteria by contracting authorities within their territory, including the application of multi-winner approaches where beneficial, based on thorough market analysis. To ensure a comprehensive approach, and considering that critical medicinal products are also relevant for outpatient sector where they are often not purchased through public procurement, these programmes may also encompass measures to strengthen supply chain resilience and ~~sustainability through measures related to pricing and reimbursement, where appropriate~~. The programmes should be shared with the Commission and the Critical Medicines Coordination Group, established by this Regulation, to facilitate the exchange of best practices and coordination between the Member States. This cooperation should enhance the overall effectiveness of the various measures put forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality RO (Comments): Our proposal is based on the fact that pricing and reimbursement policies is part of a strategy to ensure availability. We reiterate that according to the Treaties, pricing and reimbursement are an exclusively national competence and the prerogative to intervene in national policies in the field of medicines lies with national authorities.

PUBLIC

Commission proposal	Drafting suggestions and Comments
(31) Obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold contingency stocks can have a serious negative impact on the internal market and other Member States. To avoid such an impact, these obligations should be designed taking into consideration the principles of proportionality, transparency and solidarity. The Member States should give due consideration to forthcoming Commission guidelines designed to facilitate the fulfilment of Member States' obligations as regards the absence of any negative impact on the internal market when proposing and defining the scope and timing of any form of requirements for companies to hold such stocks.	AT (Comments): AT: In our view, it is essential to discuss the topic of contingency stocks/stockpiling in more depth and make appropriate distinctions between national stockpiling versus stockpiling by MAH. If there are no sustainable EU programmes, national stockpiling strategies will continue to be necessary in crisis situations, meaning that the same problems as during the Covid-19 pandemic could occur. There needs to be better harmonization with the stockpiling strategy, the Union preparedness strategy, as well as the role of the Critical Medicines Alliance. CZ (Comments): CZ supports extending the provision on contingency stocks with additional provisions concerning other security of medicine supply measures (as stated in the title of the Article 20 of draft Regulation). Ideally, these provisions should be included in the Articles of the draft Regulation, or at least in other recitals. FI (Comments): FI would propose deleting the reference to serious negative impact on the internal market. We also prefer Commission guidelines to delegated acts or other legal acts laying down legal obligations concerning national contingency stockpiles.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	FR (Drafting suggestions): 31) Obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold contingency stocks ~~can have a serious negative impact on the internal market and other Member States.~~ **are intended to reduce the impact of supply disruptions on patients. When introducing such obligations, t**he Member States **should comply with the notification obligations under Directive 2015/1535** ~~give due consideration to forthcoming Commission guidelines designed to facilitate the fulfilment of Member States' obligations as regards the absence of any negative impact on the internal market when proposing and defining the scope and timing of any form of requirements for companies to hold such stocks~~. FR (Comments): The French authorities believe that any European initiative aimed at regulating the level or methods of building up contingency stocks would be likely to contravene, on the one hand, Article 168(7) TFEU, which reserves limited supporting powers for the Union in the field of healthcare organisation, and, on the other hand, the principles of subsidiarity and proportionality. In a context of strong pressure on supply chains, it is important that Member States retain full discretion to determine the level and methods of building up security stocks, in line with their health priorities, logistical capacities and their own continuity of care strategy.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	That is why, France would like to see the recital amended. It is important to reiterate the notification obligation under the Directive 2025/1535 regardless of the nature of the obligation (text or contract). IE (Comments): As per Article 20, IE agree that it is important to avoid any negative impact of contingency stocks. LT (Comments): LT: We support the wording of this recital, but we think that Article 20 of the Regulation should be supplemented by a reference to the Commission guidelines referred to in this recital. SE (Drafting suggestions): (31) Obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold contingency stocks can have a serious negative impact on the internal market and **cause shortages in other** Member States. To avoid such an impact, these obligations **and enforcement timelines** should be designed taking into consideration the principles of proportionality, transparency and solidarity. The Member States should give due consideration to forthcoming Commission guidelines designed to facilitate the fulfilment of Member States' obligations as regards the absence of any negative impact on the internal

