**European Parliament**
2024-2029

*Plenary sitting*

**A10-0272/2025**

19.12.2025

# ***I
# REPORT

on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795
(COM(2025)0102 – C10-0048/2025 – 2025/0102(COD))

Committee on Public Health

Rapporteur: Tomislav Sokol

## *Symbols for procedures*

| | |
|---|---|
| * | Consultation procedure |
| *** | Consent procedure |
| ***I | Ordinary legislative procedure (first reading) |
| ***II | Ordinary legislative procedure (second reading) |
| ***III | Ordinary legislative procedure (third reading) |

(The type of procedure depends on the legal basis proposed by the draft act.)

## *Amendments to a draft act*

**Amendments by Parliament set out in two columns**

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

**Amendments by Parliament in the form of a consolidated text**

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (COM(2025)0102 – C10-0048/2025 – 2025/0102(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament*,

– having regard to the Commission proposal to Parliament and the Council (COM(2025)0102),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C10-0048/2025),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the French Senate and the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,

– having regard to the opinion of the European Economic and Social Committee of 18 June 2025[1],

– having regard to Rule 60 of its Rules of Procedure,

– having regard to the opinions of the Committee on the Environment, Climate and Food Safety, the Committee on Industry, Research and Energy, and the Committee on the Internal Market and Consumer Protection,

– having regard to the report of the Committee on Public Health (A10-0272/2025),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] OJ C, C/2025/4214, 20.8.2025, ELI: http://data.europa.eu/eli/C/2025/4214/oj.

**Amendment 1**

**Proposal for a regulation**
**Recital 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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***, underpinned by a resilient and competitive pharmaceutical industry and secure, reliable supply chains forming the backbone of the supply of medicine,*** is vital to achieving this objective and to safeguarding public health across the Union ***and improving the preparedness and the Union's overall security***. |

**Amendment 2**

**Proposal for a regulation**
**Recital 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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 ***and lack of transparency of supply chains*** results in serious harm or risk of serious harm to patients ***and healthcare systems***. |

**Amendment 3**

**Proposal for a regulation**
**Recital 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(2a) A stable and resilient supply of medicines critical to the health of patients in the Union is essential, as shortages can lead to deterioration of patients' health, increased healthcare costs, and significant burdens on healthcare systems and public authorities.*** |

**Amendment 4**

**Proposal for a regulation**
**Recital 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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***, including starting materials, intermediates and other raw pharmaceutical materials and feedstock***. 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. |

**Amendment 5**

**Proposal for a regulation**
**Recital 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in | (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. | particular, for key raw pharmaceutical materials and active substances. Setting up new, ***expanding*** 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 medicinal products ***whilst upholding the highest social, health and environmental standards***. ***Moreover, strengthening skills and knowledge transfer will help build a resilient and future-ready workforce capable of smoothly embracing innovation and technological advancement. At the same time, developing manufacturing capacity throughout the supply chain requires substantial long-term investment, adequate industrial infrastructure, strong research capabilities, regulatory predictability and a skilled workforce.*** |

**Amendment 6**

**Proposal for a regulation**
**Recital 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) While medicine shortages can occur for any type of product, they disproportionately affect older, off-patent, and generic medicinal products, primarily*** |

***due to their low profit margins, which reduce incentives for investment in robust manufacturing capacity. Older, off-patent, and generic medicinal products make up the majority of the medicinal products placed on the Union List of Critical Medicinal Products, due to low profit margins that limit investment in manufacturing. Many off-patent and generic medicinal products suppliers have outsourced manufacturing or relocated production of finished products outside the Union, and frequently source their APIs from third countries. Consequently, the Union relies on a limited number of API suppliers and manufacturers, many located outside its borders.***

**Amendment 7**

**Proposal for a regulation**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 production facilities or where there is a high dependency on a single or a limited number of third countries. | (7) However, despite regulatory obligations on marketing authorisation holders to ensure the continuous supply of medicinal products to meet patients' ***needs*** 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 production facilities or where there is a high dependency on a single or a limited number of third countries. |

**Amendment 8**

**Proposal for a regulation**
**Recital 8**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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***, and enhance patient's access 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***, while avoiding duplication or overlap of existing structures***. ***Furthermore, existing data infrastructures and databases should be fully leveraged in order to reduce reporting burdens, streamline the monitoring of medicinal product supply chains, and improve the efficiency of data exchange between competent authorities and stakeholders. The use of existing structures would also help ensure more stable and predictable data flows.*** |

**Amendment 9**

**Proposal for a regulation**
**Recital 9**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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.

still not be available ***and accessible*** to patients in some Member States. This may be caused by a variety of factors, including ***administrative and budgetary barriers,*** product or geographical demand market size, which can impact the timely availability of medicinal products in certain Member States ***increasing inequalities between patients in the Union and undermining the Union's commitment to achieving universal access to essential medicine by 2030 in line with the United Nations sustainable development goal 3.8***. ***This Regulation aims at strengthening the resilience of supply chains, addressing concrete security-of-supply vulnerabilities, and reducing such inequalities among Member States, ensuring more equitable access to medicinal products across the Union, so that patients enjoy the same level of access regardless of their country of residence.***

**Amendment 10**

**Proposal for a regulation**
**Recital 11**

*Text proposed by the Commission*

(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,

*Amendment*

(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. ***The***

merger and State aid rules.

***implementation of this Regulation should be coherent with Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space (EHDS) to enhance the interoperability, secure exchange, and real-time monitoring of health data relevant to the availability and supply of medicinal products. Improved integration between this Regulation and the EHDS will contribute to early detection of shortages, cross-border distribution, and streamlined access to critical medicinal products.***

**Amendment 11**

**Proposal for a regulation**
**Recital 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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, ***reducing administrative barriers,*** encouraging investment and supporting innovation in the pharmaceutical sector***. This should include fostering research and development of innovative treatments, such as alternatives to antimicrobials to address antimicrobial resistance, more targeted cancer therapies, as well as other medicinal products responding to unmet medical needs***. 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, ***strategic autonomy*** and |

economic and overall security, including when cross-border supply chains risk being disrupted. ***The past health emergencies and crises, like COVID-19, have demonstrated how the presence of critical infrastructures, including hospitals and community pharmacies, has been fundamental in achieving these objectives. Furthermore, in order to strengthen the functioning of the internal market and to ensure the uninterrupted availability of critical medicinal products across the Union, it is necessary to establish a Union coordination mechanism for critical medicinal products. Such a mechanism would enhance the Union capacity to address shortages, strengthen supply chain resilience, and enable coordinated approaches to national stockpiling and contingency stocks.***

**Amendment 12**

**Proposal for a regulation**
**Recital 13 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(13a) To ensure the effective allocation of administrative and technical resources, the application of Articles 7 to 15 to medicinal products of common interest should not affect the priority granted to strategic projects concerning critical medicinal products. Where support measures, such as the processing of building permits or the conduct of dispute-resolution procedures overlap or conflict, requests related to such strategic projects should receive priority.*** |

**Amendment 13**

**Proposal for a regulation**
**Recital 14**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (14) The availability and the security of | (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. | supply of critical medicinal products are essential to safeguard public health***, patients' safety*** and the economic and overall security of the Union and therefore should be considered strategic objectives of the Union. |

**Amendment 14**

**Proposal for a regulation**
**Recital 14 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(14a) Novel antimicrobials are essential for protecting public health and addressing the threat of antimicrobial resistance, which poses a growing threat to human health. Due to their limited and variable use across Member States, novel antimicrobials are not well-suited to volume-based pricing and reimbursement mechanisms and therefore face economic disincentives due to market failure. This could result in low and unpredictable revenues, particularly in smaller markets, and can undermine the ability of manufacturers, including SMEs, to supply these products sustainably. Consequently, the availability of newer antimicrobials has been limited, and some products have been withdrawn from the market. Ensuring a sustainable supply of low-volume, high-value antimicrobials, is therefore necessary.*** |

**Amendment 15**

**Proposal for a regulation**
**Recital 16 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(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 confusion in reporting and management, and to support targeted and proportionate Union-level actions during supply disruptions or emergencies. In the context of contingency stocks and national stockpiles, Member States should be encouraged to explore sustainable measures that contribute to reducing waste and improving the efficient use of available medicinal products in line with national law and national needs.***

**Amendment 16**

**Proposal for a regulation**
**Recital 16 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(16b) The Commission should establish and regularly update a list of medicinal products originating from third countries for which no adequate substitute produced within the Union is available, in order to identify and monitor dependencies and support measures aimed at ensuring the continuity of supply of medicinal products.*** |

**Amendment 17**

**Proposal for a regulation**
**Recital 17**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (17) Certain projects ***and technology*** can have a positive impact on security of supply as they increase the Union's manufacturing capacity for critical medicinal products***, improve efficiencies in the production of those products,*** and strengthen the resilience of the Union's supply chains. In order to encourage |

| | |
|---|---|
| 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. | private investments in these projects, the concept of ***strategic projects, inlcluding cross-border*** 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 ***be provided with adequate resources to*** 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***, whilst upholding the highest social, health and environmental standards***. National authorities should consider, when possible, their streamlining as well as enable digital submission of required information. ***To ensure the efficient use of resources and strategic coherence at Union level, the designation of strategic projects should avoid unnecessary duplication of existing or planned manufacturing capacities for the same medicinal product, its active substances, or key inputs, unless such duplication is justified by clearly demonstrated needs.*** |

**Amendment 18**

**Proposal for a regulation**
**Recital 17 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(17a) In order to safeguard the Union's strategic interests and the resilience of its industrial base, strategic projects for manufacturing critical medicinal products must operate without interruption, including during crises or supply chain disruptions. Member States should take all necessary measures to prevent or mitigate unplanned disruptions to essential supplies and to ensure the*** |

***continued availability of key personnel.***

**Amendment 19**

**Proposal for a regulation**
**Recital 18**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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) ***and small mid-cap enterprises (SMCs), as well as entities not engaged in an economic activity, with a view to ensuring that they*** have a fair chance to initiate strategic projects. ***Member States and designated authorities should pay particular attention to minimising the administrative burden on SMEs and SMCs and should provide support and clear guidance through application, permitting and regulatory processes. Furthermore, requirements should be applied in a manner that guarantees fair and equal competition among all market players, regardless of their ownership structure. To support the effective implementation of this Regulation, the Commission should provide guidance to national authorities and project promoters, intended as a practical support tool. Such guidance should assist in the preparation,*** |

***determination and support of strategic projects.***

**Amendment 20**

**Proposal for a regulation**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) To achieve the objective of contributing to the security of supply of critical medicinal products, and where relevant, medicinal products of common interest, Member States should ensure that any accelerated procedure or public funding granted under this Regulation for strategic projects requires enforceable undertakings by the beneficiary regarding security of supply, affordability of end-products, and transparency in the use of public funds, and that the resulting medicinal products are made available within the Union.*** |

**Amendment 21**

**Proposal for a regulation**
**Recital 18 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18b) To avoid a fragmented approach across the Union and to ensure coherent and coordinated implementation of this Regulation, the criteria for the determination of strategic projects should be applied in a consistent and transparent manner, while allowing for a degree of flexibility to reflect national specificities and capacities. Such a balanced approach should support a wide uptake of strategic projects across the Union.*** |

**Amendment 22**

**Proposal for a regulation**
**Recital 19 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(19a) Acknowledging the importance of international cooperation in environmental matters, this Regulation respects the obligations arising from the United Nations Economic Commission for Europe (UNECE) Conventions. In particular, it is without prejudice to the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the Aarhus Convention, 1998), as well as the UNECE Convention on Environmental Impact Assessment in a Transboundary Context (the Espoo Convention, 1991) and its Protocol on Strategic Environmental Assessment (the Kyiv Protocol, 2003).*** |

**Amendment 23**

**Proposal for a regulation**
**Recital 21**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 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 | (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 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.

will be updated as necessary. ***Furthermore, any public financial support should ensure full transparency of funding amounts and conditions, be tied to clear supply and access obligations, include effective monitoring measures, and have enforceable sanctions for non-compliance.***

**Amendment 24**

**Proposal for a regulation**
**Recital 22**

*Text proposed by the Commission*

(22) ***Union-level funding may be leveraged to facilitate investments in*** strategic projects***. Strategic projects may benefit from access to existing EU*** funding instruments, ***such as the EU4Health Programme[4] , Digital Europe Programme[5] and Horizon Europe[6] (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[7] (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***.

*Amendment*

(22) ***In order to ensure that the Union can effectively promote*** strategic projects***, it is essential to make full use of the range of Union funding available under the current and future Multiannual Financial Frameworks. Union*** funding instruments, ***including but not limited to regional policy programmes, should therefore be able to support such projects where this is not explicitly excluded by their respective legal bases and where the support is consistent with the objectives laid down in the regulations establishing those instruments. Looking ahead to the future Multiannual Financial Framework, dedicated Union funding should be provided to advance the objectives of this*** Regulation***. Within this framework, and in coordination with other relevant Union instruments, a Union medicinal security fund should be*** established in ***order to reinforce the Union's*** strategic ***capacity to ensure a secure, resilient and sustainable*** supply ***of*** medicinal products***, thereby strengthening preparedness and safeguarding public health across the Union***.

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[4] ***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)***

***[5] 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)***

***[6] 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)***

***[7] 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)***

**Amendment 25**

**Proposal for a regulation**
**Recital 23**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (23) To allow for a more coordinated approach to financial support, it is | (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[8] .

appropriate that Member States and the Commission exchange the information on financial support to strategic projects. ***In doing so, an appropriate level of confidentiality of sensitive business information and data obtained should be respected and protected, such as details of value chains, the disclosure of which could harm the competitive position of the companies involved. The Commission and the national competent authorities, their officials, employees and other persons working under the supervision of those authorities as well as officials and employees of other authorities of the Member States should not disclose information acquired or exchanged by them pursuant to this Regulation where such information is covered by the obligation of professional secrecy. This should also apply to the Critical Medicines Coordination Group. The data collated pursuant to this Regulation should be handled and stored in a secure environment.*** As regards the strategic projects that have benefitted from EU funding, the beneficiaries should follow the relevant communication and visibility rules[8].

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

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

**Amendment 26**

**Proposal for a regulation**
**Recital 24**

*Text proposed by the Commission*

(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

*Amendment*

(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. | 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 ***as well as support the commercial viability of the procurement procedures in a way that actively encourages the participation of pharmaceutical manufacturers in procurement processes***. Procurement requirements based on such considerations should include ***value-based criteria, such as product quality measured by patient impact and clinical value,*** 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. |

**Amendment 27**

**Proposal for a regulation**
**Recital 24 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(24a) In order to strengthen the resilience of supply chains for medicinal products and to mitigate the risk of supply disruptions, procurement procedures carried out under this Regulation should, where appropriate, allow for the award of contracts to multiple suppliers for the same product. Such multi-winner procurement approaches can promote diversification of supply, enhance security of supply, and ensure that production capacity is distributed across different manufacturers and geographical locations within the Union. In addition, to provide market predictability and support investment in the production of medicinal products, procurement procedures under this Regulation should, where justified, include predictable mix and weighting of qualitative criteria. Those commitments*** |

***can serve as an incentive for manufacturers to maintain or scale up production capacity, particularly for medicinal products that are essential for public health but may not be commercially attractive under standard market conditions.***

**Amendment 28**

**Proposal for a regulation**
**Recital 25**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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. ***To minimise market fragmentation and create certainty and predictability for both public health system payers as well as for pharmaceutical manufacturers, the Commission should coordinate and maintain a catalogue of such MEAT criteria, as well as relevant best practices to using them in public procurement, for use by the Member States.*** |

**Amendment 29**

**Proposal for a regulation**
**Recital 26**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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 |

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|---|---|
| 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. | 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, ***should*** 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. ***In order to ensure legal certainty and consistency in its application, it is important to determine what constitutes a significant proportion of production within the meaning of this Regulation. In that sense, a significant proportion of the production should take place within the Union or, where appropriate, the EFTA countries, in line with the objective of reinforcing the Union's open strategic autonomy.*** |

**Amendment 30**

**Proposal for a regulation**
**Recital 29**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (29) The Commission ***should, after consultation with relevant stakeholders such as patients and consumer organisations, healthcare professionals, public healthcare payers and marketing authorisation holders,*** 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 |

appropriate.

pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate.

**Amendment 31**

**Proposal for a regulation**
**Recital 30**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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. ***Such programmes should take into account the economic viability of critical medicines, and recommend relevant measures, including exemptions of specific categories of critical medicines, such as products derived of substances of human origin (SoHO), from national cost containment measures.*** 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***, as well as the exchange of best practices in stock management, real-time monitoring, expiry alerts, stock rotation, shelf-life optimisation and waste reduction to further strengthen the Union's preparedness and operational effectiveness. These practices will contribute to greater efficiency, minimise losses, and ensure the availability of critical medicinal products during periods of high demand.***

**Amendment 32**

**Proposal for a regulation**
**Recital 30 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(30a) In view of the increasing vulnerabilities in the supply chains of critical medicinal products and the resulting risks of supply disruptions and shortages that can seriously endanger public health and disrupt the functioning of the internal market, it is necessary to establish a Union coordination mechanism operated by the Commission. That mechanism should serve as a structured, solidarity-based instrument to monitor availability, coordinate responses, and, where necessary, enable medicinal products to be redistributed equitably across the Union. While safeguarding the principle of subsidiarity, the mechanism should only be activated as a measure of last resort when all other national and voluntary Union-level means have been exhausted and where shortages or disruptions in one or more Member States are likely to result in serious harm to patients or affect other Member States. Binding redistribution decisions should be based on objective risk assessments and real-time data and should ensure that the Member States providing assistance retain*** |

***adequate minimum stock levels. To support timely and informed decisions, Member States should report regularly on their national stockpiles and contingency stocks through a harmonised, digital reporting system. Additionally, fair reimbursement and cost-sharing provisions should ensure that solidarity is matched by equity. In order to ensure uniform conditions for the implementation of reporting obligations in relation to national stockpiles and contingency stocks, as well as of procedures for reimbursement or replacement, and for cost-sharing mechanisms between Member States, in the event of a binding redistribution decision, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.***

**Amendment 33**

**Proposal for a regulation**
**Recital 30 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(30b) To address vulnerabilities in the supply chains of critical medicinal products and medicinal products of common interest, a Union Stockpile may be established as a last-resort mechanism when other national or Union-level measures, including the voluntary mechanisms provided for in Union legislation, are insufficient. The Commission should be empowered to adopt delegated acts to define the categories of products, minimum quantities, and operational arrangements for storage, maintenance and deployment. The Union Stockpile should be coordinated with Member States to ensure alignment with national stocks and avoid duplication or disruption. It should be possible for Union budgetary support to*** |

***be provided where appropriate.***

**Amendment 34**

**Proposal for a regulation**
**Recital 30 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(30c) In order to promote solidarity, candidate countries should be allowed, on a voluntary basis, to participate in the procedures established by this Regulation where a bilateral agreement with the Union governing the relevant procurement activities is in place. Such participation should be without prejudice to their accession negotiations or to the rights and obligations reserved to Member States under Union law.*** |

**Amendment 35**

**Proposal for a regulation**
**Recital 30 d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(30d) To improve the functioning of the pharmaceutical market in the Union, Member States and the Commission should, when implementing pricing and public procurement practices, take action to achieve the objectives of the 2019 World Health Assembly Resolution on Improving the transparency of markets for medicines, vaccines, and other health products.*** |

**Amendment 36**

**Proposal for a regulation**
**Recital 31**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (31) Obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold | (31) Obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold |

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|---|---|
| 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. | 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 ***and non-discrimination***. 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. ***Effective coordination mechanisms at Union level are therefore necessary to address possible conflicts and to ensure that national measures do not delay patient access, distort supply chains, or fragment the internal market.*** |

**Amendment 37**

**Proposal for a regulation**
**Recital 32**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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 ***including medicines for rare diseases, antimicrobials, and other innovative, high-cost, or specialised treatments across various therapeutic areas, such as oncology***. ***Economic operators participate in collaborative procurement procedures conducted pursuant to this Regulation on a voluntary basis.*** |

**Amendment 38**

**Proposal for a regulation**
**Recital 37**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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, the Commission should chair the Critical Medicines Group and perform the functions of its secretariat. | (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 European Medicines Agency (‘the Agency) and representatives from patient organisations and healthcare professional organisations***. 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. |

**Amendment 39**

**Proposal for a regulation**
**Recital 38**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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 |

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|---|---|
| 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. | 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 order to ensure solidarity and an effective Union-level response to shortages or supply disruptions of critical medicinal products, it is necessary to establish a clear decision-making process for the redistribution of such products. To that end, the Member States should be included in the decision-making process through the Critical Medicines Group established under this Regulation.*** |

**Amendment 40**

**Proposal for a regulation**
**Recital 38 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(38a) In order to strengthen the Union's preparedness and ensure an inclusive, needs-driven, transparent and coordinated approach to future challenges in the supply of critical medicinal products, the Critical medicines group, after consultation with the Commission, the Agency and the Critical Medicines Alliance, should establish a strategic foresight process. This process should identify and assess potential strategic projects, taking into account long-term trends, vulnerabilities, and opportunities for enhancing the resilience and sustainability of supply chains within the Union, specifically based on unmet medical needs.*** |

**Amendment 41**

**Proposal for a regulation**

**Recital 39**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 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. | (39) The Union ***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 ***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. ***As part of these partnerships, the Commission should promote a collaborative innovation ecosystem that integrates small and medium-sized enterprises, start-ups and deep-tech innovators alongside established pharmaceutical companies in order to enhance resilience, foster technological advancement and boost the competitiveness of the Union's pharmaceutical sector. The Commission should specifically consider the inclusion of access to active pharmaceutical ingredients (API) and their starting materials in the scope of international partnerships.*** |

**Amendment 42**

**Proposal for a regulation**
**Recital 41**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (41) In order to ensure that this | (41) In order to ensure that this |

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|---|---|
| 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. | 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. ***When an evaluation reveals a potential risk to the availability or security of supply of a critical medicinal product in the Union, the Commission should conduct a coordinated, evidence-based assessment and, where appropriate, propose proportionate mitigating measures in consultation with Member States and relevant stakeholders to safeguard continuous supply.*** |

**Amendment 43**

**Proposal for a regulation**
**Recital 42 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(42a) In order to supplement this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the*** |

***Commission in respect of the specification and harmonisation of the conditions applicable to the determination of the categories, types and quantities of critical medicinal products to be included in the Union Stockpile, the determination of the specific arrangements for storage and maintenance of such Stockpile, and the criteria and procedures for the deployment of the stockpiled products. The exercise of these delegated powers should fully respect the principles of subsidiarity and proportionality. In order to amend this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of a temporary suspension of specific provisions of this Regulation, in the case of urgent and significant distortions of competition or serious disruptions of the functioning of the internal market, until appropriate corrective measures are adopted. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.***

**Amendment 44**

**Proposal for a regulation**
**Article 1 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The objective of this Regulation is | 1. The objective of this Regulation is |

| | |
|---|---|
| to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products. | to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ***reducing its dependency on third countries and thereby*** ensuring a high level of public health protection***, maintaining patient safety*** 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 accessibility and*** affordability of medicinal products. |

**Amendment 45**

**Proposal for a regulation**
**Article 1 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. Strengthening manufacturing capacities and the resilience of supply chains, as well as competitiveness, strategic autonomy and innovation in the Union's pharmaceutical sector, is also an objective of this Regulation.*** |

**Amendment 46**

**Proposal for a regulation**
**Article 1 – paragraph 2 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. To achieve the objectives ***referred to in paragraph 1***, the Regulation sets out a framework to: | 2. To achieve the objectives ***set out in paragraphs 1 and 1a***, the Regulation sets out a framework to: |

**Amendment 47**

**Proposal for a regulation**
**Article 1 – paragraph 2 – point a**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (a) facilitate investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union; | (a) facilitate***, support and incentivise*** investments in ***new manufacturing capacity and strengthen existing*** manufacturing capacity for critical medicinal products ***and, where applicable, medicinal products of common interest***, their active substances and other key inputs in the Union ***with a priority given to medicinal products that can become critical if vulnerabilities affect their supply chain, by making available any accelerated permit granting processes related to the strategic projects that exist in applicable Union and national law***; |

**Amendment 48**

**Proposal for a regulation**
**Article 1 – paragraph 2 – point b a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(ba) prevent shortages and strengthen availability of medicinal products by facilitating the adoption of common standards governing contingency stocks and national stockpiles of critical medicinal products and medicinal products of common interest, and by enhancing transparency and coordination among Member States in this regard;*** |

**Amendment 49**

**Proposal for a regulation**
**Article 1 – paragraph 2 – point c**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (c) leverage the aggregated demand of participating Member States through collaborative procurement procedures***, and*** | (c) leverage the aggregated demand of participating Member States through collaborative procurement procedures***;*** |

**Amendment 50**

**Proposal for a regulation**
**Article 1 – paragraph 2 – point d**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships. | (d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships ***with a priority given to medicinal products that can become critical if vulnerabilities affect their supply chain;*** |

**Amendment 51**

**Proposal for a regulation**
**Article 1 – paragraph 2 – point d a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(da) facilitate investments in critical distribution infrastructure capacity for critical medicinal products ensuring security of supply, availability and accessibility in the Union; and*** |

**Amendment 52**

**Proposal for a regulation**
**Article 1 – paragraph 2 – point d b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(db) strengthen the resilience of supply chains and promote the sustainable access to and supply of active substances of critical medicinal products, their API starting materials, and other key inputs within the Union insofar as they are used for the manufacture of critical medicinal products.*** |

**Amendment 53**

**Proposal for a regulation**
**Article 2 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products | 1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products |

referred to in Article 131 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final].

referred to in Article 131 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]***, taking into account the distinctive characteristics of each medicinal product's supply chain***.

**Amendment 54**

**Proposal for a regulation**
**Article 2 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. Chapter III also applies to active substances of critical medicinal products, their starting materials, and other key inputs within the Union, insofar as they are used for the manufacture of critical medicinal products.*** |

**Amendment 55**

**Proposal for a regulation**
**Article 2 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Chapter IV and Article 26(2) point (c) also apply to medicinal products of common interest***. Chapter III does not*** apply to medicinal products of common interest. | 2. ***Chapter III, Articles 5 to 15,*** Chapter IV ***with the exception of its Section Ia new,*** and Article 26(2)***,*** point (c), also apply to medicinal products of common interest***, where the Critical Medicines Coordination Group has issued a positive recommendation pursuant to Article 26(2)(dj).***<br><br>***Articles 16 and 17*** apply***, mutatis mutandis,*** to medicinal products of common interest ***subject to the condition that the Union funding allocation under Article 16 exceeds EUR 500 million***. |

**Amendment 56**

**Proposal for a regulation**
**Article 3 – paragraph 1 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| For the ***purpose*** of this Regulation, the | For the ***purposes*** of this Regulation, |

| | |
|---|---|
| following definitions shall apply: | ***relevant definitions laid down in Article 4 of Directive (EU) …/… [reference to be added after adoption cf. COM(2023) 192 final] and in Article 2 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] shall apply mutatis mutandis.*** The following definitions shall ***also*** apply: |

**Amendment 57**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***(1) 'medicinal product' means a medicinal product as defined in Article 4 point (1) of Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];*** | ***deleted*** |

**Amendment 58**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (2) 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including primary packaging materials, excipients, solvents and reagents; | (2) 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including primary packaging materials, excipients, solvents and reagents***, raw materials, feedstock and starting materials***; |

**Amendment 59**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***(3) 'active substance' means an active substance as defined in Article 4 point (3) of Directive (EU) …/… [reference to be*** | ***deleted*** |

***added to corresponding Article after adoption of cf. COM(2023)192 final];***

**Amendment 60**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***(4) 'critical medicinal product' means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients as defined in Article 4 point (13) of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final];*** | ***deleted*** |

**Amendment 61**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) 'substance of human origin' or 'SoHO' means 'substance of human origin' or 'SoHO', as defined in Regulation (EU) 2024/1938[1a];*** |
| | ***[1a] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.*** |

**Amendment 62**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (5) 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which | (5) 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which |

| | |
|---|---|
| in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States; | in three or more Member States the functioning of the market does not sufficiently ensure the availability***, affordability*** and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States ***or is designated as orphan medicinal product pursuant to Article 67 of Regulation (EU)…/… [reference to be added after adoption cf. COM(2023) 193 final)]***; |

**Amendment 63**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(5a) 'API starting material' means a raw material, an intermediate product, or an active substance that is used in the production of an active pharmaceutical ingredient (API) and that is incorporated as a significant structural fragment into the structure of the API;*** |

**Amendment 64**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 5 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(5b) 'systemic wholesaler' means a wholesaler of medicinal products that holds a wholesale distribution authorisation and fulfils all obligations laid down in Article 166 of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final]. They wholesale and continuously distribute either the full range of prescription medicines, meaning more than the 80%, or above 20% of the total market share of prescription medicines, available for retail sale in a Member State market;*** |

**Amendment 65**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 6**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (6) 'vulnerability in the supply chains' means risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level, taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation, that compromise the continuous supply of such medicinal products to patients in the Union; | (6) 'vulnerability in the supply chains' means ***structural and non-structural*** risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level, taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation, ***and the specific features of the supply chains of each product,*** that compromise the continuous supply of such medicinal products to patients in the Union; |

**Amendment 66**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 10**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (10) 'strategic project' means ***an industrial*** project identified pursuant to the criteria set out in Article 5; | (10) 'strategic project' means ***a strategic*** project identified pursuant to the criteria set out in Article 5 of this Regulation; |

**Amendment 67**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 10 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(10a) 'cross-border strategic project' means a strategic project identified pursuant to the criteria set out in Article 5 of this Regulation, which may be carried out by a minimum of two Member States;*** |

**Amendment 68**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 11 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(11a) 'economic operator' means an economic operator as defined in Directive 2014/24/EU;*** |

**Amendment 69**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (12) 'permit granting process' means a process covering all relevant permits to build and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures; | (12) 'permit granting process' means a process covering all relevant permits to build***, expand, convert*** and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures; |

**Amendment 70**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 13**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform ***techniques, 3D*** manufacturing; | (13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, ***automation, yield improvements or other chemistry or biotechnology process that contribute to increase the level of security, energy and environmental performance of the production, and use of*** Artificial Intelligence, platform ***technologies or 3D technologies in*** manufacturing; |

**Amendment 71**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 13 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(13a) 'contingency stock' means the quantity of critical medicinal products or, where applicable, medicinal products of common interest that manufacturers and wholesalers might be required to hold under national law in order to have a buffer when shortages or supply disruptions occur, including because of fluctuations in demand or supply;*** |

**Amendment 72**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 13 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(13b) 'contingency stock requirement' means an obligation imposed by a Member State law on manufacturers and wholesalers in the supply chain to establish buffer stocks of certain medicinal products to mitigate the risk of shortages or supply disruptions;*** |

**Amendment 73**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 13 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(13c) 'national stockpile' means the reserves of a quantity of critical medicinal products or medicinal products of common interest established under national law by a Member State for a public health use, such as national strategic reserves;*** |

**Amendment 74**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 13 d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(13d) 'redistribution' means the transfer of critical medicinal products from a contingency stock or national stockpile from one or several Member States to other Member States following a decision of the Commission in response to shortages or supply disruptions in one or more Member States;*** |

**Amendment 75**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 18**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (18) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation**.** | (18) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products ***or its supply chain, their active substances and key inputs*** that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation***;*** |

**Amendment 76**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) 'resilience of supply chains' means the ability of the supply chain to maintain a continuous and demand-oriented supply of medicinal products, active substances, API starting materials, and key inputs in the Union, even during disruptions or external shocks;*** |

**Amendment 77**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 18 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18b) 'diversification of supply chains' means the existence of several independent sources or production sites, so that the supply of a medicinal product, active substances, API starting materials, and key inputs does not depend on a single supplier or third country of supply.*** |

**Amendment 78**

**Proposal for a regulation**
**Article 4 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The security of supply ***and*** availability of critical medicinal products for patients ***is*** a strategic objective of the Union. | 1. The security of supply**,** availability ***and affordability*** of critical medicinal products ***and, where applicable, medicinal products of common interest,*** for patients ***shall be considered*** a strategic objective of the Union. ***In order to achieve such an objective, the determination of strategic projects that meet the criteria laid down in Article 5 shall be made in accordance with Article 6.*** |

**Amendment 79**

**Proposal for a regulation**
**Article 4 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. | 2. The Member States and the Commission shall work together ***to achieve the strategic objective of the Union referred to in paragraph 1 including by gathering information from healthcare professional organisations, patient organisations and economic operators including marketing authorisation holders,*** to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures ***provided for in Sections*** |

***II and III of this Chapter*** that take full advantage of the potential of the internal market***, reflecting the principles of solidarity and coordination between Member States and reducing dependencies on third countries, while ensuring predictability for project promoters***.

**Amendment 80**

**Proposal for a regulation**
**Article 4 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Commission shall support the coordinated efforts of the Members States. | 3. The Commission shall support the coordinated efforts of the Members States ***and foster a secure cross-border exchange of relevant information and facilitate the distribution of critical medicinal products throughout the Union***. |

**Amendment 81**

**Proposal for a regulation**
**Article 5 – paragraph 1 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| A project located in the Union and related to creating ***or*** increasing manufacturing capacity shall be considered as a strategic project if it meets at least one of the following criteria: | ***1.*** A project located in the Union and related to creating***, modernising,*** increasing ***or improving*** manufacturing capacity***, as well as decreasing Union dependency in relation to key inputs or otherwise contributing to the security of supply or availability of medicinal products,*** shall be considered as a strategic project if it meets at least one of the following criteria: |

**Amendment 82**

**Proposal for a regulation**
**Article 5 – paragraph 1 – point a**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (a) it creates or increases | (a) it creates or increases |

| | |
|---|---|
| manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances; | manufacturing capacity***, including through new technologies and innovative manufacturing processes,*** for one or more critical medicinal products ***or, where applicable, medicinal products of common interest,*** or for collecting or manufacturing their active substances***, or it creates capacity for compounding techniques within pharmacies or hospitals***; |

**Amendment 83**

**Proposal for a regulation**
**Article 5 – paragraph 1 – point b**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency; | (b) it modernises an existing manufacturing site***, including through new technologies and innovative manufacturing processes,*** for one or more critical medicinal products or ***where applicable, medicinal products of common interest,*** their active substances ***or key inputs to strengthen supply chain resilience,*** to ensure greater sustainability or increased efficiency; |

**Amendment 84**

**Proposal for a regulation**
**Article 5 – paragraph 1 – point c**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (c) it creates ***or*** increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances; | (c) it creates***,*** increases ***or modernises*** manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or***, where applicable, medicinal products of common interest,*** their active substances ***or key inputs***; |

**Amendment 85**

**Proposal for a regulation**
**Article 5 – paragraph 1 – point d**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs**.** | (d) it contributes to the roll-out ***or transfer*** of a technology that plays a key role in enabling the manufacturing ***or supply*** of one or more critical medicinal products, ***or, where applicable, medicinal products of common interest,*** their active substances or key inputs***;*** |

**Amendment 86**

**Proposal for a regulation**
**Article 5 – paragraph 1 – point d a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(da) it reserves a defined portion of manufacturing capacity, within a fixed timeframe, to produce specific medicinal products or, where applicable, medicinal products of common interest, their pharmaceutical forms, their active substances, key inputs, or enabling technologies, at the request of the Critical Medicines Coordination Group, in order to address current, emerging or potential shortages.*** |

**Amendment 87**

**Proposal for a regulation**
**Article 5 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Notwithstanding paragraph 1, a project shall not receive financial support from the Union pursuant to Article 16 if it results in unnecessary duplication of existing or planned manufacturing capacities for the same medicinal product, its active substances or key inputs within the Union, unless the Critical Medicines Group has assessed the need and such duplication is justified by clearly demonstrated needs related to security of supply, geographical distribution of production sites, or the overall resilience*** |

***of the Union's pharmaceutical supply chain.***

**Amendment 88**

**Proposal for a regulation**
**Article 6 – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***Recognition*** of Strategic Projects | ***Determination*** of Strategic Projects |

**Amendment 89**

**Proposal for a regulation**
**Article 6 – paragraph 1 – subparagraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Each Member State shall designate an authority ('the designated authority') ***that shall assess and verify*** whether or not a project meets at least one of the criteria set out in Article 5 and therefore ***constitutes*** a strategic project. | ***Within three months of the entry into force of this Regulation,*** each Member State shall designate an authority ('the designated authority') ***to be in charge of assessing and verifying*** whether or not a project meets at least one of the criteria set out in Article 5 and ***is*** therefore ***to be considered*** a strategic project. |

**Amendment 90**

**Proposal for a regulation**
**Article 6 – paragraph 1 – subparagraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| A promoter may request the designated authority to assess whether a project ***is*** a strategic project. | A promoter may request the designated authority to assess whether a project ***constitutes*** a strategic project. |

**Amendment 91**

**Proposal for a regulation**
**Article 6 – paragraph 1 – subparagraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Any Member State authority may request the designated authority to verify its determination of ***whether*** a project ***is*** a | Any Member State authority may request the designated authority to verify its determination of a project ***as*** a strategic |

| | |
|---|---|
| strategic project. | project. |

**Amendment 92**

**Proposal for a regulation**
**Article 6 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Commission shall provide a simple, accessible webpage on which ***the contact details and other relevant information on the Member States' designated authorities*** shall be clearly listed***.*** | 3. The Commission shall provide a simple, accessible***, and user-friendly*** webpage ***serving as the central hub for project promoters*** on which ***at least the following elements*** shall be clearly listed***:*** |

**Amendment 93**

**Proposal for a regulation**
**Article 6 – paragraph 3 – point a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(a) the contact details and other relevant information on the Member States' designated authorities;*** |

**Amendment 94**

**Proposal for a regulation**
**Article 6 – paragraph 3 – point b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(b) information on available administrative or financial support from the Union; and*** |

**Amendment 95**

**Proposal for a regulation**
**Article 6 – paragraph 3 – point c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(c) a standard template for the project promoter's request available in all official languages of the Union.*** |

**Amendment 96**

**Proposal for a regulation**
**Article 6 – paragraph 3 – subparagraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall adopt implementing acts to provide for a standard template for the project promoter's request referred to in point (c) of the first subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20e(2).*** |

**Amendment 97**

**Proposal for a regulation**
**Article 6 – paragraph 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***3a. The designated authority shall assess the project promoter's request referred to in paragraph 1, second subparagraph, within three months of that submitted request.*** |

**Amendment 98**

**Proposal for a regulation**
**Article 6 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. Where the verification whether a project ***is*** a strategic project has been performed by ***an*** authority in accordance with this Article, any other authority shall rely on that verification. | 5. Where the verification whether a project ***constitutes*** a strategic project has been performed by ***a designated*** authority in accordance with this Article, any other authority shall rely on that verification. |

**Amendment 99**

**Proposal for a regulation**
**Article 6 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

***5a. In order to promote a consistent and coordinated approach across the Union and to ensure legal certainty for project promoters, the Commission shall adopt guidelines setting out common criteria and procedural principles for the assessment and determination of projects as strategic projects for critical medicinal products and, where applicable, medicinal products of common interest. Designated authorities shall take into consideration those guidelines, as appropriate, when assessing and determining projects as strategic***

**Amendment 100**

**Proposal for a regulation**
**Article 6 – paragraph 5 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5b. The guidelines referred to in paragraph 5a shall, in particular, specify:*** |
| | ***(a) measurable criteria for the assessment of strategic relevance, including the project's potential to address supply vulnerabilities, enhance manufacturing capacity or resilience, ensure security of supply, or contribute to Union-wide public health preparedness;*** |
| | ***(b) indicative timelines for operational readiness, transparency requirements, and steps for submission and assessment of requests;*** |
| | ***(c) available mechanisms for cooperation and exchange of information between the Commission and the designated authority to allow for consistent application of the guidelines.*** |

**Amendment 101**

**Proposal for a regulation**
**Article 6 – paragraph 5 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

***5c. The Commission shall act as a coordinator for cross-border strategic projects and shall ensure effective cooperation between the designated authorities of the Member States concerned, to avoid duplication of efforts in bordering Member States and to promote complementarity and efficiency in the implementation of such projects.***

**Amendment 102**

**Proposal for a regulation**
**Article 6 – paragraph 5 d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5d. Prior to the determination of a project as strategic, the designated authority shall notify the Critical Medicines Coordination Group of its intention to make such a determination. Within one month of receipt of such notification, the Critical Medicines Coordination Group shall assess whether the project would result in a significant duplication of existing or planned manufacturing capacities within the Union. Where the Critical Medicines Coordination Group does not complete the assessment within that period, the project shall be presumed not to result in significant duplication.***<br>***Where the Critical Medicines Coordination Group considers that the project would result in a significant duplication of existing or planned manufacturing capacities within the Union, it shall inform the designated authority thereof. Such projects shall not be eligible to receive financial support from the Union pursuant to Article 16.*** |

**Amendment 103**

**Proposal for a regulation**
**Article 7 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Strategic projects shall be considered as contributing to the security of supply of critical medicinal products in the Union and, therefore, to be in the public interest. | Strategic projects shall be considered as contributing to the security of supply of critical medicinal products***, or where applicable, medicinal products of common interest,*** in the Union and, therefore, to be in the public interest ***as serving the objectives of public health, safety and the protection of patients' interests***. |

**Amendment 104**

**Proposal for a regulation**
**Article 7 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects 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. | The Member States' authorities shall ensure that the relevant permit granting processes ***and corresponding certification and inspection processes*** related to strategic projects are ***fast tracked***, making available, in particular, any form of accelerated procedures that exists in applicable Union and national law, ***while ensuring the quality and robustness of assessments and upholding the relevant environmental, health and work safety standards***. |

**Amendment 105**

**Proposal for a regulation**
**Article 8 – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Administrative support | Administrative ***and technical*** support |

**Amendment 106**

**Proposal for a regulation**
**Article 8 – paragraph 1 – point b**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (b) with regard to informing the public, with the aim of increasing public | (b) with regard to informing the public, with the aim of increasing public |

| | |
|---|---|
| acceptance of the strategic project; | acceptance of the strategic project ***and, where relevant, facilitating required consultations of local communities, organisations and social partners***; |

**Amendment 107**

**Proposal for a regulation**
**Article 8 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs) and, where appropriate, establish a dedicated channel for communication with ***SMEs*** to provide guidance and respond to queries related to the implementation of this Regulation. | 2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs)***, small mid-cap enterprises (SMCs), as well as to entities not engaged in an economic activity*** and, where appropriate, establish a dedicated channel for communication with ***them*** to provide guidance and respond to queries related to the implementation of this Regulation. |

**Amendment 108**

**Proposal for a regulation**
**Article 8 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. Member States shall ensure that a strategic project located within its territory is provided with the administrative and technical support necessary to prevent or mitigate unplanned interruptions in the supply of energy, gas or heat required for the establishment or expansion of manufacturing capacity, including facilitating timely access to relevant network connections and capacity, and coordinating with the competent network operators to ensure the stability and continuity of supply.*** |

**Amendment 109**

**Proposal for a regulation**

**Article 8 – paragraph 2 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2b. Member States shall ensure that their authorities providing administrative support and authorities involved in the permit-granting process have a sufficient number of qualified staff and sufficient financial, technical and technological resources necessary for the effective performance of their tasks under this Regulation.*** |

**Amendment 110**

**Proposal for a regulation**
**Article 11 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Upon request of a project promoter, a Member State shall provide regulatory support to a strategic project located on its territory, including by prioritising Good Manufacturing Practices inspections for approval of new ***and*** extended manufacturing sites ***and for*** the manufacturing sites modernised in the context of the concerned strategic project. | 1. Upon request of a project promoter, a Member State***, with support of the Agency as necessary and through a single point of contact,*** shall provide regulatory support to a strategic project located on its territory, including by prioritising Good Manufacturing ***and Good Distribution*** Practices inspections for approval of new ***or*** extended manufacturing sites ***or modernisation of*** the manufacturing sites modernised in the context of the concerned strategic project. |

**Amendment 111**

**Proposal for a regulation**
**Article 11 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Upon request of a project promoter, the European Medicines Agency ('the Agency') shall provide dedicated advice to assist project promoters developing projects relying on innovative manufacturing processes. | 2. Upon request of a project promoter, the European Medicines Agency ('the Agency') shall***, where appropriate, with the support of national competent authorities for medicinal products,*** provide dedicated advice to assist project promoters***, including those*** developing projects relying on innovative |

manufacturing processes.