PUBLIC

Commission proposal	Drafting suggestions and Comments
	market when proposing and defining the scope and timing of any form of requirements for companies to hold such stocks. SE (Comments): Support guidelines. We think the recital should contain more of concrete consequences for MS when requirements are changed, and that the timelines for increases of stocks matter, as the quantity of need in MS (proportionality).
(32) Availability and access disparities exist for critical medicinal products and medicinal products of common interest throughout the Union, disproportionately affecting some Member States. The collaborative procurement of critical medicinal products and of medicinal products of common interest can be a powerful tool to improve their security of supply and accessibility.	BG (Drafting suggestions): (32) Availability ~~and access~~ disparities **may** exist for critical medicinal products ~~and medicinal products of common interest~~ throughout the Union, disproportionately affecting some Member States. The collaborative procurement of critical medicinal products and of medicinal products of common interest can be a ~~powerful~~ tool to improve their security of supply and accessibility. BG (Comments): In view of the SWD, a more moderate wording is more appropriate. IT (Comments): IT Comment: See comment to Recital 10.

PUBLIC

Commission proposal	Drafting suggestions and Comments
(33) Directive 2014/24/EU of the European Parliament and of the Council[10] provides for the possibility of procurement involving contracting authorities from different Member States. Whereas it has been found helpful to make small markets attractive for suppliers, thereby achieving better availability of medicinal products, its implementation is time- and resource-intensive, especially in the starting phase, and considered a limiting factor. To facilitate the deployment of procurement initiatives involving contracting authorities from different Member States, the Commission, when requested, should provide its assistance during the preliminary phase of setting up such a procurement initiative.	BG (Comments): Reserve on all references related to Art. 22 and Art. 23. EE (Comments): Second sentence – could some examples be included to the reference based on which it is argued that joint procurements have been found to make small markets attractive?
(34) Taking into account experiences resulting from the implementation of joint procurement of medical countermeasures pursuant to Regulation (EU) 2022/2371 of the European Parliament and of the Council[11] and of COVID-19 vaccines, pursuant to Council Regulation (EU) 2016/369[12] in the context of the EU Vaccines Strategy and acknowledging potential benefits that leveraging of several Member States demand in one procurement procedure may have, Member States	BG (Drafting suggestions): [~~(34) Taking into account experiences resulting from the implementation of joint procurement of medical countermeasures pursuant to Regulation (EU) 2022/2371 of the European Parliament and~~

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

[11] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

[12] Council Regulation (EU) 2016/296 of 15 March 2016 on the provision of the emergency support within the Union (OJ L 70, 13.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/369/oj)

PUBLIC

Commission proposal	Drafting suggestions and Comments
should be able to consider the use of joint procurement or to consider requesting the Commission to procure on their behalf, or in their name, where such procurement could contribute to the achievement of the objectives of this Regulation.	~~of the Council[13] and of COVID-19 vaccines, pursuant to Council Regulation (EU) 2016/369[14] in the context of the EU Vaccines Strategy and acknowledging potential benefits that leveraging of several Member States demand in one procurement procedure may have, Member States should be able to consider the use of joint procurement or to consider requesting the Commission to procure on their behalf, or in their name, where such procurement could contribute to the achievement of the objectives of this Regulation.]~~ BG (Comments): Reserve on all references related to Art. 22 and Art. 23. We note that experiences from joint procurement of medical countermeasures would justify in principle the inclusion in the scope of only this category of medicines. The lack of positive experiences at Union level with other medicines speaks against, rather than in favor of scaling up joint procurement.
(35) To ensure that the collaborative procurement initiatives contribute to the achievement of the objectives of this Regulation, while fully respecting the principle of subsidiarity, the Commission's involvement in joint procurement and procurement on behalf, or in the name of the	CZ (Drafting suggestions):

[13] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

[14] Council Regulation (EU) 2016/296 of 15 March 2016 on the provision of the emergency support within the Union (OJ L 70, 13.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/369/oj)