**Amendment 112**

**Proposal for a regulation**
**Article 12 – paragraph 1 – subparagraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[15] , Directive 2000/60/EC of the European Parliament and of the Council[16] , Directive 2001/42/EC of the European Parliament and of the Council[17] , Directive 2008/98/EC of the European Parliament and of the Council[18] , Directive 2009/147/EC of the European Parliament and of the Council[19] , Directive 2010/75/EU of the European Parliament and of the Council[20] , Directive 2011/92/EU of the European Parliament and of the Council[21] or Directive 2012/18/EU of the European Parliament and of the Council[22] , that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts ***are*** applied. | A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[15] , Directive 2000/60/EC of the European Parliament and of the Council[16] , Directive 2001/42/EC of the European Parliament and of the Council[17] , Directive 2008/98/EC of the European Parliament and of the Council[18] , Directive 2009/147/EC of the European Parliament and of the Council[19] , Directive 2010/75/EU of the European Parliament and of the Council[20] , Directive 2011/92/EU of the European Parliament and of the Council[21] or Directive 2012/18/EU of the European Parliament and of the Council[22] , that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts ***is*** applied. ***The application of the joint or coordinated procedure shall not affect the content or quality of the environmental impact assessment.*** |

[15] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj).

[16] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

[17] Directive 2001/42/EC of the European Parliament and of the Council of 27 June

[15] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj).

[16] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

[17] Directive 2001/42/EC of the European Parliament and of the Council of 27 June

2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj).

[18] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj).

[19] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj).

[20] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

[21] Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj).

[22] Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2012/18/oj).

2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj).

[18] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj).

[19] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj).

[20] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

[21] Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj).

[22] Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2012/18/oj).

**Amendment 113**

**Proposal for a regulation**
**Article 12 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Member States shall ensure that the competent authorities issue the reasoned | 2. Member States shall ensure that the competent authorities issue the reasoned |

| | |
|---|---|
| conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information. | conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information ***pursuant to Articles 5, 6 and 7 of that Directive and after completing the consultations referred to in Articles 6 and 7 of that Directive, with a possibility of extension by a maximum of 45 days in duly justified cases***. |

**Amendment 114**

**Proposal for a regulation**
**Article 12 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5a. Member States shall ensure that their competent authorities and other authorities designated pursuant to Article 6(1) of Directive 2011/92/EU have a sufficient number of qualified staff and sufficient financial, technical and technological resources necessary to fulfil their obligations under this Article.*** |

**Amendment 115**

**Proposal for a regulation**
**Article 13 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant spatial planning data ***is*** available. | 1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant ***planning authorities have the resources needed to decide upon, in a timely manner, any planning application and that all relevant*** spatial planning data ***are*** available ***and accessible, including*** |

***online***.

**Amendment 116**

**Proposal for a regulation**
**Article 13 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[23] , the combined assessment shall also cover those impacts. | 2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[23] , the combined assessment shall also cover those impacts. ***The fact that assessments are combined pursuant to this paragraph shall not affect their content, or quality or robustness of the assessment.*** |
| [23] Directive 2014/89/EU of the European Parliament and of the Council of 23 ELI: http://data.europa.eu/eli/dir/2014/89/oj July 2014 establishing a framework for maritime spatial planning (OJ L 257, 28.8.2014, p. 135, ELI: http://data.europa.eu/eli/dir/2014/89/oj). | [23] Directive 2014/89/EU of the European Parliament and of the Council of 23 ELI: http://data.europa.eu/eli/dir/2014/89/oj July 2014 establishing a framework for maritime spatial planning (OJ L 257, 28.8.2014, p. 135, ELI: http://data.europa.eu/eli/dir/2014/89/oj). |

**Amendment 117**

**Proposal for a regulation**
**Article 13 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. Where the development of*** |

***Strategic Projects or their related infrastructure has potential cross-border implications, the Member States concerned shall coordinate their planning and assessment procedures, with the support of the Commission, in order to avoid duplication of efforts, ensure complementarity, and reflect the principles of solidarity and cooperation between Member States.***

**Amendment 118**

**Proposal for a regulation**
**Article 14 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. All decisions adopted pursuant to the Articles in this section shall be made publicly available. | 2. All decisions adopted pursuant to the Articles in this section shall be made publicly available ***in an easily understandable manner, including online, and all decisions concerning one project shall be available on the same website***. |

**Amendment 119**

**Proposal for a regulation**
**Article 15 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Without prejudice to Articles 107 and 108 TFEU, Member States ***may*** prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines Group referred to in Article 26(2) point (a). | 1. Without prejudice to Articles 107 and 108 TFEU, Member States ***shall*** prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products***, and, where applicable, medicinal products of common interest,*** identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines Group referred to in Article 26(2) point (a). ***Financial support shall be proportionate to the financing needs of the strategic project and shall be subject to transparency requirements.*** |

**Amendment 120**

**Proposal for a regulation**
**Article 15 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. Member States may, at the request of the Critical Medicines Group, establish contractual arrangements with economic operators on strategic projects to dedicate a portion of their manufacturing capacity to produce specific medicinal products, their pharmaceutical forms, their active substances and key inputs or technologies, or categories thereof, in order to address current, emerging or potential shortages within a fixed timeframe, determined by the Critical Medicines Group.*** |

**Amendment 121**

**Proposal for a regulation**
**Article 15 – paragraph 1 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1b. The Commission shall facilitate the consistent application of this Article by providing sufficient guidance to Member States on the possibilities offered under existing State aid rules for the granting of State aid to strategic projects that meet the criteria of Article 5. This guidance shall in particular facilitate the financing of strategic projects that are aimed to improve the security of supply of medicinal products in the Union, both in terms of manufacturing capacity and in terms of innovative manufacturing processes.*** |

**Amendment 122**

**Proposal for a regulation**
**Article 15 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. For as long as the critical medicinal | 2. For as long as the critical medicinal |

product is on the Union List of Critical Medicinal Products, ***an undertaking*** that has benefitted from financial support for a strategic project shall prioritise supply to the Union market and ***use its very best efforts to*** ensure that the critical medicinal product remains available in the Member States where it is being marketed.

product is on the Union List of Critical Medicinal Products, ***a project promoter*** that has benefitted from financial support ***by a Member State*** for a strategic project shall prioritise ***appropriate and continued*** supply to the Union market ***so that the needs of patients in the Member State in question are covered*** and ensure that the critical medicinal product remains available in the Member States where it is being marketed. ***This paragraph applies mutatis mutandis to medicinal products of common interest.***

**Amendment 123**

**Proposal for a regulation**
**Article 15 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. The Member State providing financial support to a strategic project shall require the beneficiary economic operator to adopt measures that contribute to the availability and affordability of the critical medicinal product and medicinal project of common interest in the Union market, following guidelines referred to in Article 26(2)(ca).*** |

**Amendment 124**

**Proposal for a regulation**
**Article 15 – paragraph 3 – subparagraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The Member State that provided financial support to a strategic project may request such ***undertaking to*** provide the necessary supplies of a critical medicinal product, active substance or key inputs, as applicable, to the Union market to avoid shortages in one or several Member States. | The Member State that provided financial support to a strategic project may request such ***project promoter to prioritise and*** provide the necessary supplies of a critical medicinal product***, or, where applicable, medicinal product of common interest***, active substance or key inputs, as applicable, to the Union market ***as a priority*** to avoid shortages in one or several Member States. |

**Amendment 125**

**Proposal for a regulation**
**Article 15 – paragraph 3 – subparagraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Any Member State that encounters a threat of shortages of the critical medicinal product in question may demand the Member State that provided financial support to submit a request on its behalf. | Any Member State that encounters a threat of shortages of the critical medicinal product ***or medicinal product of common interest*** in question may demand the Member State that provided financial support to submit a request on its behalf. ***The project promoter shall undertake its very best efforts to supply such products in the requesting Member State.*** |

**Amendment 126**

**Proposal for a regulation**
**Article 15 – paragraph 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***3a. Where a project promoter that receives financial support fails to comply with the obligations in paragraphs 2 and 3, the financial support granted to the strategic project may be suspended, revoked or recovered, in whole or in part, by the Member State concerned. In addition, the project promoter may be subject to an effective, proportionate and dissuasive financial penalty in accordance with national law of the Member State concerned or an exclusion from funding proportionate to the impact and severity of non-compliance.*** |

**Amendment 127**

**Proposal for a regulation**
**Article 15 – paragraph 3 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***3b. Where there is a substantiated risk that export of a critical medicinal product or, where applicable, medicinal product of*** |

***common interest, would undermine supply within the Union, and upon request by at least one Member State, the Commission may require the project promoter benefiting from financial support to obtain an export authorisation before transferring such products outside the Union. This measure shall be proportionate, time-limited and targeted to safeguard public health within the Union.***

**Amendment 128**

**Proposal for a regulation**
**Article 15 – paragraph 3 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***3c. Where financial support has been granted, the project promoter shall demonstrate that the funds have been used within the territory of the Union.*** |

**Amendment 129**

**Proposal for a regulation**
**Article 16 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. ***For the duration of the*** Multiannual Financial ***Framework 2021-2027***[24] strategic projects ***may be supported by Union funding, including but not limited to such Union*** programmes ***as the EU4Health Programme***[25] ***, Horizon Europe***[26] ***, and the Digital Europe Programme***[27] provided that such support is in line with the objectives set out in the regulations establishing those programmes. | 1. ***All the Union funding under the current and future*** Multiannual Financial ***Frameworks, including regional policy funding programmes, may support*** strategic projects ***unless explicitly excluded by the legal basis or the scope of relevant*** programmes ***and*** provided that such support is in line with the objectives set out in the regulations establishing those programmes. |

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***[24] Council Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for years 2021 to 2027, as amended (OJ LI 433, 22.12.2020, p.11, ELI: http://data.europa.eu/eli/reg/2020/2093/oj )***

*[25] 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)*

*[26] 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)*

*[27] 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)*

**Amendment 130**

**Proposal for a regulation**
**Article 16 – paragraph 1 – subparagraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Subject to a Council regulation laying down the multiannual financial framework for the years 2028 to 2034 (MFF 2028–2034), strategic projects may be supported by Union funding, including any relevant Union instrument financed within the limits of the ceilings established in the MFF 2028–2034, provided that such support is in line with the objectives set out in the regulations establishing any such relevant instrument. A critical medicines security fund shall be established within the framework of MFF*** |

***2028–2034, in coordination with other relevant Union instruments, to support the achievement of the objectives of this Regulation.***

**Amendment 131**

**Proposal for a regulation**
**Article 16 – paragraph 1 – subparagraph 1 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***If a project promoter has received financial support for a strategic project from Union funding, it shall prioritise supply to the Union market and shall ensure that the critical medicinal product or, where applicable, medicinal product of common interest, remains available in the Member States where it is being marketed.*** |

**Amendment 132**

**Proposal for a regulation**
**Article 16 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. A project promoter receiving Union financial support under this Article shall comply with any obligations linked to such support including any reporting obligations pursuant to Article 57 of Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final]. Where a project promoter fails to comply with those obligations, the Commission may suspend, revoke or recover the funding, in whole or in part, in accordance with the applicable rules. In addition, the Commission may impose a financial penalty or exclusion from future funding that is proportionate to the impact of the non-compliance, time-limited, and targeted to safeguard public health within the Union.*** |

**Amendment 133**

**Proposal for a regulation**
**Article 16 – paragraph 2 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2b. Where there is a substantiated risk that export of a critical medicinal product would undermine supply within the Union, and upon request by at least one Member State, the Commission may require the project promoter benefiting from financial support to obtain an export authorisation before transferring such products outside the Union. This measure shall be proportionate, time-limited, and targeted to safeguard public health within the Union.*** |

**Amendment 134**

**Proposal for a regulation**
**Article 16 – paragraph 2 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2c. The Commission shall establish a 'one-stop-shop' to coordinate the award of Union funds pursuant to this Article and to support Member States' authorities with the prioritisation of financial support to strategic projects pursuant to Article 15.*** |

**Amendment 135**

**Proposal for a regulation**
**Article 16 – paragraph 2 d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2d. Where financial support has been granted, the project promoter shall demonstrate that the funds have been used within the territory of the Union.*** |

**Amendment 136**

**Proposal for a regulation**
**Article 17 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article ***24*** of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article ***25***. | 1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article ***25*** of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article ***26***. ***This information shall include a description of how the project meets one or more of the criteria listed in Article 5.*** |

**Amendment 137**

**Proposal for a regulation**
**Article 17 – paragraph 2 – subparagraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The Commission shall inform ***periodically*** the Critical Medicines Group of the strategic projects that benefited from financial support from the Union. | The Commission shall ***regularly*** inform the Critical Medicines Group of the strategic projects that benefited from financial support from the Union ***including information on how these projects meet the criteria listed in Article 5***. |

**Amendment 138**

**Proposal for a regulation**
**Article 17 – paragraph 2 – subparagraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The Commission ***may*** inform the Critical Medicines Group of ***the*** intention to propose the establishment of funding possibilities ***specifically designed to address vulnerabilities in the supply chains as well as*** inform of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes. | The Commission ***shall*** inform the Critical Medicines Group of ***its*** intention to propose the establishment of funding possibilities ***to support strategic projects. It shall also*** inform ***the Critical Medicines Group*** of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes. |

**Amendment 139**

**Proposal for a regulation**
**Article 18 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria ***such as procurement*** requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may ***relate to stockholding obligations***, the number of diversified suppliers, monitoring of supply chains, ***their*** transparency ***to*** the contracting authority and contract performance clauses on timely delivery. | 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall ***implement multi-winner procurements, wherever feasible, the scope of which is designed based on clinical needs and the size of the patient population in consultation with healthcare professionals, with predictable procurement timelines and predictable mix and weighting of qualitative criteria, and shall*** apply procurement requirements other than price-only award criteria***. Those*** requirements ***shall include award criteria*** that promote the resilience of supply in the Union***, support the diversification of supply sources, and take into account the distance between manufacturing sites and points of delivery within the Union. Such criteria shall form the main basis for award decisions and shall, in any case, be given greater weight than price in the evaluation of tenders***. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may ***also include innovation, supply chain robustness***, the number of diversified suppliers, ***obligations on the*** monitoring of supply chains, transparency ***of supply chains upon request of*** the contracting authority and contract performance clauses on timely delivery. |

**Amendment 140**

**Proposal for a regulation**
**Article 18 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

| | |
|---|---|
| | ***1a. In contracts which provide for the possibility of unilateral prolongation by the contracting authority, suppliers shall have, where duly justified, a mechanism allowing for price adjustments.*** |

**Amendment 141**

**Proposal for a regulation**
**Article 18 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union***. These*** requirements shall be applied in compliance with the Union's international commitments. | 2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union***, while taking into account the distinctive characteristics of the supply chains of different medicinal products. Those*** requirements shall be applied in compliance with the Union's international commitments. |

**Amendment 142**

**Proposal for a regulation**
**Article 18 – paragraph 2 – subparagraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***For the purposes of this paragraph, a 'significant proportion' of the manufacture of a critical medicinal product shall be considered to take place within the Union if at least one of the following conditions is met:*** |
| | ***(a) at least 50% of the active substance used in the manufacture of the product is produced within the Union or, where appropriate, the EFTA countries;*** |

***(b) at least 50 % of the value of the final medicinal product results from manufacturing or processing operations carried out within the Union or, where appropriate, the EFTA countries;***

***(c) essential manufacturing steps, including the synthesis or biological production of active substances, are carried out within the Union or, where appropriate, the EFTA countries.***

**Amendment 143**

**Proposal for a regulation**
**Article 18 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities ***may*** apply procurement requirements that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments. | 3. With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities ***shall*** apply procurement requirements that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union ***and shall take into account the distinctive characteristics of the supply chains of different medicinal products***. These requirements shall be applied in compliance with the Union's international commitments. |

**Amendment 144**

**Proposal for a regulation**
**Article 18 – paragraph 3 – subparagraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***For the purposes of this paragraph, a 'significant proportion' of the manufacture of a medicinal product of common interest shall be considered to take place within the Union if at least one of the following conditions is met:*** |
| | ***(a) at least 50 % of the active*** |

***substance used in the manufacture of the product is produced within the Union or, where appropriate, the EFTA countries; or, in the case of medicinal products of common interest for which no relevant substitute is produced within the Union, any third country with which the Union has established a strategic partnership within the meaning of Article 27 of this Regulation;***

***(b) at least 50 % of the value of the final medicinal product results from manufacturing or processing operations carried out within the Union or, where appropriate, the EFTA countries; or, in the case of medicinal products of common interest for which no relevant substitute is produced within the Union, any third country with which the Union has established a strategic partnership within the meaning of Article 27 of this Regulation;***

***(c) at least 50 % of the value of the final medicinal product results from manufacturing or processing operations carried out within the Union or, where appropriate, the EFTA countries; or, in the case of medicinal products of common interest for which no relevant substitute is produced within the Union, any third country with which the Union has established a strategic partnership within the meaning of Article 27 of this Regulation;***

***(d) essential manufacturing steps, including the synthesis or biological production of active substances, are carried out within the Union or, where appropriate, the EFTA countries; or, in the case of medicinal products of common interest for which no relevant substitute is produced within the Union, any third country with which the Union has established a strategic partnership within the meaning of Article 27 of this Regulation.***

**Amendment 145**

**Proposal for a regulation**
**Article 18 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. ***This Article*** shall ***not preclude contracting authorities from using*** additional qualitative ***requirements***, ***including in relation*** to environmental sustainability and social rights. | 4. ***Procurement procedures under this Chapter*** shall***, include*** additional qualitative ***criteria***, ***in particular criteria relating*** to environmental sustainability and ***the promotion of*** social rights. |

**Amendment 146**

**Proposal for a regulation**
**Article 18 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2 ***and 3*** where justified ***by*** market analysis ***or considerations related to the financing of health services***. | 5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2***, 3 and 4*** where ***such a decision is duly*** justified ***on the basis of a documented*** market analysis***, or where the application of those paragraphs would result in a disproportionately high price in a specific procurement procedure***. ***Such derogation shall be accompanied by a written justification specifying the relevant reasons and circumstances, and shall be subject to ex post verification by the competent supervisory authority designated by the Member State.*** |

**Amendment 147**

**Proposal for a regulation**
**Article 18 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5a. To support the implementation of this Article by Member States, the Commission shall develop guidelines for the application of non-price award criteria by ... [18 months from the date of entry into force of this Regulation].*** |

**Amendment 148**

**Proposal for a regulation**
**Article 19 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes ***may also*** include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures. | 1. By 6 months after entry into force of this Regulation each Member State shall establish***, after having consulted patient and consumer organisations and healthcare professional organisations,*** a national programme supporting security of supply of critical medicinal products, including in public procurement procedures***. National programmes shall include measures to promote the use of procurement award criteria relating to supply chain resilience and diversification of supply sources in accordance with Article 18***. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis ***and shall align reporting and shortage signals with mechanisms operated by MSSG to avoid duplication***. Such programmes ***shall also, where appropriate,*** include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures ***as well as review any price freezes, cost containment measures or stockholding obligations applicable***. ***Member States may involve their national pricing and reimbursement authorities in the planning and evaluation of such programmes.*** |

**Amendment 149**

**Proposal for a regulation**
**Article 19 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

| | |
|---|---|
| 2. Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Group. The Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion aiming to ensure coordination of national programmes including as regards the application of criteria mentioned in Article 18(2) and may issue opinions. Where the Critical Medicines Group issues an opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes. | 2. Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Group. The Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion***, involving representatives of marketing authorisation holders, patient and consumer organisations and healthcare professional organisations, and other relevant actors in the supply chain,*** aiming to ensure coordination of national programmes including as regards the application of criteria mentioned in Article 18(2) and may issue opinions. Where the Critical Medicines Group issues an opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes. |

**Amendment 150**

**Proposal for a regulation**
**Article 20 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Measures ***on*** security of supply applied in one Member ***State*** shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for ***companies*** to hold contingency stocks. | Measures ***relating to*** security of supply applied in one ***or more*** Member ***States*** shall not result in any negative impact ***on the availability of critical medicinal products and medicinal products of common interest*** in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for ***economic operators*** to hold contingency stocks. |

**Amendment 151**

**Proposal for a regulation**
**Article 20 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Member States shall ensure that any | Member States shall ensure that any |

requirements they impose on ***companies*** in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency ***and*** solidarity.

***national measures or*** requirements they impose on ***economic operators*** in the supply chain to hold contingency stocks are proportionate***, targeted, evidence-based*** and respect the principles of transparency***,*** solidarity ***and non-discrimination***.

**Amendment 152**

**Proposal for a regulation**
**Article 20 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Where Member Stats impose contingency stock requirements on economic operators, they shall notify the Commission and the Agency. Member States shall also encourage the implementation of rolling stockpiling systems amongst manufactures.*** |

**Amendment 153**

**Proposal for a regulation**
**Article 20 – paragraph 2 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***All contingency stock requirements and other security of supply measures shall be implemented in a manner that minimises waste and environmental impact, including through effective stock rotation based on the 'first expired, first out' system to prevent the destruction of medicinal products.*** |

**Amendment 154**

**Proposal for a regulation**
**Article 20 – paragraph 2 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall, following a consultation with relevant stakeholders, including patient and consumer organisations, healthcare professional*** |

***organisations, public healthcare payers, and marketing authorisation holders, issue Union guidelines recommending the establishment of common standards for contingency stocks and national stockpiles to support Member State activities, ensuring predictability for economic operators. Those common standards may include:***

***(a) the establishment of maximum quantitative thresholds for contingency stocks at both national and aggregated Union level, to be determined in cooperation with economic operators and reviewed periodically in light of evolving risk assessments;***

***(b) provisions allowing for the holding of contingency stocks in the form of white-label semi-finished or bulk products, where appropriate to ensure flexibility and timely deployment;***

***(c) the use of harmonised packaging formats, including multi-language or Union-wide packs, with a view to facilitating cross-border supply and reducing relabelling burdens;***

***(d) practices on sustainable stockpiling, including practices to reduce emissions, improve packing, including leaflet, manager expiry dates, and ensure responsible disposal of unused or obsolete medicinal products.***

**Amendment 155**

**Proposal for a regulation**
**Article 20 – paragraph 2 d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***During health emergencies and crises, Member States authorities and Union preparedness authorities shall closely coordinate the distribution of critical medicinal products, in particular with systemic wholesalers, in order to ensure equitable and fair distribution. Member*** |

***States may also undertake the distribution of critical medicinal products via their civil preparedness authorities or military authorities if deemed necessary in accordance with national law.***

**Amendment 156**

**Proposal for a regulation**
**Chapter IV – Section I a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Ia UNION COORDINATION MECHANISM FOR CRITICAL MEDICINAL PRODUCTS*** |

**Amendment 157**

**Proposal for a regulation**
**Article 20 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 20a*** |
| | ***Establishment of a Union coordination mechanism for critical medicinal products*** |
| | ***A Union coordination mechanism for national stockpiles and contingency stocks of critical medicinal products is hereby established. It shall be operated by the Commission in collaboration with the Agency and the Critical Medicines Coordination Group. Through that coordination mechanism, the Commission shall:*** |
| | ***(a) monitor the availability and distribution of critical medicinal products across the Union;*** |
| | ***(b) enable effective and equitable redistribution in cases of a shortage or a supply disruption in one or more Member States that has a negative impact on the internal market or on other Member States.*** |

**Amendment 158**

**Proposal for a regulation**
**Article 20 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article20b*** |
| | ***Redistribution decisions*** |
| | ***1. Where a shortage or a supply disruption of a critical medicinal product is identified in one or more Member States, the Commission shall, as a last resort and only after all other measures have been exhausted, including the voluntary mechanisms provided for in Union legislation, and upon a justified and substantiated request of one or more Member States concerned and subject to the prior approval of the Critical Medicines Group, adopt a binding decision requiring redistribution from a national stockpile or a contingency stock.*** |
| | ***2. Any distribution decision as referred to in the first paragraph shall:*** |
| | ***(a) be based on an objective risk assessment and regularly updated data establishing both the shortage or supply disruption resulting in serious harm or risk of serious harm to patients and the negative impact in the internal market;*** |
| | ***(b) specify the quantities to be transferred, the timeframe for delivery, and any other necessary logistical arrangements;*** |
| | ***(c) ensure that transferring Member States retain adequate minimum levels of the relevant medicinal product.*** |
| | ***3. A distribution decision adopted pursuant to this Article shall specify the date at which it takes effect and shall be notified by the Commission to the Member States concerned without delay/within ... [and at least 20 days before its date of application].*** |

**Amendment 159**

**Proposal for a regulation**
**Article 20 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 20c*** |
| | ***Appeal mechanism*** |
| | ***1. A Member State concerned by a redistribution decision adopted and notified pursuant to Article 20b may submit a reasoned request for a review of the decision referred to in that Article. Such a request shall be submitted to the Commission within 10 days of the notification referred to in that Article and shall state in detail the reasons for which that Member State considers that the decision does not comply with the conditions laid down in that Article or that its application would pose a disproportionate risk to public health.*** |
| | ***2. Following consultation of the Critical Medicines Coordination Group, the Commission shall adopt a review decision within 10 days of receipt of the reasoned request referred to in paragraph 1. That decision shall confirm, amend or revoke the distribution decision adopted and notified pursuant to Article 20b and shall state the reasons on which it is based.*** |
| | ***3.The submission of a request for review shall not suspend the application of the distribution decision adopted and notified pursuant to Article 20b, unless the Commission, on duly justified grounds, decides to grant a suspension pending the outcome of the review.*** |

**Amendment 160**

**Proposal for a regulation**
**Article 20 d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 20d*** |

***Stockpile information and reporting obligations***

***1. The Commission shall establish and maintain a digital reporting system that enables real-time updates on the status of national stockpiles and contingency stocks where such national stockpiles or contingency stocks are established under national law. Each Member State shall report to the European Commission at least quarterly on the status of their national stockpiles and contingency stocks, and immediately upon any significant change in stock levels.***

***2. The report referred to in paragraph 1 shall include the following information:***

***(a) a list of critical medicinal products for which contingency stocks or a national stockpile are held;***

***(b) the quantities of such stocks;***

***(c) the measures in place to ensure proper stock management, including rotation and the prevention of expiry.***

***3. For the purposes of this Article, the Commission shall make use of existing Union data infrastructures and reporting mechanisms, including but not limited to the Technical Regulation Information System (TRIS), the European Medicines Verification System (EMVS), the European Shortages Monitoring Platform (ESMP), EudraGMDP, the Industry Single Point of Contact (iSPOC) network, and relevant instruments established under the Union Civil Protection Mechanism. The Commission shall be granted timely access to data held by the Agency, and by the competent authorities of the Member States in accordance with national law, to the extent necessary to support its mandate in the areas of situational awareness and risk assessment, as well as coordination under this Chapter.***

***4. Information reported under this Article that relates to national stockpiles and***

***contingency stocks shall be treated as strictly confidential. Such information shall not be made publicly available and shall be used solely for the purposes of this Chapter. The Commission and the competent authorities of the Member States shall ensure that commercially sensitive information, including trade secrets within the meaning of Directive (EU) 2016/943, and information the disclosure of which may compromise national security is protected under the applicable Union and national rules on confidentiality and the handling of sensitive or classified information. The Commission shall not publish, disseminate or otherwise disclose such information to third parties.***

***5. The Commission may adopt implementing acts specifying the format, structure and detailed content of the reports referred to in paragraphs 2 and 3 of this Article and of the digital reporting system referred to paragraph 1 in order to ensure their consistency, completeness and comparability across Member States. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20e(2).***

**Amendment 161**

**Proposal for a regulation**
**Article 20 e (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 20e*** |
| | ***Committee procedure*** |
| | ***1. The Commission shall be assisted by the Standing Committee on medicinal products for human use established by Article 214 of Directive (EU) …/… of the European Parliament and of the Council [reference to be added after adoption cf. COM(2023) 192 final]. That committee shall be a committee within the meaning*** |

***of Regulation (EU) No 182/2011.***

***2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.***

**Amendment 162**

**Proposal for a regulation**
**Article 20 f (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 20f*** |
| | ***Obligations of Member States*** |
| | ***Where the Commission adopts a redistribution decision pursuant to Article 20b, Member States shall:*** |
| | ***(a) comply with that redistribution decision;*** |
| | ***(b) notify, without undue delay, the Commission and the Agency if they impose contingency stocks requirements on economic operators;*** |
| | ***(c) cooperate fully and without delay and, where necessary, provide mutual support to any other Member State that has requested assistance pursuant to Article 20b(1), with a view to preventing or mitigating shortages of critical medicinal products.*** |

**Amendment 163**

**Proposal for a regulation**
**Article 20 g (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 20g*** |
| | ***Reimbursement and replacement*** |
| | ***1. Where a Member State or economic operator transfers critical medicinal products in accordance with a binding decision adopted pursuant to Article 20b, it shall be entitled to full reimbursement*** |

***from the receiving Member State for the value of the critical medicinal products transferred and the costs of transport and a reasonable mark-up.***

***2. The value of the medicinal products shall be determined on the basis of their wholesale acquisition cost or an equivalent fair market value, as agreed between the Member States concerned.***

***The transferring Member State or economic operator shall be entitled to reimbursement of the determined value as soon as possible, but not later than 30 day from the date of receipt of concerned medicinal product by receiving Member State.***

***The Commission is empowered to adopt delegated acts in accordance with Article 30a, to supplement this Regulation by laying down procedures for reimbursement or replacement, and for cost-sharing mechanisms between Member States where appropriate.***

**Amendment 164**

**Proposal for a regulation**
**Article 20 h (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 20h*** |
| | ***Union Stockpile*** |
| | ***1. In order to ensure the timely and effective availability of critical medicinal products with identified vulnerabilities in their supply chains, a Union Stockpile may be established as a last-resort mechanism to be activated in situations where the Union coordination mechanism for critical medicinal products indicates the existence of a recurrent or persistent shortage in national stockpiles and contingency stocks.*** |
| | ***2. The Commission is empowered to adopt delegated acts in accordance with Article*** |

***30a to supplement this Regulation by establishing:***

***(a) the categories and specific types of critical medicinal products to be included in the Union Stockpile;***

***(b) the minimum quantities to be stocked for each product, taking into account Union-level risk assessments, supply vulnerabilities, and public health needs;***

***(c) the logistical, technical and operational arrangements for storage and maintenance of the Union stockpile;***

***(d) the criteria and procedures for the deployment of the stockpiled products in coordination with Member States.***

***3. In the event that the Commission decides to establish a Union Stockpile for critical medicinal products with identified vulnerabilities in accordance with paragraphs 1 and 2, it shall:***

***(a) coordinate with national competent authorities to ensure alignment and ensure that the Union stockpile does not duplicate national contingency stock arrangements:***

***(b) design and implement the measures to be taken in a way that does not result in any negative impact on availability of medicinal products in other Member States;***

***(c) in accordance with applicable law, ensure that packaging, labelling, and storage conditions are such as to enable the rapid and safe distribution and use of the products across the Union.***

***4. The establishment, maintenance, and deployment of the Union Stockpile shall be supported by the Union budget. Expenditures under this article shall be subject to annual reporting to the European Parliament and the Council, and to audits by the European Court of Auditors.***

**Amendment 165**

**Proposal for a regulation**
**Article 21 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Upon a reasoned request of three or more Member States ('the request'), the Commission ***may*** act as facilitator for the requesting Member States' cross-border procurement as laid down in Article 39 of Directive of the European Parliament and of the Council ***2014/24/EC***[28] for medicinal products of common interest. | 1. Upon a reasoned request of three or more Member States ('the request'), the Commission ***shall*** act as facilitator for the requesting Member States' cross-border procurement as laid down in Article 39 of Directive ***2014/24/EC*** of the European Parliament and of the Council for medicinal products of common interest. |

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

**Amendment 166**

**Proposal for a regulation**
**Article 21 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall communicate to the ***interested*** Member States its decision on whether it agrees, or not, to facilitate the proposed initiative within three weeks of receiving the request. | 3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall communicate to the ***requesting*** Member States its decision on whether it agrees, or not, to facilitate the proposed initiative within three weeks of receiving the request. ***It shall inform the European Parliament thereof.*** |

**Amendment 167**

**Proposal for a regulation**
**Article 21 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

| | |
|---|---|
| 5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the interested Member States. The Commission shall facilitate communication and cooperation between the ***involved*** Member States and provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products. | 5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the interested Member States. The Commission shall facilitate communication and cooperation between the ***interested*** Member States and provide advice on applicable Union public procurement rules***, including on the use of award criteria as set out in Article 18*** and on regulatory matters related to medicinal products. |

**Amendment 168**

**Proposal for a regulation**
**Article 21 – paragraph 6**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 6. The facilitation offered by the Commission shall be limited in time and end ***at the latest*** upon signature of the procurement contract by the participating contracting authorities. | 6. The facilitation offered by the Commission shall be limited in time and end***, unless otherwise requested by the requesting Member States,*** upon signature of the procurement contract by the participating contracting authorities. ***Where requested by requesting Member States, the facilitation offered by the Commission shall end upon delivery of the medicinal products of common interest.*** |

**Amendment 169**

**Proposal for a regulation**
**Article 21 – paragraph 6 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***6a. The Commission shall act as a facilitator under this Article subject to the acceptance of the following conditions by the requesting Member States:*** |
| | ***(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available*** |

***to cover patients needs in their territory;***

***(b) commercially sensitive information is treated in accordance with Directive (EU) 2016/943 and with applicable Union and national law on the protection of trade secrets, and is protected as such;***

***(c) participating Member States, for the duration of the contract, refrain from unilateral renegotiation of the agreed commercial terms, except where this is explicitly provided for in the contract;***

***(d) regulatory flexibilities available under applicable Union law are applied to facilitate the process, including but not limited to the use of electronic packaging information (ePI), the harmonisation of pack sizes, and labelling flexibilities;***

***(e) participating Member States refrain, for the duration of the joint procurement procedure and resulting contract, from conducting separate negotiations or procurements for the same product.***

**Amendment 170**

**Proposal for a regulation**
**Article 21 – paragraph 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***7a. The provisions of this Article shall apply, mutatis mutandis, to candidate countries that choose to participate in the procedures established herein and with which the Union has entered into a bilateral agreement governing the facilitation of cross-border procurement, without prejudice to their accession negotiations or to the rights and obligations reserved to Member States under Union law. The participation of candidate countries shall not affect the need for three or more Member States to initiate the procedure.*** |

**Amendment 171**

**Proposal for a regulation**
**Article 22 – paragraph 1 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where ***nine or more*** Member States jointly request the Commission to procure on their behalf, or in their name, the Commission ***may*** initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below***;*** | 1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where ***five*** Member States jointly request the Commission to procure on their behalf, or in their name, the Commission ***shall*** initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below: |

**Amendment 172**

**Proposal for a regulation**
**Article 22 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The joint request referred to in paragraph 1 shall only be made where the medicinal product concerned fulfils one of the criteria set out in that paragraph and if the requested procurement procedure will help to improve the security of supply ***and*** availability of critical medicinal products in the Union or ensure the availability ***and*** accessibility of medicinal products of common interest, as applicable. | 2. The joint request referred to in paragraph 1 shall only be made where the medicinal product concerned fulfils one of the criteria set out in that paragraph and if the requested procurement procedure will help to improve the security of supply***,*** availability ***and affordability*** of critical medicinal products in the Union or ***to*** ensure the availability***,*** accessibility ***and affordability*** of medicinal products of common interest, as applicable. |

**Amendment 173**

**Proposal for a regulation**
**Article 22 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request, through the Critical Medicines Group, and invite them to join the procedure. | 3. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the ***joint*** request ***referred to in paragraph 1***, through the Critical Medicines Group, and |

invite them to join the procedure.

**Amendment 174**

**Proposal for a regulation**
**Article 22 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. The Commission shall assess the utility, necessity and proportionality of the request and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition. | 4. The Commission shall assess the utility, necessity and proportionality of the ***joint*** request ***referred to in paragraph 1*** and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition. |

**Amendment 175**

**Proposal for a regulation**
**Article 22 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. The Commission shall ***inform the interested*** Member States within one month of the request of its decision and state its reasons in case of a refusal. | 5. The Commission shall ***communicate to the requesting*** Member States ***its decision*** within one month of the request of its decision and state its reasons in case of a refusal. ***It shall inform the European Parliament thereof.*** |

**Amendment 176**

**Proposal for a regulation**
**Article 22 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5a. The Commission shall ensure that any procurement procedure under this Article applies to the award criteria and requirements referred to in Article 18(1) to (4), including those on supply chain resilience, diversification and innovation.*** |

**Amendment 177**

**Proposal for a regulation**
**Article 22 – paragraph 5 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5b. The Commission shall conduct a procurement on behalf or in the name of Member States under this Article subject to the acceptance of the following conditions by the requesting Member States:*** |
| | ***(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patient needs in their territory;*** |
| | ***(b) commercially sensitive information is treated in accordance with Directive (EU) 2016/943 and with applicable Union and national law on the protection of trade secrets, and is protected as such;*** |
| | ***(c) participating Member States, for the duration of the contract, refrain from unilateral renegotiation of the agreed commercial terms, except where this is explicitly provided for in the contract;*** |
| | ***(d) regulatory flexibilities available under applicable Union law are applied to facilitate the process, including but not limited to the use of electronic packaging information (ePI), the harmonisation of pack sizes, and labelling flexibilities;*** |
| | ***(e) participating Member States refrain, for the duration of the joint procurement procedure and resulting contract, from conducting separate negotiations or procurements for the same product.*** |

**Amendment 178**

**Proposal for a regulation**
**Article 22 – paragraph 5 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

| | |
|---|---|
| | ***5c. The provisions of this Article shall apply, mutatis mutandis, to candidate countries that choose to participate in the procurement procedure established herein and with which the Union has concluded a bilateral agreement providing for such a participation, without prejudice to their accession negotiations or to the rights and obligations reserved to Member States under Union law. The participation of candidate countries shall not affect the requirement of a minimum of five participating Member States in accordance with paragraph 1.*** |

**Amendment 179**

**Proposal for a regulation**
**Article 22 – paragraph 6**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.*** | ***deleted*** |

**Amendment 180**

**Proposal for a regulation**
**Article 23 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least ***nine*** Member States may engage, as contracting parties, in a joint procurement | 1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least ***five*** Member States may engage, as contracting parties, in a joint procurement |

procedure.

procedure.

**Amendment 181**

**Proposal for a regulation**
**Article 23 – paragraph 2 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. A joint procurement procedure ***may*** be organised following a request by the Member States or at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below: | 2. A joint procurement procedure ***shall*** be organised following a request by the Member States or ***may be organised*** at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below: |

**Amendment 182**

**Proposal for a regulation**
**Article 23 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply ***and*** availability of critical medicinal products in the Union or ensure the availability ***and*** accessibility of medicinal products of common interest, as applicable. | 3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply**,** availability ***and affordability*** of critical medicinal products in the Union or ***to*** ensure the availability**,** accessibility ***and affordability*** of medicinal products of common interest, as applicable. |

**Amendment 183**

**Proposal for a regulation**
**Article 23 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure. | 4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure. ***It shall inform the European Parliament thereof.*** |

**Amendment 184**

**Proposal for a regulation**
**Article 23 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition. | 5. The Commission shall assess the necessity of a joint action and whether the request ***referred in paragraph 2*** is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition. |

**Amendment 185**

**Proposal for a regulation**
**Article 23 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5a. The Commission shall ensure that any procurement procedure under this Article applies to the award criteria and requirements referred to in Article 18(1) to (4), including those on supply chain resilience, diversification and innovation.*** |

**Amendment 186**

**Proposal for a regulation**
**Article 23 – paragraph 5 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5b. The Commission shall conduct a joint procurement under this Article subject to the acceptance of the following conditions by requesting Member States:*** |
| | ***(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patient needs in their territory;*** |
| | ***(b) commercially sensitive information is treated in accordance with Directive (EU)*** |

***2016/943 and with applicable Union and national law on the protection of trade secrets, and is protected as such;***

***(c) participating Member States, for the duration of the contract, refrain from unilateral renegotiation of the agreed commercial terms, except where this is explicitly provided for in the contract;***

***(d) regulatory flexibilities available under applicable Union law are applied to facilitate the process, including but not limited to the use of electronic packaging information (ePI), the harmonisation of pack sizes, and labelling flexibilities;***

***(e) participating Member States refrain, for the duration of the joint procurement procedure and resulting contract, from conducting separate negotiations or procurements for the same product.***

**Amendment 187**

**Proposal for a regulation**
**Article 23 – paragraph 5 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5c. The provisions of this Article shall apply, mutatis mutandis, to candidate countries that choose to participate in the procedures established herein and with which the Union has entered into a bilateral agreement governing the procurement activities referenced in this Article, without prejudice to their accession negotiations or to the rights and obligations reserved to Member States under Union law. The participation of candidate countries shall not affect the need for five Member States to engage in the procedure.*** |

**Amendment 188**

**Proposal for a regulation**
**Article 23 – paragraph 6**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***6. If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.*** | ***deleted*** |

**Amendment 189**

**Proposal for a regulation**
**Article 23 – paragraph 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 7. The Commission shall ***inform the interested*** Member States within one month of the request ***of its decision*** and state its reasons in case of a refusal. | 7. The Commission shall ***communicate to the requesting*** Member States ***its decision*** within one month of the request***,*** and state its reasons in case of a refusal. |

**Amendment 190**

**Proposal for a regulation**
**Article 24 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Member States participating in the procurement procedures covered by Articles 22 and 23 shall share with the Commission any information relevant for the procurement procedure. Member States shall provide resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge. | 1. Member States participating in the procurement procedures covered by Articles 22 and 23 shall share with the Commission any information relevant for the procurement procedure. Member States shall provide resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge. ***Procurement procedures shall ensure that smaller Member States and SMEs can participate effectively, avoiding market distortion and ensuring equitable access to critical medicinal products.*** |