PUBLIC

Commission proposal	Drafting suggestions and Comments
Member States, should be limited to defined cases. For this reason derogations from Article 168 (2) and (3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[15] should be provided.	(35) To ensure that the collaborative procurement initiatives contribute to the achievement of the objectives of this Regulation, while fully respecting the principle of subsidiarity, the Commission's involvement in joint procurement and procurement on behalf, or in the name of the Member States, should be limited to ~~defined~~ cases **where the conditions set out in the relevant Articles are met.** For this reason, derogations from Article 168 (2) and (3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[16] should be provided. CZ (Comments): CZ considers limitation to *defined cases* specified in the recital as unclear. CZ believes that the Commission should be automatically involved in collaborative procurements if the Member States request and once the conditions of Articles 21, 22 or 23 have been met. Please see the changes in wording proposed.
(36) To ensure transparency, legal clarity, and effective coordination, structured agreement between the Member States and the Commission should govern procurement procedures under this Regulation that rely on an active Commission involvement. Such agreement should set out the	BG (Comments):

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

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

PUBLIC

Commission proposal	Drafting suggestions and Comments
division of responsibilities, decision-making processes, the information to be shared as relevant to the procurement procedure, including information on Member States' participation in parallel negotiations through different channels in relation to the same medicinal products or the same active substances as appropriate, and liability provisions, ensuring a fair and efficient framework for participating Member States while preventing market distortions and supply disruptions. This Regulation is without prejudice to and does not prevent the use of joint procurement procedures established under Regulation (EU) 2022/2371 of the European Parliament and of the Council for those critical medicinal products and other medicinal products that also fall within the definition of medical countermeasures as set out in that Regulation. For such medicinal products, the objective of the joint procurement initiative should determine the applicable framework. Where a joint procurement procedure is initiated with the aim of advance purchasing of these medicinal products as medical countermeasures to prepare for and respond to serious cross-border threats to health, such a procurement procedure should be carried out in accordance with Regulation (EU) 2022/2371. This Regulation is without prejudice to Council Regulation (EU) 2022/2372[17] setting the framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.	This recital should be reconsidered in the light of the articles. Member states should preserve the possibility to participate in national negotiations in any case. EE (Comments): We consider it more efficient to extend the scope of existing frameworks and use the existing structures to be able to rely on the existing expertise and avoid duplication. We suggest that 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.
(37) Ensuring a structured and coordinated approach to strengthening the security of supply of critical medicinal products requires collaboration	AT

[17] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj)

PUBLIC

Commission proposal	Drafting suggestions and Comments
between the Member States and the Commission. To facilitate this, the Critical Medicines Coordination Group ('the Critical Medicines Group') should be established to facilitate effective coordination across the relevant policy areas. The Critical Medicines Group should be composed of high-level representatives of Member States with expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. The Commission should be a member of the group. To ensure structured discussions, the Commission should chair the Critical Medicines Group and perform the functions of its secretariat.	(Comments): AT: We still have reservations against the establishment of a separate Critical Medicines Coordination Group. Due to a relatively large number of already established structures (e.g. extended EMA mandate, MSSG), we see a risk of duplication. Additional infrastructure such as committees, coordination or working groups are particularly problematic for smaller member states, as they require additional qualified personnel to staff these boards. BG (Drafting suggestions): (37) Ensuring a structured and coordinated approach to strengthening the security of supply of critical medicinal products requires collaboration between the Member States and the Commission. To facilitate this, the Critical Medicines Coordination Group ('the Critical Medicines Group') should be established to facilitate **sharing of good practices between Member states.** ~~**effective coordination across the relevant policy areas.**~~ The Critical Medicines Group should be composed of high-level representatives of Member States with expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. The Commission should be a member of the group. To ensure structured discussions, the Commission **and two representatives of the Member states** should **co-**chair the Critical Medicines Group and perform the functions of its secretariat. BG (Comments): The Critical Medicines Coordination Group should have an advisory role.

PUBLIC

Commission proposal	Drafting suggestions and Comments
	CZ (Drafting suggestions): (37) Ensuring a structured and coordinated approach to strengthening the security of supply of critical medicinal products requires collaboration between the Member States and the Commission. To facilitate this, the Critical Medicines Coordination Group ('the Critical Medicines Group') should be established to facilitate effective coordination across the relevant policy areas. The Critical Medicines Group should be composed of high-level representatives of Member States with expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. The Commission should be a member of the group. To ensure structured discussions, **a representative of the Member States and a representative of the Commission should co-chair** ~~the Commission should chair~~ the Critical Medicines Group and **the Commission should** perform the functions of its secretariat. CZ (Comments): CZ believes it would be more appropriate to include representative of Member States as co-chair of Critical Medicines Coordination Group as mentioned in our previous comments related to Article 25 of the draft Regulation. Please see the changes in wording proposed. ES (Drafting suggestions):

PUBLIC

Commission proposal	Drafting suggestions and Comments
	(…) The Critical Medicines Group should be composed of high-level representatives of Member States with ~~expertise~~ **national competences** in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. The Commission should be a member of the group. (…) ES (Comments): We believe it is essential that members of this Group are not only experts in the field, but also have national competencies in pharmaceutical policy, ensuring appropriate institutional representation. IT (Comments): IT Comment: With reference to the establishment of a new group, in order to avoid potential overlaps of responsibilities with existing groups and misalignments in the management of individual cases, it is important to clearly describe the competences of the new group as well as the institutions/resources to be involved. SE (Drafting suggestions): (37) Ensuring a structured and **coherent information** and coordinated approach to strengthening the security of supply of critical medicinal products requires collaboration between the Member States and the Commission. To facilitate this, the Critical Medicines Coordination Group ('the Critical Medicines Group') should be established to facilitate

PUBLIC

Commission proposal	Drafting suggestions and Comments
	effective coordination across the relevant policy areas. The Critical Medicines Group should be composed of high-level representatives of Member States with expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. The Commission should be a member of the group. To ensure structured discussions, the Commission should chair the Critical Medicines Group and perform the functions of its secretariat. SE (Comments): The Commission has responsibilities also in the other legal Acts, relevant to communicate in the Coordination Group, e.g. actions in Article 134 of the proposed Pharmaceutical Regulation.
(38) To ensure coordinated implementation of this Regulation, the Critical Medicines Group should enable exchanges of information related to funding of strategic projects and facilitate the strategic orientation of financial support for strategic projects. The Critical Medicines Group should also facilitate the exchange of information on national programmes, including on the approach to contingency stock requirements in public procurement contracts. When relevant, the Critical Medicines Group should facilitate the coordination of national programmes. The Critical Medicines Group should furthermore facilitate discussions on the need to launch a collaborative procurement initiative and the need to prioritise the vulnerability evaluation for specific critical medicinal products.	BG (Drafting suggestions): ~~To ensure coordinated implementation of this Regulation, the Critical Medicines Group should enable exchanges of information related to funding of strategic projects and facilitate the strategic orientation of financial support for strategic projects. The Critical Medicines Group should also facilitate the exchange of information on national programmes, including on the approach to contingency stock requirements in public procurement contracts. When relevant, the Critical Medicines Group should facilitate the coordination of national programmes. The Critical Medicines Group should furthermore facilitate discussions on the need to launch a collaborative procurement initiative~~

PUBLIC

Commission proposal	Drafting suggestions and Comments
	~~and the need to prioritise the vulnerability evaluation for specific critical medicinal products.~~ CZ (Drafting suggestions): (38) To ensure coordinated implementation of this Regulation, the Critical Medicines Group should enable exchanges of information related to funding of strategic projects and facilitate the strategic orientation of financial support for strategic projects **based on the Union investment strategy for critical medicinal products**. The Critical Medicines Group should also facilitate the exchange of information on national programmes, including on the approach to contingency stock requirements in public procurement contracts. When relevant, the Critical Medicines Group should facilitate the coordination of national programmes. The Critical Medicines Group should furthermore facilitate discussions on the need to launch a collaborative procurement initiative and the need to prioritise the vulnerability evaluation for specific critical medicinal products. CZ (Comments): In general, CZ supports the extension of competences of Critical Medicines Coordination Group. Moreover, we propose to create the Union investment strategy for critical medicinal products with the aim to ensure a diversified market and to avoid supporting similarly targeted strategic projects, which should also simplify strategic orientation of financial support for strategic