**Amendment 191**

**Proposal for a regulation**
**Article 24 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. | 2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. ***Those practical arrangements shall also cover, where appropriate, the designation of the contracting authority, the distribution of procured stocks, and the identification of storage locations. Regulatory flexibilities may be granted with regard to packaging and labelling requirements, including the use of electronic package leaflets, while ensuring that patients retain the right to request paper leaflet.*** |

**Amendment 192**

**Proposal for a regulation**
**Article 24 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. The Commission shall, following a consultation with relevant stakeholders, including patient and consumer organisations, healthcare professional organisations, public healthcare payers, and marketing authorisation holders, issue Union guidelines recommending common standards for procurement activities under Articles 22 and 23 of this Regulation, ensuring predictability for companies.*** |

**Amendment 193**

**Proposal for a regulation**
**Article 25 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The Member States ***and*** the | 2. The Member States***, the Agency,*** |

Commission ***are*** Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed ***permanent*** representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have ***an*** observer status.

the Commission ***and representatives from patient organisations and healthcare professional organisations shall be*** Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed ***national*** representatives shall ensure the necessary coordination within their respective Member State. The Agency shall ***appoint two members of the MSSG as representatives. The Critical Medicines Group shall appoint two representatives from patient organisations and two permanent representatives from healthcare professional organisations. The European Parliament shall*** have observer status ***and shall be represented by two Members of the European Parliament***. ***The European Parliament shall be entitled to receive meeting agendas, documents, reports, and any other materials circulated to members of the Critical Medicines Group, and to participate in debates. The European Parliament shall not have voting rights and shall not be counted for the purpose of determining the quorum.***

**Amendment 194**

**Proposal for a regulation**
**Article 25 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. The representatives appointed to the Critical Medicines Group and its working group or working groups shall make a declaration of their financial and other interests and update it annually and whenever necessary. They shall disclose any other facts of which they become***

***aware that might in good faith reasonably be expected to involve, or give rise to, a conflict of interest.***

**Amendment 195**

**Proposal for a regulation**
**Article 25 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Critical Medicines Group shall work closely with the MSSG, the Agency, and national authorities responsible for medicinal products. For discussions where input from the ***medicines*** regulatory authorities' perspective is necessary, the Critical Medicines Group ***may*** organise joint meetings ***with the MSSG***. | 3. The Critical Medicines Group shall work closely with the MSSG, the Agency, ***the Commission*** and national authorities responsible for medicinal products. For discussions where input from the ***national*** regulatory authorities***' responsible for medicinal products***' perspective is necessary, the Critical Medicines Group ***and the MSSG shall*** organise joint meetings***. The Group shall also cooperate closely with patient and consumer organisations, healthcare professional organisations, and relevant marketing authorisation holders to fulfil its tasks, consulting them and other stakeholders as needed, including through structured joint meetings***. |

**Amendment 196**

**Proposal for a regulation**
**Article 25 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. The Commission shall organise and coordinate the work of the Critical Medicines Group ***by means of the Secretariat***. | 4. The Commission***, acting as the Secretariat of the Critical Medicines Group,*** shall organise ***regular meetings*** and coordinate the work of the Critical Medicines Group. |

**Amendment 197**

**Proposal for a regulation**
**Article 25 – paragraph 6**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

| | |
|---|---|
| 6. The Critical Medicines Group, at the proposal of the Chair or any its members, may decide to establish ***a*** working ***group***. | 6. The Critical Medicines Group, at the proposal of the Chair or any ***of*** its members, may***, on a case-by-case basis,*** decide to establish ***one or more*** working ***groups***. |

**Amendment 198**

**Proposal for a regulation**
**Article 25 – paragraph 6 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***6a. The Critical Medicines Group shall have biannual meetings, and additional meetings when needed, to consult with the Critical Medicines Alliance on vulnerabilities in supply chains and on mitigation measures to address structural risks and reinforce supply. The Critical Medicines Group shall take into account the findings from the Critical Medicines Alliance, where relevant. The Commission, as the Group's secretariat, shall ensure regular and transparent communication with the Alliance.*** |

**Amendment 199**

**Proposal for a regulation**
**Article 26 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission**,** so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market. | 1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market ***or on national healthcare systems***. |

**Amendment 200**

**Proposal for a regulation**
**Article 26 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. The Critical Medicines Group shall include in its rules of procedure provisions for the systematic consultation of Union and national patient organisations and other relevant stakeholder to encourage the exchange of information about the working group's activities and promote transparency. It shall ensure alignment and data coherence with the EMA's MSSG.*** |

**Amendment 201**

**Proposal for a regulation**
**Article 26 – paragraph 2 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. In order to attain the objectives referred to in paragraph 1, the Critical Medicines Group shall perform the following tasks: | 2. In order to attain the objectives referred to in paragraph 1, the Critical Medicines Group shall perform the following tasks ***in compliance with the necessary guarantees of protection of commercial confidential information***: |

**Amendment 202**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point a**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (a) facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security ***and*** availability of critical medicinal products within the Union; | (a) facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States***, as well as critical distribution infrastructure capacity*** and facilitate discussion on the capacity needed in the Union to strengthen its supply security***,*** availability ***and affordability*** of critical medicinal products***, active substances and key inputs*** within the Union***, as well as to ensure that the public health and patient safety implications are explicitly assessed*** |

***and taken into account in all related decisions***;

**Amendment 203**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point c a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(ca) issue guidelines on measures to support availability and affordability in the Union market of critical medicinal products in the context of strategic projects that have received financial support;*** |

**Amendment 204**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (d) ***advise*** the MSSG ***to provide the*** order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of existing evaluations where necessary**.** | (d) ***provide recommendations to*** the MSSG ***on*** order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of existing evaluations where necessary***;*** |

**Amendment 205**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(da) facilitate discussion and exchange among members of the Critical Medicines Group and, where appropriate, coordinate and exchange with the EU stockpiling network, as established by the Commission with Member States, in relation to Article 20 , specifically sharing best practices in stock management, including real-time tracking, condition monitoring, expiry alerts, stock rotation, shelf-life and waste management,*** |

***including waste reduction facilities, and evaluations where necessary;***

**Amendment 206**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(db) assess national stockpiling strategies, their proportionality, compatibility with the internal market, and feasibility for implementation by industry, and, where appropriate, issue recommendations on Union-wide minimum standards;*** |

**Amendment 207**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(dc) decide on whether to give to the Commission its prior approval to requests for the redistribution of critical medicinal products submitted by one or more Member States pursuant to Article 20b in the event of a shortage or supply disruption;*** |

**Amendment 208**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(dd) assess Union needs to determine whether specific projects concerning medicinal products of common interest should qualify as strategic projects;*** |

**Amendment 209**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d e (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(de) assess Union needs to reserve a defined portion of manufacturing capacity, within a fixed timeframe, for the production of specific medicinal products, including their pharmaceutical forms, active substances, key inputs, or enabling technologies;*** |

**Amendment 210**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d f (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(df) assess, in accordance with Article 6, whether a proposed strategic project would result in a significant duplication of existing or planned manufacturing capacities within the Union;*** |

**Amendment 211**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d g (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(dg) recommend minimum common indicators for monitoring the environmental and supply-resilience performance of national programmes referred to in Article 19, ensuring proportionality and avoiding duplication;*** |

**Amendment 212**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d h (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(dh) based on relevant financial expertise, examine the bottlenecks and Union wide financial needs of strategic projects, advise on ways of coordinating*** |

***Union and national financing with regard to those financial needs, and share best practices;***

**Amendment 213**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d i (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(di) establish the process for the strategic foresight report and prepare the annual strategic foresight report on strategic projects in accordance with Article 26a;*** |

**Amendment 214**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d j (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(dj) issue a recommendation concerning the applicability of any of the provisions referred to in Article 2 (2a) to medicinal products of common interest.*** |

**Amendment 215**

**Proposal for a regulation**
**Article 26 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. In carrying out the task referred to in paragraph 2(dc) of this Article, only the representatives of the Member States within the Critical Medicines Group shall have the right to vote. The decision shall be adopted by a two-thirds majority of the Member States present and voting.*** |

**Amendment 216**

**Proposal for a regulation**
**Article 26 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
| --- | --- |
| | ***5a. The Critical Medicines Group shall assess the Union-wide financial needs of strategic projects and issue recommendations on how to ensure adequate financing, including through the Union budget, in order to support the achievement of the objectives of this Regulation; and advise on the coordination of financing by the Union, Member States, the European Investment Bank and the private sector.*** |

**Amendment 217**

**Proposal for a regulation**
**Article 26 a (new)**

| *Text proposed by the Commission* | *Amendment* |
| --- | --- |
| | ***Article 26a*** |
| | ***Strategic Foresight on Critical Medicinal Products*** |
| | ***1. In order to strengthen the Union's preparedness and ensure a coordinated approach to future challenges in the supply of critical medicinal products, the Critical Medicines Group shall establish a strategic foresight process.*** |
| | ***2. The strategic foresight process shall be established after consultation with the Commission, the Agency, and the Critical Medicines Alliance.*** |
| | ***3. The strategic foresight process shall identify medicinal products of common interest that would advance the objectives of this Regulation if included in Chapter III.*** |
| | ***4. The strategic foresight process shall identify and assess potential strategic projects, taking into account long-term trends, vulnerabilities, opportunities for enhancing the resilience and sustainability of supply chains within the Union, and patients' unmet medical*** |

***needs.***

***5. The Critical Medicines Group shall prepare the report and communicate it to the Commission, the Agency and the European Parliament.***

***6. Following the preparation of the foresight report, the Critical Medicines Group shall make recommendations to the Commission and Member States on actions to be taken, including the identification and support of projects. Where there is a need to strategically reserve manufacturing capacity, recommendations shall specifically include proposals for strategic projects pursuant to Article 5(2), for the production of specific pharmaceutical forms, active substances, key inputs, or technologies within a defined timeframe.***

**Amendment 218**

**Proposal for a regulation**
**Article 27 – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Strategic partnerships | ***International cooperation and*** strategic partnerships |

**Amendment 219**

**Proposal for a regulation**
**Article 27 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Without prejudice to the prerogatives of the Council, the Commission, shall ***explore possibilities of concluding*** strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also ***explore the possibility of building*** on existing forms of cooperation, when possible, to support security of | Without prejudice to the prerogatives of the Council, the Commission, shall ***seek to conclude*** strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also ***aim to build*** on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the |

| | |
|---|---|
| supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. | production of critical medicinal products in the Union. |

**Amendment 220**

**Proposal for a regulation**
**Article 27 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall endeavour to incorporate health security aspects into strategic partnerships. Such aspects may include measures to promote open and resilient supply chains, including through crisis response mechanisms and collaboration to prevent export restrictions during public health emergencies and to foster regulatory convergence and cooperation in the pharmaceutical sector. The Commission shall endeavour the inclusion of access to active substances and API starting materials within strategic partnerships, in order to ensure timely availability of critical medicinal products under this mechanism.*** |

**Amendment 221**

**Proposal for a regulation**
**Article 27 – paragraph 1 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall establish and regularly update a list of countries that meet Union regulatory standards for the quality and safety of medicinal products, including key inputs and active substances. It shall make that list available to contracting authorities and healthcare professionals involved in the selection, procurement, prescribing, management, dispensing, and monitoring of such products.*** |

**Amendment 222**

**Proposal for a regulation**
**Article 27 – paragraph 1 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***In the context of accession negotiations, the Commission shall support the progressive alignment of candidate countries with the Union acquis in the field of pharmaceuticals, with a view to facilitating their gradual integration into the Union's internal market and strengthening the resilience of the Union's supply chains for critical medicinal products.*** |

**Amendment 223**

**Proposal for a regulation**
**Article 27 – paragraph 1 d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall inform the Critical Medicines Group about possible strategic partnerships on an annual basis.*** |

**Amendment 224**

**Proposal for a regulation**
**Article 27 – paragraph 1 e (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall, within the framework of strategic partnerships, promote the harmonisation of Union quality, safety and environmental standards for pharmaceutical production between the Union and third countries.*** |

**Amendment 225**

**Proposal for a regulation**
**Article 27 – paragraph 1 f (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***By ... [two years from the entry into force*** |

***of this Regulation], the Commission shall develop a structured methodology when identifying and prioritising such partnerships, distinguishing between:***

***(a) partnerships designed to leverage and strengthen existing cooperation frameworks and trade relations that contribute to security of supply and supply chain stability; and***

***(b) partnerships designed to develop new or intensified cooperation to reduce strategic dependencies and ensure geographical diversification of supply chains.***

**Amendment 226**

**Proposal for a regulation**
**Article 27 – paragraph 1 g (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Strategic partnerships shall also seek to address trade and regulatory barriers that impede supply chain resilience, promote regulatory cooperation to facilitate faster and more predictable market access, and support the smooth cross-border movement of medicinal products and critical components, while remaining fully consistent with the Union's international obligations.*** |

**Amendment 227**

**Proposal for a regulation**
**Article 27 – paragraph 1 h (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall also build on existing forms of cooperation, where relevant, to reinforce efforts to strengthen the production and supply resilience of critical medicinal products, their active substances and key inputs in the Union and globally.*** |

**Amendment 228**

**Proposal for a regulation**
**Article 28 – paragraph 1 – point a**
Regulation (EU) 2024/795
Article 2 – paragraph 1 – point a – point iii

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (iii) biotechnologies, and ***any other*** technologies ***relevant for*** manufacturing of critical medicinal products as defined in Critical Medicines Act *; | (iii) biotechnologies, and ***directly related enabling*** technologies ***necessary for the development or*** manufacturing of critical medicinal products***, including their active substances and key inputs,*** as defined in Critical Medicines Act*; |
| _____ | _____ |
| * Regulation (EU) … of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of critical medicinal products as well as for improving the availability of, and access to, medicinal products of common interest, and amending Regulation (EU) 2024/795.' [*D.G.: reference to be completed with the definitive title of the 'Critical Medicines Act' and with its publications references once they are available*] | * Regulation (EU) … of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of critical medicinal products as well as for improving the availability of, and access to, medicinal products of common interest, and amending Regulation (EU) 2024/795.' [*D.G.: reference to be completed with the definitive title of the 'Critical Medicines Act' and with its publications references once they are available*] |

**Amendment 229**

**Proposal for a regulation**
**Article 29 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation. | 1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission***, the Agency*** or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation. |

**Amendment 230**

**Proposal for a regulation**
**Article 29 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The Commission and national authorities of the Member States shall ***aim*** to avoid duplication of the information requested and submitted. | 2. The Commission***, the Agency*** and national authorities of the Member States shall ***take all appropriate measures*** to avoid duplication of the information requested and submitted***, making full use of information already available to them under Union pharmaceutical legislation, including data submitted in the context of marketing authorisation procedures, variations, inspections, and other regulatory filings, so as to minimise additional administrative burden on economic operators***. ***Requests for supplementary information shall be limited to what is necessary to ensure effective monitoring, analysis and assessment.*** |

**Amendment 231**

**Proposal for a regulation**
**Article 29 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Commission ***and*** national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other economic operators, requested to provide information per paragraph 1, ***and*** shall protect any information that is commercially confidential against unjustified disclosure. | 3. The Commission***, the Agency and the competent*** national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other economic operators, requested to provide information per paragraph 1, shall protect any information that is commercially confidential against unjustified disclosure***, and shall restrict access to such information strictly to staff responsible for applying this Regulation***. ***The Commission and the national authorities, their officials, employees and other persons working under the supervision of those authorities shall ensure the confidentiality of information*** |

***obtained in carrying out their tasks and activities in accordance with relevant Union and national law. This paragraph shall also apply to all representatives of Member States, observers, experts and other participants attending meetings of the Critical Medicines Group. In addition, they shall also ensure that digital systems used for data collection and analysis include appropriate cybersecurity measures.***

**Amendment 232**

**Proposal for a regulation**
**Article 29 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 29a*** |
| | ***Obligation of the Commission to collect information on medicinal products with no adequate Union substitute*** |
| | ***1. The Commission shall collect the necessary information from the Agency and national authorities of the Member States and establish, taking as a basis the list of critical shortages of medicinal products referred to in Chapter X of Regulation (EU) No …/… [reference to be added after adoption cf. COM(2023) 193 final], a list of critical medicinal products originating from third countries for which no adequate substitute produced within the Union is available. The Commission shall maintain and keep that list regularly updated.*** |
| | ***2. The list referred to in paragraph 1 shall serve to identify and monitor strategic dependencies and to support the adoption of appropriate measures under this Regulation aimed at ensuring the continuous supply and availability of such medicinal products within the Union.*** |
| | ***3. In developing and updating the list referred to in paragraph 1, the Commission shall take into account the*** |

***public health relevance, therapeutic importance, and criticality of the medicinal products.***

**Amendment 233**

**Proposal for a regulation**
**Article 30 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. By [OP please insert the date of:] five years after the date of application of this Regulation and every five years thereafter, the Commission shall ***evaluate*** this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions. | 1. ***The Commission shall regularly monitor the implementation of this Regulation and its impact on the functioning of the internal market, competition, and the security of supply of medicinal products in the Union. In addition,*** by [OP please insert the date of:] five years after the date of application of this Regulation and every five years thereafter, the Commission shall ***within its evaluation assess the impact of other relevant Union legislation on*** this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions. |

**Amendment 234**

**Proposal for a regulation**
**Article 30 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1 have been achieved. | 2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1 have been achieved. ***The evaluation shall in particular assess:*** |

**Amendment 235**

**Proposal for a regulation**
**Article 30 – paragraph 2 – point a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(a) data on the number of new manufacturing sites opened or modernised within the Union and the number of existing manufacturing lines extended;*** |

**Amendment 236**

**Proposal for a regulation**
**Article 30 – paragraph 2 – point b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(b) the number and nature of projects confirmed, supported, or recommended by the Critical Medicines Group under this Regulation;*** |

**Amendment 237**

**Proposal for a regulation**
**Article 30 – paragraph 2 – point c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(c) progress made in diversifying sources of active substances, starting materials, and other key inputs;*** |

**Amendment 238**

**Proposal for a regulation**
**Article 30 – paragraph 2 – point d (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(d) the effectiveness of measures adopted to mitigate structural risks and strengthen supply resilience;*** |

**Amendment 239**

**Proposal for a regulation**
**Article 30 – paragraph 2 – point e (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

***(e) unintended effects on market concentration, competition including impact on SMEs, innovation incentives, or barriers to entry, and assess whether the Regulation remains proportionate and effective.***

**Amendment 240**

**Proposal for a regulation**
**Article 30 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The national authorities and the economic operators shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1. | 3. The national authorities and the economic operators***, patient and consumer organisations, as well as healthcare professional organisations*** shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1. |

**Amendment 241**

**Proposal for a regulation**
**Article 30 – paragraph 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***3a. Where the evaluation referred to in paragraph 1 identifies a potential risk to the availability or security of supply of a critical medicinal product in the Union, the Commission shall carry out a coordinated, evidence-based impact assessment and, where appropriate, propose proportionate and appropriate mitigating measures in consultation with the Member States and relevant stakeholders.*** |

**Amendment 242**

**Proposal for a regulation**
**Article 30 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

***Article 30a***

***Exercise of the delegation***

***1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.***

***2. The power to adopt delegated acts referred to in Articles 20g(4) and 20h(2) shall be conferred on the Commission for an indeterminate period from … [date of application of this Regulation].***

***3. The delegation of power referred to in Articles 20g(4) and 20h(2) may be revoked at any time by the European Parliament or the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.***

***4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.***

***5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.***

***6. A delegated act adopted pursuant to Articles 20g(4) and 20h(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act. to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament***

***or of the Council.***

## ANNEX: DECLARATION OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur declares that he included in his report input on matters pertaining to the subject of the file that he received, in the preparation of the draft report, from the following interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register[1], or from the following representatives of public authorities of third countries, including their diplomatic missions and embassies:

| **1. Interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register** |
|---|
| EUROPEAN ORGANISATION FOR RARE DISEASES |
| European Society for Paediatric Oncology |
| European Patients' Forum (EPF) |
| European Federation of Pharmaceutical Industries and Associations |
| MEDICINES FOR EUROPE |
| BGP Products Operations GmbH a Viatris Company |
| CSL Behring |
| Sandoz International GmbH |
| Fondazione Telethon ETS |
| Pharmaceutical Group of the European Union |
| AbbVie |
| European Patient Organisation for Dysimmune and Inflammatory Neuropathies |
| European Social Insurance Platform AISBL |
| Bureau Européen des Unions de Consommateurs |
| BioForum |
| Deutsche Sozialversicherung Europavertretung |
| Merck |
| Teva Pharmaceuticals Europe BV |
| European Haemophilia Consortium |
| Cerus Europe B.V. |
| The European Association of Hospital Pharmacists |
| EuropaBio |
| Affordable Medicines Europe |
| Coalition for Epidemic Preparedness Innovations |
| A. Menarini Industrie Farmaceutiche Riunite s.r.l. |
| Novo Nordisk A/S |
| Bristol-Myers Squibb Company |
| European Blood Alliance |
| European Healthcare Distribution Association |
| Johnson & Johnson |
| Flint Europ |
| A. Menarini Industrie Farmaceutiche Riunite s.r.l. |
| Pfizer Inc. |
| SPARC Europe |

[1] Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register (OJ L 207, 11.6.2021, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2021/611/oj).

| |
|---|
| Xellia |
| BIOTON |
| European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) |
| Permanent Representation of the Kingdom of the Netherlands to the European Union |
| Permanent Representation of the Czech Republic to the European Union |
| Représentation permanente de la France auprès de l'Union européenne |
| Permanent representation of Finland to the EU |
| Permanent Representation of Denmark to the European Union |
| Health Emergency Preparedness and Response Authority (DG HERA, European Commission) |
| Directorate-General for Health & Food Safety (DG SANTE, European Commission) |
| The European Medicines Agency (EMA) |
| **2. Representatives of public authorities of third countries, including their diplomatic missions and embassies** |
| The Mission of Japan to the EU |

The list above is drawn up under the exclusive responsibility of the rapporteur.