PUBLIC

Commission proposal	Drafting suggestions and Comments
	projects. Further clarification is needed on how to *facilitate the strategic orientation of financial support for strategic projects* as well. CZ supports the inclusion of exchanges of information, particularly in the context of contingency stocks requirements. Please see the changes in wording proposed. EE (Drafting suggestions): (38) To ensure coordinated implementation of this Regulation, the Critical Medicines Group should enable exchanges of information related to funding of strategic projects and facilitate the strategic orientation of financial support for strategic projects. The Critical Medicines Group should also facilitate the exchange of information on national programmes, including on the approach to contingency stock requirements in public procurement contracts. When relevant, the Critical Medicines Group should facilitate the coordination of national programmes. The Critical Medicines Group should furthermore facilitate discussions on the need to launch a collaborative procurement initiative and the need to prioritise the vulnerability evaluation for specific critical medicinal products in addition to the procedure for and criteria of the prioritisation of the vulnerability evaluation referred in the Regulation x Article 130 p 1 (b). EE (Comments): Scres concerning national programmes. It should be specified how the CMG prioritisation of vulnerability analysis fits into to the Agency´s procedure for and criteria of the

PUBLIC

Commission proposal	Drafting suggestions and Comments
	prioritisation of the vulnerability evaluation referred in the Regulation Article 130 p 1 (b) in the EU pharmaceutical package. FR (Drafting suggestions): …/… ~~including on the approach to contingency stock requirements in public procurement contracts~~. …/…. FR (Comments): The French authorities have questions about the words 'including on the approach to contingency stock requirements in public procurement contracts'. At this stage, pending clarification, it would be preferable not to maintain this part of the sentence.
(39) The Union could further enhance the availability and security of supply of critical medicinal products by providing access to alternative sources of supply in third countries through international trade agreements or other forms of international cooperation. The Union could, to that end, rely on its network of existing trade agreements and additionally pursue strategic partnerships with third countries to further deepen bilateral cooperation, especially with candidate countries. In this context, the Commission should assess whether existing partnerships effectively address the intended aims or could be further improved or	CZ (Comments): CZ supports the inclusion of the third countries into the collaborative procurement mechanism. Please see our previous written comments related to the Article 27 of the draft Regulation. CZ believes this proposal should be mentioned in a Recital 39 as well. RO

PUBLIC

Commission proposal	Drafting suggestions and Comments
upgraded, and what types of potential partnerships could be concluded with the most relevant third countries. This should be done without prejudice to the prerogatives of the Council in accordance with the Treaties.	(Drafting suggestions): The Union ~~could~~ **should** further enhance the availability and security of supply of critical medicinal products by providing access to alternative sources of supply in third countries through international trade agreements or other forms of international cooperation. The Union ~~could~~ **should**, to that end, rely on its network of existing trade agreements and additionally pursue strategic partnerships with third countries to further deepen bilateral cooperation, especially with candidate countries. In this context, the Commission should assess whether existing partnerships effectively address the intended aims or could be further improved or upgraded, and what types of potential partnerships could be concluded with the most relevant third countries. This should be done without prejudice to the prerogatives of the Council in accordance with the Treaties. **Strategic partnerships should aim to remove trade barriers, including non-tariff barriers, facilitate the cross-border movement of medicines and raw materials and promote regulatory cooperation supporting predictable and efficient supply chains, in full respect of the Union's international obligations.** RO (Comments): Our proposal is based on the data and information that Union have, on the availability and security of the supply chain of centrally authorised medicines for human use. At Union level, the negotiating capacity is more flexible, based on existing and possible trade agreements with third countries. The suggestion of strategic partnerships, in our proposal, emphasizes the importance of speed in terms of patient access to medication, by eliminating market barriers, facilitating the cross-border