Where natural persons are identified in the list by their name, by their function or by both, the rapporteur declares that he has submitted to the natural persons concerned the European Parliament's Data Protection Notice No 484 (https://www.europarl.europa.eu/data-protect/index.do), which sets out the conditions applicable to the processing of their personal data and the rights linked to that processing.

**OPINION OF THE COMMITTEE ON THE ENVIRONMENT, CLIMATE AND FOOD SAFETY**

**European Parliament**
2024-2029

*Committee on the Environment, Climate and Food Safety*

**2025/0102(COD)**

6.11.2025

# OPINION

of the Committee on the Environment, Climate and Food Safety

for the Committee on Public Health

on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795
(COM(2025)0102 – C10-0048/2025 – 2025/0102(COD))

Rapporteur for opinion: Michele Picaro

## SHORT JUSTIFICATION

The amendments proposed by the rapporteur in his opinion on the proposal for a Regulation of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of critical medicinal products, as well as the availability and accessibility of medicinal products of common interest, and amending Regulation (EU) 2024/795, aim to boost EU manufacturing of critical medicines by fast-tracking permits, simplifying environmental assessments, and supporting strategic projects. The proposal also promotes better coordination among Member States and introduces limited reporting obligations.

To avoid unintended disruptions resulting from overlapping environmental and chemical legislation, a balanced, data-driven approach is needed, one that safeguards the availability of medicines while upholding high environmental standards. The rapporteur believes that coordination between pharmaceutical, environmental, and chemical legislation is essential to prevent negative impacts on patient access to medicines and to ensure the sustainability and competitiveness of the European pharmaceutical and healthcare sectors.

To ensure transparency, all data related to environmental assessments, authorisations, and planning should be easily accessible (including online) and presented clearly through a centralised portal. These procedures must be efficient, time-bound, and must not create undue financial or administrative burdens, aligned with international conventions.
Rapid timelines for activating strategic projects should be maintained, especially when urgent action is needed to respond to shortages of critical medicines.

## AMENDMENTS

The Committee on the Environment, Climate and Food Safety submits the following to the Committee on Public Health, as the committee responsible:

**Amendment 1**
**Proposal for a regulation**
**Recital 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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.

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, ***upholding social, health and environmental standards,*** 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.

**Amendment 2**
**Proposal for a regulation**
**Recital 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) The 2019 Commission Strategic Approach to Pharmaceuticals in the Environment acknowledges that pharmaceuticals may pose risks to the environment and human health and highlights the need for a comprehensive and proportionate strategy, consistent with the Union's commitment to the One Health approach.*** |

**Amendment 3**
**Proposal for a regulation**
**Recital 17**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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.

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***, upholding social, health and environmental standards***. National authorities should consider, when possible, their streamlining as well as enable digital submission of required information.

**Amendment 4**
**Proposal for a regulation**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) It is essential to ensure that the production of pharmaceutical products within the Union is conducted in a safe, responsible and sustainable manner over the long term, such as by reducing environmental pollution by manufacturing waste, this form of pollution may contribute to the spread of antimicrobial resistance, impact ecosystems and biodiversity, and thereby create possible risks for public health.*** |

**Amendment 5**
**Proposal for a regulation**
**Recital 19**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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 |

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.

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, ***without undermining the quality and robustness of the assessments and*** while not lowering the level of ***health and*** environmental protection.

**Amendment 6**
**Proposal for a regulation**
**Recital 24**

*Text proposed by the Commission*

(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.

*Amendment*

(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 ***an appropriate and predictable balance of qualitative criteria including product quality measured by patient impact and clinical value, environmental sustainability, such as the use of sustainable and innovative manufacturing technologies and the minimisation of active substance emissions during production, pharmaceutical innovation for patients, and the society, in addition to*** 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.

**Amendment 7**
**Proposal for a regulation**
**Recital 39**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 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. | (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 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. ***Any such partnership should support a high level of safety, environmental protection, quality, and efficacy.*** |

**Amendment 8**
**Proposal for a regulation**
**Recital 41**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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. | 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. ***At the same time and to safeguard the availability and security of supply of critical medicinal products, all market actors, competent authorities, Member States and the Commission should ensure that all barriers, such as regulatory, economic and market-based, are identified and evaluated as part of the Commission's assessment on the achievement of the objectives of this Regulation.*** 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. |

**Amendment 9**
**Proposal for a regulation**
**Recital 41 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(41a) This Regulation should be implemented in line with existing Union legislation. Where the evaluation has identified that such legislation has the possibility to impact in an adverse manner on the accessibility, availability or affordability of medicinal products, the Commission should carry out comprehensive, evidence-based assessments and, where appropriate, propose proportionate mitigating*** |

***measures to safeguard supply, availability and affordability of medicinal products and to support the Union's competitiveness.***

**Amendment 10**
**Proposal for a regulation**
**Article 3 – paragraph 1 – point 13**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform techniques, 3D manufacturing; | (13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, ***yield improvements or other chemistry or biotechnology process that contribute to increasing the level of security, energy efficiency and environmental performance of the production,*** Artificial Intelligence, platform techniques, 3D manufacturing ***and sustainable manufacturing methods***; |

**Amendment 11**

**Proposal for a regulation**
**Article 5 – paragraph 1 – point b**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency; | (b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater ***environmental sustainability, overall*** sustainability or increased efficiency***, such as innovative processes that improve production quality, resilience, or reliability***; |

**Amendment 12**

**Proposal for a regulation**
**Article 7 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|

| | |
|---|---|
| The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects 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. | The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects 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***, while ensuring compliance with the highest social, health and environmental standards***. |

**Amendment 13**
**Proposal for a regulation**
**Article 12 – paragraph 1 – subparagraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[15] , Directive 2000/60/EC of the European Parliament and of the Council[16] , Directive 2001/42/EC of the European Parliament and of the Council[17] , Directive 2008/98/EC of the European Parliament and of the Council[18] , Directive 2009/147/EC of the European Parliament and of the Council[19] , Directive 2010/75/EU of the European Parliament and of the Council[20] , Directive 2011/92/EU of the European Parliament and of the Council[21] or Directive 2012/18/EU of the European Parliament and of the Council[22] , that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied. | A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[15] , Directive 2000/60/EC of the European Parliament and of the Council[16] , Directive 2001/42/EC of the European Parliament and of the Council[17] ,Directive 2008/98/EC of the European Parliament and of the Council[18] , Directive 2009/147/EC of the European Parliament and of the Council[19] , Directive 2010/75/EU of the European Parliament and of the Council[20] , Directive 2011/92/EU of the European Parliament and of the Council[21] or Directive 2012/18/EU of the European Parliament and of the Council[22] , that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied. ***The application of the joint or coordinated procedure shall not affect the content or quality of the environmental impact assessment.*** |
| [15] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj). | [15] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj). |

[16] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

[17] Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj).

[18] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj).

[19] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj).

[20] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

[21] Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj).

[22] Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2012/18/oj).

[16] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

[17] Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj).

[18] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj).

[19] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj).

[20] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

[21] Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj).

[22] Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2012/18/oj).

**Amendment 14**
**Proposal for a regulation**
**Article 12 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information. | 2. Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information ***pursuant to Articles 5, 6 and 7 of that Directive and after completing the consultations referred to in Articles 6 and 7 of that Directive, with a possibility of extension by a maximum of 45 days in duly justified cases***. |

**Amendment 15**
**Proposal for a regulation**
**Article 12 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5a. Member States shall ensure that their competent authorities and other authorities designated pursuant to Article 6(1) of Directive 2011/92/EU have a sufficient number of qualified staff and sufficient financial, technical and technological resources necessary to fulfil their obligations under this Article.*** |

**Amendment 16**
**Proposal for a regulation**
**Article 13 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all | 1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all |

| | |
|---|---|
| relevant spatial planning data is available. | relevant ***planning authorities have the resources needed to decide upon, in a timely manner, any planning application and that all relevant*** spatial planning data is available ***and accessible, including online***. |

**Amendment 17**
**Proposal for a regulation**
**Article 13 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[23] , the combined assessment shall also cover those impacts. | 2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[23], the combined assessment shall also cover those impacts. ***The fact that assessments are combined pursuant to this paragraph shall not affect their content or quality or robustness of the assessment.*** |
| [23] Directive 2014/89/EU of the European Parliament and of the Council of 23 ELI: http://data.europa.eu/eli/dir/2014/89/oj July 2014 establishing a framework for maritime spatial planning (OJ L 257, 28.8.2014, p. 135, ELI: http://data.europa.eu/eli/dir/2014/89/oj). | [23] Directive 2014/89/EU of the European Parliament and of the Council of 23 ELI: http://data.europa.eu/eli/dir/2014/89/oj July 2014 establishing a framework for maritime spatial planning (OJ L 257, 28.8.2014, p. 135, ELI: http://data.europa.eu/eli/dir/2014/89/oj). |

**Amendment 18**
**Proposal for a regulation**
**Article 14 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. All decisions adopted pursuant to the Articles in this section shall be made publicly available. | 2. All decisions adopted pursuant to the Articles in this section shall be made publicly available ***in an easily understandable manner, including online, and all decisions concerning one project shall be available on the same website***. |

**Amendment 19**
**Proposal for a regulation**
**Article 18 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. | 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall ***wherever feasible implement multi-winner procurements, which scope is designed based on clinical needs in consultation with healthcare professionals and relevant experts, with predictable procurement timelines. Contracting authorities in the Member States shall*** apply procurement requirements***,*** other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and ***shall include several qualitative criteria, such as patient impact and clinical value, environmental sustainability, innovation, diversity and robustness of supply chain,*** may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority***,*** and contract performance clauses on timely delivery. |

**Amendment 20**
**Proposal for a regulation**
**Article 18 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights. | 4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability**,** and social rights. ***In order to safeguard the integrity of the Single Market, the Commission shall support coordination and the exchange of best practices between Member States.*** |

**Amendment 21**

**Proposal for a regulation**
**Article 19 – paragraph 1 – subparagraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Member States shall aim to ensure that the design and periodic review of such programmes involve health professionals and patient organisations, as well as environmental expertise, to balance public health needs, affordability and sustainability.*** |

**Amendment 22**

**Proposal for a regulation**
**Article 20 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Stockpiling management system shall apply a "first in, first out" principle and promote the use of shelf-life extension studies, in order to reduce expiry-related waste. The Commission, in cooperation with the Member States and the relevant agencies, shall adopt guidelines on sustainable stockpiling, including measures to reduce emissions, improve packaging, manage expiry dates, and ensure the environmentally sound disposal of unused or obsolete medicinal products.*** |

**Amendment 23**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(da) recommend minimum common indicators for monitoring the environmental and supply-resilience performance of procurement programmes, ensuring proportionality and avoiding duplication.*** |

**Amendment 24**
**Proposal for a regulation**
**Article 27 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. | Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. ***Such partnership shall support a high level of safety, environmental protection, quality, and efficacy.*** |

**Amendment 25**
**Proposal for a regulation**
**Article 30 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. By [OP please insert the date of:] five years after the date of application of this Regulation and every five years thereafter, the Commission shall ***evaluate*** this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and | 1. By [OP please insert the date of:] five years after the date of application of this Regulation and every five years thereafter, the Commission shall ***within its evaluation assess the impact of other relevant Union legislation on*** this Regulation and present a report on the |

| | |
|---|---|
| Social Committee**,** and the Committee of the Regions. | main findings to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. |

**Amendment 26**
**Proposal for a regulation**
**Article 30 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. Where the evaluation referred to in paragraph 1 identifies a potential risk to the availability or security of supply of a critical medicinal product in the Union, the Commission shall carry out a coordinated, evidence-based impact assessment and, where appropriate, propose proportionate and appropriate mitigating measures in consultation with the Member States and relevant stakeholders.*** |

## ANNEX: DECLARATION OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur for opinion declares that he included in his opinion input on matters pertaining to the subject of the file that he received, in the preparation of the opinion, prior to the adoption thereof in committee, from the following interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register[1], or from the following representatives of public authorities of third countries, including their diplomatic missions and embassies:

| **1. Interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register** |
|---|
| Federchimica |
| Farmindustria |
| Menarini |
| **2. Representatives of public authorities of third countries, including their diplomatic missions and embassies** |

The list above is drawn up under the exclusive responsibility of the rapporteur for opinion.

Where natural persons are identified in the list by their name, by their function or by both, the rapporteur for opinion declares that he has submitted to the natural persons concerned the European Parliament's Data Protection Notice No 484 (https://www.europarl.europa.eu/data-protect/index.do), which sets out the conditions applicable to the processing of their personal data and the rights linked to that processing.

[1] Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register (OJ L 207, 11.6.2021, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2021/611/oj).

## PROCEDURE – COMMITTEE ASKED FOR OPINION

| | |
|---|---|
| **Title** | Laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 |
| **References** | COM(2025)0102 – C10-0048/2025 – 2025/0102(COD) |
| **Committee(s) responsible**<br>Date announced in plenary | SANT<br>21.5.2025 |
| **Opinion by**<br>Date announced in plenary | ENVI<br>21.5.2025 |
| **Rapporteur for the opinion**<br>Date appointed | Michele Picaro<br>18.6.2025 |
| **Date adopted** | 4.11.2025 |
| **Result of final vote** | +: 63<br>–: 4<br>0: 11 |
| **Members present for the final vote** | Christine Anderson, Pascal Arimont, Bartosz Arłukowicz, Sakis Arnaoutoglou, Anja Arndt, Monika Beňová, Alexander Bernhuber, Barbara Bonte, Stine Bosse, Lynn Boylan, Jorge Buxadé Villalba, Laurent Castillo, Mohammed Chahim, Christophe Clergeau, Annalisa Corrado, Ivan David, Ondřej Dostál, Viktória Ferenc, Heléne Fritzon, Andreas Glück, Hanna Gronkiewicz-Waltz, Martin Günther, Roman Haider, Esther Herranz García, Radan Kanev, Ondřej Knotek, Stefan Köhler, András Tivadar Kulja, Peter Liese, Javi López, César Luena, Elżbieta Katarzyna Łukacijewska, Ignazio Roberto Marino, Catarina Martins, Tilly Metz, Dolors Montserrat, Jana Nagyová, Jutta Paulus, Michele Picaro, Nicola Procaccini, Massimiliano Salini, Silvia Sardone, Majdouline Sbai, Lena Schilling, Günther Sidl, Jonas Sjöstedt, Sander Smit, Antonín Staněk, Marta Temido, Ingeborg Ter Laak, Beatrice Timgren, Zala Tomašič, Dimitris Tsiodras, Ana Vasconcelos, Aurelijus Veryga, Kristian Vigenin, Emma Wiesner, Michal Wiezik, Tiemo Wölken |
| **Substitutes present for the final vote** | Jeannette Baljeu, Biljana Borzan, Marie-Luce Brasier-Clain, Daniel Buda, Per Clausen, Raúl de la Hoz Quintano, Valérie Deloge, Sigrid Friis, Jens Gieseke, Michalis Hadjipantela, Martin Häusling, Paolo Inselvini, Sara Matthieu, Valentina Palmisano, Raffaele Topo, Laurence Trochu, Vlad Vasile-Voiculescu, Anders Vistisen |
| **Members under Rule 216(7) present for the final vote** | Francesco Torselli |

## FINAL VOTE BY ROLL CALL
## BY THE COMMITTEE ASKED FOR OPINION

| 63 | + |
|---|---|
| ECR | Paolo Inselvini, Michele Picaro, Nicola Procaccini, Francesco Torselli, Laurence Trochu, Aurelijus Veryga |
| NI | Monika Beňová, Ondřej Dostál |
| PPE | Pascal Arimont, Bartosz Arłukowicz, Alexander Bernhuber, Daniel Buda, Laurent Castillo, Raúl de la Hoz Quintano, Jens Gieseke, Hanna Gronkiewicz-Waltz, Michalis Hadjipantela, Esther Herranz García, Radan Kanev, Stefan Köhler, András Tivadar Kulja, Peter Liese, Elżbieta Katarzyna Łukacijewska, Dolors Montserrat, Massimiliano Salini, Sander Smit, Ingeborg Ter Laak, Zala Tomašič, Dimitris Tsiodras |
| Renew | Jeannette Baljeu, Stine Bosse, Sigrid Friis, Andreas Glück, Ana Vasconcelos, Vlad Vasile-Voiculescu, Emma Wiesner, Michal Wiezik |
| S&D | Sakis Arnaoutoglou, Biljana Borzan, Mohammed Chahim, Christophe Clergeau, Annalisa Corrado, Heléne Fritzon, Javi López, César Luena, Günther Sidl, Marta Temido, Raffaele Topo, Kristian Vigenin, Tiemo Wölken |
| The Left | Lynn Boylan, Per Clausen, Martin Günther, Catarina Martins, Valentina Palmisano, Jonas Sjöstedt |
| Verts/ALE | Martin Häusling, Ignazio Roberto Marino, Sara Matthieu, Tilly Metz, Jutta Paulus, Majdouline Sbai, Lena Schilling |

| 4 | - |
|---|---|
| ESN | Christine Anderson, Anja Arndt, Ivan David |
| PfE | Roman Haider |

| 11 | 0 |
|---|---|
| ECR | Beatrice Timgren |
| PfE | Barbara Bonte, Marie-Luce Brasier-Clain, Jorge Buxadé Villalba, Valérie Deloge, Viktória Ferenc, Ondřej Knotek, Jana Nagyová, Silvia Sardone, Antonín Staněk, Anders Vistisen |

Key to symbols:
+ : in favour
- : against
0 : abstention

11.11.2025

## OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on Public Health

on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795
(COM(2025)0102 – C10-0048/2025 – 2025/0102(COD))

Rapporteur for opinion: Oliver Schenk

## SHORT JUSTIFICATION

The Critical Medicines Act is of major importance in the broader context of strengthening the availability and security of supply of critical medicinal products. Its aim is to ensure a high level of public health protection while contributing to the Union's overall resilience and strategic security.

Considering this, the rapporteur welcomes the Commission's proposal as a timely and necessary initiative. However, the European pharmaceutical industry - the backbone of medicines supply - continues to face major challenges in maintaining global competitiveness and securing stable, resilient supply chains for critical medicines. The Commission proposal addresses many of these issues but does not fully tackle the underlying structural causes.

This opinion seeks to enhance the effectiveness, clarity and practical implementation of the Regulation. The proposed amendments reflect the rapporteur's commitment to building a stronger and more responsive Union framework - one that ensures the continuous availability of essential medicines and supports a resilient, inclusive and innovation-driven pharmaceutical ecosystem.

One of the key priorities is to promote inclusive and transparent governance. The opinion emphasises the importance of involving stakeholders from across the supply chain - such as patient organisations, healthcare providers and industry representatives - whose practical knowledge is essential to ensure that Union measures reflect the specificities of healthcare systems and pharmaceutical production.

To enable the development of innovative solutions and support forward-looking investment, the opinion refines the scope of strategic projects. These projects are essential tools for addressing structural vulnerabilities, boosting resilience and stimulating pharmaceutical innovation.

The opinion also advocates for a balanced and coordinated approach to public funding and State aid. While supporting the availability of financial assistance for strategic projects, it underlines that such support must remain proportionate, transparent and in line with State aid rules. To this end, the Commission is encouraged to provide guidance to national authorities and project promoters to reduce legal uncertainty and facilitate implementation.

At the same time, the amendments call for the better use of existing data infrastructures and digital tools to improve coordination and minimise administrative burden. Rather than introducing new systems, the Regulation should build on what already exists - thereby streamlining reporting requirements, accelerating implementation and improving communication between institutions and stakeholders. The opinion also proposes incorporating the findings of the Critical Medicines Alliance to strengthen coordination efforts.

Throughout the text, a clear commitment is made to uphold the principles of subsidiarity and democratic accountability. The opinion calls for structured cooperation between the Commission, Member States, the European Parliament and stakeholders. Governance structures such as the Critical Medicines Group should operate transparently and inclusively, with appropriate involvement of Parliament and relevant actors from across the supply chain.

Furthermore, the opinion connects the goals of health resilience with the Union's industrial and technological ambitions. The security of supply of critical medicinal products must go hand in hand with predictable regulation, sustainable production capacity, and Europe's broader efforts to strengthen technological sovereignty. These factors are essential to long-term resilience and global competitiveness.

To support strategic investment in innovative technologies, the opinion also endorses extending the scope of the STEP instrument to cover biomanufacturing, which has been recognised as a key enabling technology for the Union's health and industrial future.

The opinion also underscores the need to ensure the confidentiality and secure handling of sensitive information exchanged under the Regulation. Trade secrets, business-sensitive data and classified materials must be protected in accordance with Union and national law. Maintaining stakeholder trust and effective cooperation depends on safeguarding this information at all levels.

In addition, the opinion highlights the strategic value of international partnerships for the Union's health security. It calls on the Commission to include relevant provisions in future agreements and to promote alignment of quality, safety and environmental standards with third countries. This would help diversify supply chains while ensuring fair competition and a level playing field for EU manufacturers.

Finally, the opinion stresses the importance of small and medium-sized enterprises (SMEs) and small mid-caps (SMCs) in driving innovation and production in the pharmaceutical sector. It calls for equitable access to funding and simplified procedures, recognising the challenges faced by smaller actors operating with limited resources.

Taken together, the proposed changes aim to make the Regulation more effective, targeted and future-proof - capable of addressing immediate risks while laying the foundation for a

more resilient, sustainable and competitive pharmaceutical sector in the European Union.

## AMENDMENTS

The Committee on Industry, Research and Energy submits the following to the Committee on Public Health, as the committee responsible:

**Amendment 1**
**Proposal for a regulation**
**Citation 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Having regard to the Treaty on the Functioning of the European Union, and in particular ***Article 114*** thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular ***Articles 114 and 173*** thereof, |

**Amendment 2**
**Proposal for a regulation**
**Recital 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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***, underpinned by a resilient and competitive pharmaceutical industry and secure, reliable supply chains forming the backbone of the supply of medicine,*** is vital to achieving this objective and to safeguarding public health across the Union ***and improving the preparedness and the Union's overall security***. |

**Amendment 3**
**Proposal for a regulation**
**Recital 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (2) In recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages which ***have resulted*** in serious harm or risk of serious harm to patients***' health and safety***. ***Beyond their impact on healthcare systems, such shortages could also undermine national security, disrupt critical supply chains, and have detrimental effects on the broader economy.*** |

**Amendment 4**
**Proposal for a regulation**
**Recital 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (3) Shortages of medicinal products 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. ***Addressing those challenges requires*** diversification of supply sources and ***substantial investments in modern production facilities, research and development, and workforce training within the Union. However, factors such as complex permitting and regulatory processes, significant investments needed to maintain high-quality*** production, ***and the demand for specialised skilled labour necessitate targeted efforts to expand local manufacturing capacities. Furthermore, strengthening the resilience of pharmaceutical supply chains requires enhanced coordination with industry*** |

***stakeholders to promote innovation, transparency and flexibility. Through those measures*** the Union can reduce its risk of exposure to shortages of medicinal products ***in the long term***.

**Amendment 5**
**Proposal for a regulation**
**Recital 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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***, expanding***, 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***, in compliance with Union environmental, health, and social standards,*** can contribute to supporting efforts to increase manufacturing capacities in the Union and strengthen the supply chains for critical medicines. ***Moreover, strengthening skills and knowledge transfer will help build a resilient and future-ready workforce capable of smoothly embracing innovation and technological advancement.*** |

**Amendment 6**
**Proposal for a regulation**
**Recital 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) A horizontal approach should guide both existing and new legislative acts of the Union to ensure coherence between policy objectives. Such an approach would help avoid unintended overlaps or conflicting requirements and support the Union's broader goal of strengthening resilience, security of supply and competitiveness across strategic sectors, including the pharmaceutical industry. While doing so, coherence between environmental and health policy objectives should be ensured through structured coordination, dialogue with stakeholders and impact assessments that take into account the specificities of pharmaceutical manufacturing.*** |

**Amendment 7**
**Proposal for a regulation**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 production facilities or where there is a | (7) However, despite regulatory obligations on marketing authorisation holders to ensure the continuous supply of medicinal products to meet patients' demand ***and needs*** 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 production facilities or where there is a |

high dependency on a single or a limited number of third countries.

high dependency on a single or a limited number of third countries.

**Amendment 8**
**Proposal for a regulation**
**Recital 8**

*Text proposed by the Commission*

(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.

*Amendment*

(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***, while avoiding duplication or overlap of existing structures***. ***That principle should also apply to existing Union law, including the ongoing revision of the general pharmaceutical legislative acts, the European Health Data Space (Regulation (EU) 2025/327 of the European Parliament and of the Council[1a]), the Clinical Trials Regulation (Regulation (EU) No 536/2014 of the European Parliament and of the Council [1b]), and other relevant legal frameworks, with a view to ensuring consistency. Furthermore, existing data infrastructures and databases, such as epidemiological data from the European Centre for Disease Prevention and Control (ECDC), should be fully leveraged in order to reduce reporting burdens, streamline the monitoring of medicinal product supply chains, and improve the efficiency of data exchange***

***between competent authorities and stakeholders. The use of existing structures would also help ensure more stable and predictable data flows.***

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***[1a] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj);***

***[1b] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, ELI: http://data.europa.eu/eli/reg/2014/536/oj).***

**Amendment 9**
**Proposal for a regulation**
**Recital 10**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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 ***along the entire supply chain*** 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 |

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.

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.

**Amendment 10**
**Proposal for a regulation**
**Recital 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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***. | (12) ***Strengthening*** the security of supply and ***ensuring*** the availability***, and supporting the accessibility*** of critical medicinal products and of medicinal products of common interest, ***and strengthening*** the Union's competitiveness ***in the pharmaceutical sector are key and mutually reinforcing objectives of this Regulation. This Regulation should foster a*** stable and predictable market environment, ***encourage*** investment***, and promote*** innovation ***across the Union. Enhancing*** the availability and accessibility of ***critical and*** other medicinal products of common interest***, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products,*** should ***also*** contribute to the Union's preparedness, resilience, ***strategic autonomy and overall*** economic and ***strategic*** security, ***particularly in the face of potential disruptions to*** cross-border supply chains. |

**Amendment 11**
**Proposal for a regulation**
**Recital 12 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(12a) To ensure Europe's long-term strategic autonomy in the pharmaceutical sector, it is imperative to prioritise the*** |

***reinforcement of European manufacturing capacity through strategic projects that secure raw materials supply, the continuous and reliable production of critical medicines and active pharmaceutical ingredients in the Union. By investing in research and innovation, supporting the modernisation of infrastructure, the Union can strengthen its pharmaceutical industrial base, reduce dependencies on third countries, and diversify supply chains.***

**Amendment 12**
**Proposal for a regulation**
**Recital 17**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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***, including cross-border joint 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 ***be provided with adequate resources to*** 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 their streamlining as well as enable digital submission of required information. |

**Amendment 13**
**Proposal for a regulation**
**Recital 18**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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, Member States should give particular attention to small and medium sized enterprises (SMEs) ***and small mid-cap enterprises (SMCs), with a view to ensuring that they*** have a fair chance to initiate strategic projects. ***Member States and designated authorities should pay particular attention to minimising the administrative burden on SMEs and SMCs and should provide support and clear guidance through the application, permitting and regulatory processes. Furthermore, requirements should be applied in a manner that guarantees fair and equal competition among all market players, regardless of their ownership structure. To support the effective implementation of this Regulation, the Commission should provide guidance to national authorities and project promoters, intended as a practical support tool. Such guidance should assist in the preparation, recognition and support of strategic projects.*** |

**Amendment 14**
**Proposal for a regulation**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) To avoid a fragmented approach across the Union and to ensure coherent and coordinated implementation of this Regulation, the criteria for the recognition of strategic projects should be applied in a consistent and transparent manner, while allowing for a degree of flexibility to reflect national specificities and capacities. Such a balanced approach should support a wide uptake of strategic projects across the Union.*** |

**Amendment 15**
**Proposal for a regulation**
**Recital 21**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 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. | (21) ***The establishment or expansion of existing manufacturing capacities for critical medicinal products and their supply chains requires significant financial investment. Private investment by companies and financial investors is essential.*** 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, private investment alone ***may not always be*** sufficient***. In such cases, the effective roll-out of projects across the supply chain may require public*** support***, for example in the form of guarantees, loans or equity and quasi-equity*** investments***. Such public support can include State aid. Such State aid should have an incentive effect and be necessary, appropriate and proportionate***. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, ***in accordance with Union*** State aid rules. For this purpose, the Commission services ***have provided specific guidance to assist Member States in the application of the*** |

***Union's State aid framework, which*** will be updated as necessary. ***In order to ensure that public support effectively contributes to strengthening the Union's security of supply, strategic projects receiving financial support should prioritise supply to the Union market for as long as the medicinal product concerned remains on the Union List of Critical Medicinal Products. Those strategic projects should make reasonable efforts to maintain the availability of those products in the Member States where they are placed on the market, without undermining their supply to other Union markets. That obligation should apply without prejudice to situations of force majeure, such as natural disasters or cyberattacks that significantly affect the manufacturing site, which shall not be considered a breach of that obligation.***

**Amendment 16**
**Proposal for a regulation**
**Recital 22**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (22) Union-level funding may be leveraged to facilitate investments in strategic projects. Strategic projects may benefit from access to existing EU funding instruments, such as the EU4Health Programme[4] , Digital Europe Programme[5] and Horizon Europe[6] ***(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[7] (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 | (22) Union-level funding may be leveraged to facilitate investments in strategic projects. Strategic projects may benefit from access to existing EU funding instruments, such as the EU4Health Programme[4] , Digital Europe Programme[5] and Horizon Europe[6] , as well as the Strategic Technologies for Europe Platform (STEP), when they fulfil the criteria established in these instruments. ***Moreover, STEP should contribute to more effectively channelling existing Union funds towards supporting the development of strategic projects.*** Authorities in charge of ***STEP*** should ***support*** in particular strategic projects ***aiming to establish or expand manufacturing capacities for critical medicines products or*** addressing a vulnerability in the supply chains of critical medicinal products and therefore |

amended.

Regulation (EU) 2024/795 should be amended ***accordingly***. ***In that context, strategic projects receiving public support should be compliant with relevant Union law. To ensure the continued implementation of this Regulation after 2027, Union level funding should be considered in the context of the multi-annual financial framework for 2028-2034.***

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[4] 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)

[5] 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)

[6] 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)

[7] 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)

[4] 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)

[5] 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)

[6] 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)

[7] 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)

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)

**Amendment 17**
**Proposal for a regulation**
**Recital 23**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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[8] . | (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. ***In doing so, an appropriate level of confidentiality of sensitive business information and data obtained should be respected and protected, such as details of value chains, the disclosure of which could harm the competitive position of the companies involved. The Commission and the national competent authorities, their officials, employees and other persons working under the supervision of those authorities as well as officials and employees of other authorities of the Member States should not disclose information acquired or exchanged by them pursuant to this Regulation where such information is covered by the obligation of professional secrecy. This should also apply to the Critical Medicines Coordination Group. The data collated pursuant to this Regulation should be handled and stored in a secure environment.*** As regards the strategic projects that have benefitted from EU funding, the beneficiaries should follow the relevant communication and visibility rules[8] . |

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

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

**Amendment 18**
**Proposal for a regulation**
**Recital 31**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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***,*** solidarity ***and non-discrimination. To ensure transparency and mutual understanding among Member States they should notify the Critical Medicines Group of planned measures before their implementation***. The Member States should give due consideration to forthcoming Commission guidelines***, to be regularly reviewed,*** designed to facilitate the fulfilment of Member States' obligations as regards the absence of any negative impact on the internal market***, supply continuity and patient access*** when proposing and defining the scope and timing of any form of requirements for companies to hold such stocks. ***When drafting the guidelines the Commission should consult with relevant stakeholders, including market authorisation holders, and take into account transparency and waste management measures.*** |

**Amendment 19**
**Proposal for a regulation**
**Recital 37**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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 |

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|---|---|
| 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. | 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. ***The Critical Medicines Group should furthermore be able to allow the participation of other parties as observers, in particular representatives of the European Parliament.*** |

**Amendment 20**
**Proposal for a regulation**
**Recital 37 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(37a) The effective implementation of this Regulation requires the meaningful involvement of relevant stakeholders across the pharmaceutical supply chain. To that end, the Critical Medicines Group should be able to establish working groups and invite key actors such as patient organisations, marketing authorisation holders, manufacturers, relevant social partners, and social insurance bodies to contribute their expertise and perspectives. The work of the Critical Medicines Group should build on and be informed by the insights of the Critical Medicines Alliance, which brings together a wide range of public and private stakeholders. Regular and structured cooperation between the Critical Medicines Group and the Critical Medicines Alliance should help ensure that actions taken under this Regulation are grounded in practical experience, scientific knowledge and the needs of*** |

***patients and healthcare systems.***

**Amendment 21**
**Proposal for a regulation**
**Recital 38**

| *Text proposed by the Commission* | *Amendment* |
| --- | --- |
| (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. | (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, the Critical Medicines Group should facilitate discussion, and advise the Commission on the implementation of the objectives of this Regulation and on a horizontal approach guiding existing and new legislative acts of the Union to ensure coherence between policy objectives. Such an approach would help avoid unintended overlaps or conflicting requirements and support the Union's broader goal of strengthening resilience, security of supply and competitiveness across strategic sectors, including the pharmaceutical industry. Furthermore, the Critical Medicines Group should facilitate discussions on measures to be taken during public health crises in order to support the continuity of the supply of medicines in the Union.*** |

**Amendment 22**
**Proposal for a regulation**
**Recital 38 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(38a) The Critical Medicines Group, where appropriate within a dedicated working group, should, at the request of a strategic project promoter, discuss and advise on how the financing of the project could be completed, taking into account the funding already secured and considering additional private sources of financing, support through resources from the EIB Group or other international financial institutions including the European Bank for Reconstruction and Development, existing Member State instruments and programmes, including from national promotional banks, institutions and Export Credit Agencies, and relevant Union funding and financing programmes. The Critical Medicines Group should regularly provide recommendations on ways to ensure sufficient funding, including through the Union budget, to pursue the objectives of this Regulation.*** |

**Amendment 23**
**Proposal for a regulation**
**Recital 39**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (39) The Union could further enhance the availability and security of supply of critical medicinal products***, as well as their active substances and key inputs needed for their manufacturing,*** 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 |

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|---|---|
| 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. | 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. |

**Amendment 24**
**Proposal for a regulation**
**Recital 40**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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. ***In order to ensure trust-based and constructive cooperation between economic operators and competent authorities at both Union and national level, all parties involved in the implementation and evaluation of this Regulation should respect the confidentiality of any information and data obtained in the performance of their tasks.*** |

**Amendment 25**
**Proposal for a regulation**
**Article 1 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The objective of this Regulation is | 1. The objective of this Regulation is |

| | |
|---|---|
| to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products. | to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products. ***Strengthening manufacturing capacities and the resilience of supply chains, as well as competitiveness, strategic autonomy and innovation in the Union's pharmaceutical sector, is an integral part of the objectives of this Regulation.*** |

**Amendment 26**
**Proposal for a regulation**
**Article 1 – paragraph 2 – point a**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (a) facilitate investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union; | (a) facilitate***, support and incentivise*** investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union; |

**Amendment 27**
**Proposal for a regulation**
**Article 1 – paragraph 2 – point a a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(aa) simplify and accelerate administrative and permit-granting processes related to the strategic projects, and provide regulatory support;*** |

**Amendment 28**
**Proposal for a regulation**
**Article 3 – paragraph 1 – point 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (2) 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including primary packaging materials, excipients, solvents and reagents; | (2) 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including ***raw materials, intermediates,*** primary packaging materials***, including those with safety-related features***, excipients, solvents and reagents***, as well as technical and technological resources necessary for the manufacturing processes***; |

**Amendment 29**
**Proposal for a regulation**
**Article 3 – paragraph 1 – point 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (12) 'permit granting process' means a process covering all relevant permits to build and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures; | (12) 'permit granting process' means a process covering all relevant permits to build***, expand, convert*** and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures; |

**Amendment 30**
**Proposal for a regulation**
**Article 3 – paragraph 1 – point 13**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform techniques, 3D manufacturing; | (13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, ***automation,*** Artificial Intelligence, platform techniques, 3D manufacturing; |

**Amendment 31**
**Proposal for a regulation**
**Article 3 – paragraph 1 – point 18**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (18) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation. | (18) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products ***or its supply chain*** that is established through a non-binding instrument ***setting out actions of mutual interest*** and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation. |

**Amendment 32**
**Proposal for a regulation**
**Article 3 – paragraph 1 – point 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) 'cross-border joint strategic project' means a strategic project that meets the standards established in Article 5 and is conducted between at least two Member States.*** |

**Amendment 33**
**Proposal for a regulation**
**Article 4 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. | 2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. ***In doing so, they shall take into account the roles of relevant stakeholders, including the pharmaceutical industry, in particular manufacturers and marketing authorisation holders, as well as relevant social partners, patient and healthcare organisations, and health insurance*** |

***bodies, and shall involve them, where appropriate.***

**Amendment 34**
**Proposal for a regulation**
**Article 5 – paragraph 1 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| A project located in the Union and related to creating or increasing manufacturing capacity shall be considered as a strategic project if it meets at least one of the following criteria: | A project located in the Union and related to creating***, improving*** or increasing manufacturing capacity shall be considered as a strategic project if it meets at least one of the following criteria: |

**Amendment 35**
**Proposal for a regulation**
**Article 5 – paragraph 1 – point a**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances; | (a) it creates or increases manufacturing capacity***, including through new technologies and innovative manufacturing processes,*** for one or more critical medicinal products or for collecting or manufacturing their active substances; |

**Amendment 36**
**Proposal for a regulation**
**Article 5 – paragraph 1 – point b**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency; | (b) it modernises an existing manufacturing site***, including through new technologies and innovative manufacturing processes,*** for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency; |

**Amendment 37**
**Proposal for a regulation**
**Article 5 – paragraph 1 – point d**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs. | (d) it contributes to the roll-out ***or transfer*** of a technology***, including through new and innovative technologies,*** that plays a key role in enabling the manufacturing ***or strengthening the resilience of supply chain*** of one or more critical medicinal products, their active substances or key inputs. |

**Amendment 38**
**Proposal for a regulation**
**Article 5 – paragraph 1 – point d a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(da) it reserves a clearly defined share of its manufacturing capacity for one or more critical medicinal products or their active substances or for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances, upon request by the Critical Medicines Coordination Group and within a specified timeframe, in order to address potential, emerging or existing shortages;*** |

**Amendment 39**
**Proposal for a regulation**
**Article 5 – paragraph 1 – point d b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(db) it makes a meaningful contribution to strengthening the security of supply and the availability of critical medicinal products in the Union.*** |

**Amendment 40**
**Proposal for a regulation**
**Article 6 – paragraph 1 – subparagraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Each Member State shall designate ***an*** | Each Member State shall ***within 90 days*** |

authority ('the designated authority') that shall assess and verify whether or not a project meets at least one of the criteria set out in Article 5 and therefore constitutes a strategic project.

***from the date of entry into force of this Regulation*** designate ***a single*** authority ('the designated authority') that shall assess and verify whether or not a project meets at least one of the criteria set out in Article 5 and therefore constitutes a strategic project. ***Strategic projects shall be implemented in compliance with Union environmental, health, and social standards.***

**Amendment 41**
**Proposal for a regulation**
**Article 6 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Commission shall provide a simple, accessible webpage ***on which*** the contact details and other relevant information on the Member States' designated authorities ***shall be clearly listed***. | 3. The Commission shall provide a simple, accessible webpage ***for project promoters and national authorities. That webpage shall provide*** the contact details and other relevant information on the Member States' designated authorities***, guidance documents prepared by the Commission, intended as a practical support tool to assist national authorities and project promoters in the preparation, recognition and support of strategic projects, as well as information on opportunities for financial and, where applicable, other forms of support from the Union***. |

**Amendment 42**
**Proposal for a regulation**
**Article 7 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Strategic projects shall be considered as contributing to the security of supply of critical medicinal products in the Union and, therefore***,*** to be in the public interest. | Strategic projects shall be considered as contributing to the security of supply of critical medicinal products in the Union and ***as serving the interests of public health and safety***, ***and shall*** therefore ***be deemed*** to be in the public interest. |

**Amendment 43**
**Proposal for a regulation**
**Article 7 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***The Member States' authorities shall ensure that the relevant permit granting*** processes related to strategic projects ***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. | ***For the purpose of ensuring the efficient administration of the permit-granting and regulatory*** processes related to strategic projects ***in the Union, project promoters and all authorities concerned shall ensure that that process is*** carried out in the ***most rapid*** way possible, ***and*** making available any form of accelerated procedures that exists in applicable Union and national law. |

**Amendment 44**
**Proposal for a regulation**
**Article 7 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The application of accelerated administrative and permit-granting procedures for strategic projects shall be without prejudice to the timely and proper processing of other single permitting procedures not covered by this Regulation, such as those related to manufacturing projects for non-critical medicinal products that fall outside the scope of strategic projects.*** |

**Amendment 45**
**Proposal for a regulation**
**Article 8 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs) and***, where*** appropriate***, establish a dedicated channel for communication with SMEs to provide*** guidance and ***respond*** to queries related to | 2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State ***and its authorities*** shall pay particular attention to small and medium size enterprises (SMEs) and ***small mid-cap enterprises (SMCs) and shall provide those undertakings with the*** appropriate guidance and ***assistance for*** |

| | |
|---|---|
| the implementation of this Regulation. | ***the implementation of this Regulation, including responding*** to queries related to the implementation of this Regulation. |

**Amendment 46**
**Proposal for a regulation**
**Article 8 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. Member States shall ensure that their authorities providing administrative support and authorities involved in the permit-granting process have a sufficient number of qualified staff and sufficient financial, technical and technological resources necessary for the effective performance of their tasks under this Regulation.*** |

**Amendment 47**
**Proposal for a regulation**
**Article 9 – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***Request for*** granting the status of highest national significance | Granting the status of highest national significance |

**Amendment 48**
**Proposal for a regulation**
**Article 9 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. ***A project promoter may request that their application for a permit is*** granted the status of the highest national significance***, when*** such a status exists in national law, and be treated accordingly. | 1. ***Without prejudice to obligations provided for in Union law, strategic projects in the Union shall be*** granted the status of the highest national significance ***possible, where*** such a status exists in national law, and be treated accordingly ***in the permit-granting processes***. |