PUBLIC

Commission proposal	Drafting suggestions and Comments
	movement of medicines, essential materials, such as secondary packaging, but also supporting cooperation in terms of regulations and authorization by complying with legal provisions at the European Union level.
(40) To ensure the application of this Regulation, it is necessary that economic operators make available information and data to public authorities. The Member States and the Commission must therefore be able to request, when necessary and avoid duplication of information requests, the information necessary for the application of this Regulation, including its evaluation, from any economic operator in the supply and distribution chains of critical medicinal products and medicinal products of common interest.	ES (Drafting suggestions): To ensure the application of this Regulation, it is necessary that economic operators make available information and data to public authorities. The Member States and the Commission must therefore be able to request, when necessary and avoid duplication of information requests, the information necessary for the application of this Regulation, including its evaluation, from any economic operator in the supply and distribution chains of critical medicinal products and medicinal products of common interest. **In addition, economic operators 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): Strategic projects supported by public funding should be required to provide detailed information on the financial support received when requested since this might be decisive in decision-making for pricing and reimbursement at a national level.

PUBLIC

Commission proposal	Drafting suggestions and Comments
(41) In order to ensure that this Regulation effectively meets its objectives, it is essential to assess its implementation and impact over time. The Commission should carry out an evaluation of this Regulation five years after its application and every five years thereafter. This evaluation should include an assessment of the extent to which the Regulation's objectives, as set out in Article 1, have been achieved, including its impact on stakeholders, regulatory procedures, and market dynamics. In particular, the Commission's evaluation should take into account the views of Member States, economic operators, and other relevant stakeholders, ensuring that their feedback contributes to the continuous improvement of the regulatory framework. The results of this evaluation should be presented to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. In order to facilitate this evaluation, national authorities and economic operators should provide relevant data and information upon request to support the Commission's assessment.	IT (Comments): IT Comment: With regard to the financial incentives provided under this Regulation, we believe that there should be monitoring mechanisms and possible safeguard measures in place (e.g., suspension or revocation of funding) applicable to those cases in which a project no longer qualifies as "strategic", and/or a company, without justified reason, systematically fails to prioritise the supply to the EU market and/or does not make every effort to ensure that the critical medicine remains available in the Member States where it is marketed. SE (Comments): SE is flexible to a adopt a shorter interval for the first examination by the Commission.
(42) Since the objectives of this Regulation to establish a framework to strengthen the availability and security of supply of critical medicinal products within the Union and to improve the availability and accessibility of medicinal products of common interest through coordinated and targeted action of Member States cannot be sufficiently achieved by the Member States acting alone, but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the TFEU. In accordance with the principle of	BG (Drafting suggestions): ~~(42) Since the objectives of this Regulation to establish a framework to strengthen the availability and security of supply of critical medicinal products within the Union and to improve the availability and accessibility of medicinal products of common interest through coordinated and targeted action of Member States cannot be sufficiently achieved by the Member States acting alone, but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity, as set out in~~

PUBLIC

Commission proposal	Drafting suggestions and Comments
proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve its objectives.	~~Article 5 of the TFEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve its objectives.~~ BG (Comments): At this stage we have concerns both in terms of subsidiarity and proportionality. Once addressed, this recital would be revised. LU (Drafting suggestions): (42) Since the objectives of this Regulation to establish a framework to strengthen the availability**,** ~~**and**~~ security **and free movement** of supply of critical medicinal products within the Union **internal market** and to improve the availability and accessibility of medicinal products of common interest through coordinated and targeted action of Member States cannot be sufficiently achieved by the Member States acting alone, but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the TFEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve its objectives. LU (Comments): See comments on recital 1.

PUBLIC

Commission proposal	Drafting suggestions and Comments
HAVE ADOPTED THIS REGULATION:	