**Amendment 49**
**Proposal for a regulation**
**Article 9 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***2. National authorities shall grant the status of the highest national significance to an application for a permit without prejudice to obligations provided for in Union law.*** | ***deleted*** |

**Amendment 50**
**Proposal for a regulation**
**Article 11 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. ***Upon request of a project promoter, a*** Member State shall provide regulatory support to a strategic project located on its territory, including by prioritising Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project. | 1. ***Each*** Member State***, including all levels of administration,*** shall provide regulatory support ***and a single contact point*** to a strategic project located on its territory, including by prioritising Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project. |

**Amendment 51**
**Proposal for a regulation**
**Article 11 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. At the request of a promoter of a strategic project, a Member State may offer regulatory assistance for critical medicinal products produced at a manufacturing facility classified as a strategic project, including accelerated procedures and fast-tracked reimbursement processes.*** |

**Amendment 52**
**Proposal for a regulation**
**Article 11 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Upon request of a project promoter, | 2. Upon request of a project promoter, |

| | |
|---|---|
| the European Medicines Agency ('the Agency') shall provide dedicated advice to assist project promoters developing projects relying on innovative manufacturing processes. | the European Medicines Agency ('the Agency') shall provide dedicated ***technical and administrative*** advice ***and fast-tracked review process*** to assist project promoters developing projects relying on innovative manufacturing processes ***for medicinal products, their active substances, or key inputs***. |

**Amendment 53**
**Proposal for a regulation**
**Chapter III – Section III – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Financial incentives | ***Accelerating implementation of strategic projects, including*** financial incentives |

**Amendment 54**
**Proposal for a regulation**
**Article 15 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Without prejudice to Articles 107 and 108 TFEU, Member States ***may*** prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products ***identified*** following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines Group referred to in Article 26(2) point (a). | 1. Without prejudice to Articles 107 and 108 TFEU, Member States ***are encouraged to*** prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products ***and meet the criteria as set out in Article 5*** following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines Group referred to in Article 26(2) point (a). |

**Amendment 55**
**Proposal for a regulation**
**Article 15 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from financial support for a strategic project shall prioritise supply to the Union market and use its very best | 2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from financial support ***by a Member State*** for a strategic project shall prioritise supply to the Union market and |

efforts to ensure that the critical medicinal product remains available in the Member States where it is being marketed.

use its very best efforts to ensure that the critical medicinal product remains available in the Member States where it is being marketed***, while ensuring that availability in other Union markets is not undermined***. ***Force majeure situations shall not be considered to be a breach of that obligation.***

**Amendment 56**
**Proposal for a regulation**
**Article 15 – paragraph 3 – subparagraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Any Member State that encounters a threat of shortages of the critical medicinal product in question may ***demand*** the Member State that provided financial support to submit a request on its behalf. | Any Member State that encounters a threat of shortages of the critical medicinal product in question may ***request*** the Member State that provided financial support to submit a request on its behalf. |

**Amendment 57**
**Proposal for a regulation**
**Article 16 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. For the duration of the Multiannual Financial Framework 2021-2027[24] strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme[25] , Horizon Europe[26] , and the Digital Europe Programme[27] provided that such support is in line with the objectives set out in the regulations establishing those programmes. | 1. For the duration of the Multiannual Financial Framework 2021-2027[24] strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme[25], Horizon Europe[26], and the Digital Europe Programme[27] provided that such support is in line with the objectives set out in the regulations establishing those programmes. ***To ensure the continued implementation of this Regulation after 2027, Union level funding may be considered in the context of the multi-annual financial framework for 2028-2034.*** |

[24] Council Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for years 2021 to 2027, as amended (OJ LI 433, 22.12.2020,

[24] Council Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for years 2021 to 2027, as amended (OJ LI 433, 22.12.2020,

p.11, ELI: http://data.europa.eu/eli/reg/2020/2093/oj)

[25] 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)

[26] 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)

[27] 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)

p.11, ELI: http://data.europa.eu/eli/reg/2020/2093/oj)

[25] 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)

[26] 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)

[27] 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)

**Amendment 58**
**Proposal for a regulation**
**Article 17 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article 24 of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article 25. | 1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article 24 of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article 25. ***While doing so, Member States shall provide information about the characteristics of the relevant strategic projects.*** |

**Amendment 59**
**Proposal for a regulation**
**Article 17 – paragraph 2 – subparagraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The Commission ***may*** inform the Critical Medicines Group of the intention to propose the establishment of funding possibilities ***specifically designed to address vulnerabilities in the supply chains as well as*** inform of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes. | The Commission ***shall*** inform the Critical Medicines Group of the intention to propose the establishment of funding possibilities ***to support strategic projects. It shall also*** inform ***the Critical Medicines Group*** of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes. |

**Amendment 60**
**Proposal for a regulation**
**Article 20 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Measures on security of supply applied in one Member ***State*** shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. | Measures on security of supply applied in one ***or more*** Member ***States*** shall not result in any negative impact in other Member States ***including the availability of the relevant medicinal products***. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. |

**Amendment 61**
**Proposal for a regulation**
**Article 20 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. | Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate***, targeted, and evidence-based*** and respect the principles of transparency and solidarity ***and non-discrimination***. |

**Amendment 62**
**Proposal for a regulation**
**Article 20 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Those requirements shall also avoid unintended consequences for supply continuity and patient access in the Union.*** |

**Amendment 63**
**Proposal for a regulation**
**Article 20 – paragraph 2 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Member States shall notify the Critical Medicines Group of planned measures before their implementation.*** |

**Amendment 64**
**Proposal for a regulation**
**Article 20 – paragraph 2 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall adopt guidelines to the Member States on ways to avoid negative impacts on the internal market of requirements for companies to hold contingency stocks.*** |

**Amendment 65**
**Proposal for a regulation**
**Article 25 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The Member States and the Commission are Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may | 2. The Member States and the Commission are Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may |

appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status.

appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status. ***The European Parliament may appoint representatives to the Critical Medicines Group in the capacity of observers.***

**Amendment 66**
**Proposal for a regulation**
**Article 25 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Critical Medicines Group shall work closely with the MSSG, the Agency, and national authorities responsible for medicinal products. For discussions where input from the medicines regulatory authorities' perspective is necessary, the Critical Medicines Group may organise joint meetings with the MSSG. | 3. The Critical Medicines Group shall work closely with ***the relevant stakeholders, including but not limited to marketing authorisation holders, industry representatives, relevant social partners, patient and consumer organisations, healthcare professionals,*** the MSSG, the Agency, and national authorities responsible for medicinal products. For discussions where input from the medicines regulatory authorities' perspective is necessary, the Critical Medicines Group may organise joint meetings with the MSSG. |

**Amendment 67**
**Proposal for a regulation**
**Article 25 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. The Commission shall organise and coordinate the work of the Critical Medicines Group by means of the Secretariat. | 4. The Commission shall organise and coordinate the work of the Critical Medicines Group by means of the Secretariat. ***Meetings of the Critical Medicines Group shall be convened by the Commission on a regular basis.*** |

**Amendment 68**
**Proposal for a regulation**
**Article 25 – paragraph 6**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 6. The Critical Medicines Group, at the proposal of the Chair or any its members, may decide to establish a working group. | 6. The Critical Medicines Group, at the proposal of the Chair or any its members, may decide to establish a working group. ***The working group may invite relevant stakeholders, including, but not limited to patients' and doctors' organisations, pharmacists, research and developments institutes, marketing authorisation holders, manufacturers, relevant social partners, and social insurance bodies, to participate in its meetings, in order to ensure that the implementation of this Regulation duly takes into account the distinctive characteristics of the supply chain for critical medicines products.*** |

**Amendment 69**
**Proposal for a regulation**
**Article 26 – paragraph 2 – point a a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(aa) facilitate coordination and implementation of cross-border joint strategic projects;*** |

**Amendment 70**
**Proposal for a regulation**
**Article 26 – paragraph 2 – point b a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(ba) facilitate discussion on contingency stocks and other security of supply measures;*** |

**Amendment 71**
**Proposal for a regulation**
**Article 26 – paragraph 2 – point c a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(ca) facilitate discussion on measures to be taken during public health crises;*** |

**Amendment 72**
**Proposal for a regulation**
**Article 26 – paragraph 2 – point d a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(da) facilitate discussion and advise the Commission on the implementation of the objectives of this Regulation and a horizontal approach guiding existing and new legislative acts of the Union to ensure coherence between policy objectives. Such an approach would help avoid unintended overlaps or conflicting requirements and support the Union's broader goal of strengthening resilience, security of supply and competitiveness across strategic sectors, including the pharmaceutical industry;*** |

**Amendment 73**
**Proposal for a regulation**
**Article 26 – paragraph 2 – point d b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(db) enable dialogue with relevant stakeholders regarding implementation of this Regulation and its objectives;*** |

**Amendment 74**
**Proposal for a regulation**
**Article 26 – paragraph 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***4a. The Critical Medicines Group shall examine the bottlenecks and Union-wide financial needs of strategic projects, advise on ways of coordinating Union and national financing with regard to those financial needs, and share best practices. While doing so the Critical Medicines Group shall ensure relevant financial expertise necessary to undertake that task.*** |

**Amendment 75**
**Proposal for a regulation**
**Article 26 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5a. When invited to do so, the Critical Medicines Group shall inform the European Parliament about its activities and tasks.*** |

**Amendment 76**
**Proposal for a regulation**
**Article 26 – paragraph 5 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5b. The Critical Medicines Group shall perform its tasks in compliance with the necessary confidentiality requirements, including those laid down in Article 30a.*** |

**Amendment 77**
**Proposal for a regulation**
**Article 26 – paragraph 5 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5c. The findings from the Critical Medicines Alliance shall be taken into account and actively incorporated into the work of the Critical Medicines Group, where relevant and in accordance with relevant Union or national law. The Commission, in its role as the secretariat of the Critical Medicines Group, shall ensure regular, targeted and transparent communication with the Critical Medicines Alliance.*** |

**Amendment 78**
**Proposal for a regulation**
**Chapter VI – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| International cooperation | International cooperation ***and strategic*** |

***partnerships***

**Amendment 79**
**Proposal for a regulation**
**Article 27 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Without prejudice to the prerogatives of the Council, the Commission, shall explore ***possibilities of concluding*** strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also ***explore the possibility of building*** on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. | Without prejudice to the prerogatives of the Council, the Commission, shall explore ***and, when possible, seek to conclude*** strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs ***taking into account the full breadth of the supply chain*** to increase the security of supply of critical medicinal products in the Union***, and in order to achieve the objectives of this Regulation***. The Commission shall also ***aim to build*** on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. |

**Amendment 80**
**Proposal for a regulation**
**Article 27 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall explore the possibility of including in existing and future partnerships, agreements, and other relevant international cooperation frameworks chapters related to health security that support the achievement of the objectives of this Regulation, promote open and resilient supply chain and foster cooperation in the pharmaceutical sector.*** |

**Amendment 81**
**Proposal for a regulation**
**Article 27 – paragraph 1 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***To ensure fair competition and avoid disadvantages for producers in the Union, the Commission shall, within the framework of strategic partnerships, promote the harmonisation of quality, safety and environmental standards for pharmaceutical production between the Union and third countries. Those partnerships shall include regulatory measures requiring third-country manufacturers exporting to the Union to comply with standards equivalent to those applicable in the Union for imported critical medicinal products, active pharmaceutical ingredients and key inputs.*** |

**Amendment 82**
**Proposal for a regulation**
**Article 27 – paragraph 1 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall inform the Critical Medicines Group about possible strategic partnerships on an annual basis.*** |

**Amendment 83**
**Proposal for a regulation**
**Article 28 – paragraph 1 – point a**
Regulation (EU) 2024/795
Article 2 – paragraph 1 – point a – point iii

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| biotechnologies, and any other technologies relevant for manufacturing of critical medicinal products as defined in Critical Medicines Act *; | biotechnologies, ***biomanufacturing*** and any other technologies relevant for manufacturing of critical medicinal products as defined in Critical Medicines Act *; |
| * Regulation (EU) … of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of | * Regulation (EU) … of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of |

critical medicinal products as well as for improving the availability of, and access to, medicinal products of common interest, and amending Regulation (EU) 2024/795.' [D.G.: reference to be completed with the definitive title of the 'Critical Medicines Act' and with its publications references once they are available];'

critical medicinal products as well as for improving the availability of, and access to, medicinal products of common interest, and amending Regulation (EU) 2024/795.' [D.G.: reference to be completed with the definitive title of the 'Critical Medicines Act' and with its publications references once they are available];'

**Amendment 84**
**Proposal for a regulation**
**Article 29 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation. | 1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission or national authorities, as relevant, ***proportionate and clearly defined,*** the requested information necessary for the purpose of application of this Regulation***, with due regard to the principles of the Better Regulation framework***. |

**Amendment 85**
**Proposal for a regulation**
**Article 29 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted. | 2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted ***by optimising the use of data already provided by marketing authorisation holders***. ***To that end, existing data infrastructures and relevant databases at national and Union level, including but not limited to epidemiological data compiled by the European Centre for Disease Prevention and Control and the European Shortages Monitoring Platform (ESMP), shall be*** |

***fully utilised with a view to minimising administrative and reporting obligations.***

**Amendment 86**
**Proposal for a regulation**
**Article 30 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 30a*** |
| | ***Handling of confidential information*** |
| | ***1. Information acquired in the course of implementing this Regulation shall be used only for the purposes of this Regulation and shall be protected by the relevant Union and national law.*** |
| | ***2. Member States and the Commission shall ensure the protection of trade and business secrets and other commercially confidential information obtained and processed in application of this Regulation, including recommendations and measures to be taken, in accordance with the relevant Union and national law.*** |
| | ***3. The Commission and the national authorities, their officials, employees and other persons working under the supervision of those authorities shall ensure the confidentiality of information obtained in carrying out their tasks and activities in accordance with relevant Union and national law. This paragraph shall also apply to all representatives of Member States, observers, experts and other participants attending meetings of the Critical Medicines Group.*** |
| | ***4. Any obligations on sharing information pursuant to this Regulation shall not apply to data that concerns the essential interests of the Member States' security.*** |

## ANNEX: DECLARATION OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur for opinion declares that he included in his opinion input on matters pertaining to the subject of the file that he received, in the preparation of the draft opinion (prior to the adoption thereof in committee), from the following interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register[1], or from the following representatives of public authorities of third countries, including their diplomatic missions and embassies:

| **1. Interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register** |
|---|
| European Commission, Directorate-General for Health and Food Safety<br>Directorate-General for Health and Food Safety |
| European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs |
| European Investment Bank, Life Sciences and Health Division |
| European Federation of Pharmaceutical Industries and Associations (EFPIA) |
| Medicines for Europe |
| Bundesverband der Pharmazeutischen Industrie e.V. |
| Pharma Deutschland e.V. |
| Verband forschender Arzneimittelhersteller (vfa) |
| European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) |
| |
| **2. Representatives of public authorities of third countries, including their diplomatic missions and embassies** |
| Mission of Japan to the EU |
| |

The list above is drawn up under the exclusive responsibility of the rapporteur for opinion.

Where natural persons are identified in the list by their name, by their function or by both, the rapporteur declares that he has submitted to the natural persons concerned the European Parliament's Data Protection Notice No 484 (https://www.europarl.europa.eu/data-protect/index.do), which sets out the conditions applicable to the processing of their personal data and the rights linked to that processing.

[1] Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register (OJ L 207, 11.6.2021, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2021/611/oj).

## PROCEDURE – COMMITTEE ASKED FOR OPINION

| | |
|---|---|
| **Title** | Laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 |
| **References** | COM(2025)0102 – C10-0048/2025 – 2025/0102(COD) |
| **Committee(s) responsible**<br>Date announced in plenary | SANT<br>21.5.2025 |
| **Opinion by**<br>Date announced in plenary | ITRE<br>21.5.2025 |
| **Rapporteur for the opinion**<br>Date appointed | Oliver Schenk<br>15.4.2025 |
| **Discussed in committee** | 4.9.2025 |
| **Date adopted** | 11.11.2025 |
| **Result of final vote** | +: 52<br>–: 9<br>0: 7 |
| **Members present for the final vote** | Wouter Beke, Hildegard Bentele, Tom Berendsen, Michael Bloss, Paolo Borchia, Markus Buchheit, Raúl de la Hoz Quintano, Pilar del Castillo Vera, Matthias Ecke, Christian Ehler, Sofie Eriksson, Jan Farský, Sigrid Friis, Lina Gálvez, Alexandra Geese, Bart Groothuis, Christophe Grudler, Elisabetta Gualmini, András Gyürk, Niels Flemming Hansen, Eero Heinäluoma, Ivars Ijabs, Seán Kelly, Ondřej Knotek, Michał Kobosko, Ondřej Krutílek, Eszter Lakos, Morten Løkkegaard, Sara Matthieu, Eva Maydell, Marina Mesure, Dan Nica, Aleksandar Nikolic, Mirosława Nykiel, Daniel Obajtek, Nikos Pappas, Thomas Pellerin-Carlin, Tsvetelina Penkova, Pascale Piera, Jüri Ratas, Julie Rechagneux, Aura Salla, Elena Sancho Murillo, Paulius Saudargas, Diego Solier, Nicolae Ștefănuță, Anna Stürgkh, Dario Tamburrano, Bruno Tobback, Matej Tonin, Kris Van Dijck, Yvan Verougstraete, Mariateresa Vivaldini, Andrea Wechsler, Angelika Winzig, Anna Zalewska, Auke Zijlstra |
| **Substitutes present for the final vote** | René Aust, Marc Botenga, Annalisa Corrado, Krzysztof Hetman, Rihards Kols, Lara Magoni, Oliver Schenk, Virginijus Sinkevičius, Marion Walsmann |
| **Members under Rule 216(7) present for the final vote** | Francisco Assis, Marieke Ehlers, Hanna Gronkiewicz-Waltz, Volker Schnurrbusch |

## FINAL VOTE BY ROLL CALL
## BY THE COMMITTEE ASKED FOR OPINION

| 52 | + |
|---|---|
| ECR | Rihards Kols, Ondřej Krutílek, Lara Magoni, Daniel Obajtek, Diego Solier, Kris Van Dijck, Mariateresa Vivaldini, Anna Zalewska |
| PPE | Wouter Beke, Hildegard Bentele, Tom Berendsen, Pilar del Castillo Vera, Raúl de la Hoz Quintano, Christian Ehler, Jan Farský, Hanna Gronkiewicz-Waltz, Niels Flemming Hansen, Krzysztof Hetman, Seán Kelly, Eszter Lakos, Eva Maydell, Mirosława Nykiel, Jüri Ratas, Aura Salla, Paulius Saudargas, Oliver Schenk, Matej Tonin, Marion Walsmann, Andrea Wechsler, Angelika Winzig |
| PfE | Ondřej Knotek, Julie Rechagneux |
| Renew | Sigrid Friis, Bart Groothuis, Christophe Grudler, Ivars Ijabs, Michał Kobosko, Morten Løkkegaard, Anna Stürgkh, Yvan Verougstraete |
| S&D | Francisco Assis, Annalisa Corrado, Matthias Ecke, Sofie Eriksson, Lina Gálvez, Elisabetta Gualmini, Eero Heinäluoma, Dan Nica, Thomas Pellerin-Carlin, Tsvetelina Penkova, Elena Sancho Murillo, Bruno Tobback |

| 9 | - |
|---|---|
| ESN | René Aust, Markus Buchheit, Volker Schnurrbusch |
| PfE | Marieke Ehlers, Auke Zijlstra |
| The Left | Marc Botenga, Marina Mesure, Nikos Pappas, Dario Tamburrano |

| 7 | 0 |
|---|---|
| PfE | Paolo Borchia, András Gyürk |
| Verts/ALE | Michael Bloss, Alexandra Geese, Sara Matthieu, Virginijus Sinkevičius, Nicolae Ștefănuță |

Key to symbols:
+ : in favour
- : against
0 : abstention

11.11.2025

# OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION

for the Committee on Public Health

on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795
(COM(2025)0102) – C10-0048/2025 – 2025/0102(COD))

Rapporteur for opinion: Marion Walsmann

PA_Legam

## SHORT JUSTIFICATION

The Critical Medicines Act is an important step towards ensuring the availability and security of critical medicinal products and other medicinal products of common interest throughout the EU. Its objectives are ambitious yet essential: ensuring timely access for patients, enhancing the resilience of supply chains, and reducing vulnerabilities in the European pharmaceutical system.

Against this background, the rapporteur welcomes the Commission's proposal as a solid and pragmatic foundation. However, further targeted improvements are necessary to ensure that the Regulation can deliver on its objectives and be implemented effectively. The proposed amendments in this opinion focus on four key priorities to reinforce resilience, improve coherence, and strengthen legal certainty.

A first priority is the reform of procurement practices. The current framework places excessive emphasis on the lowest price, which undermines resilience and availability. To safeguard equal and timely access for patients throughout the Union, procurement procedures must prioritise security of supply, stability of deliveries and fair competition. However, flexibility is also crucial: multi-winner procedures can reduce dependency on single suppliers, and carefully designed exemptions are necessary in specific market segments, such as orphan medicines, where diversification is not feasible.

The second area of focus is strengthening joint procurement initiatives at the Union level. These mechanisms are particularly beneficial for smaller Member States, embodying the principle of solidarity within the internal market. However, to ensure they provide genuine added value, the provisions must be streamlined to avoid duplication and ensure they are coherent with existing tools.

The third objective is to clarify the role of sustainability criteria in procurement. While environmental and social considerations are important in many policy areas, they must not conflict with this Regulation's primary aim of safeguarding the security of supply of critical medicinal products. The inconsistent application of such criteria could unintentionally restrict availability. Therefore, a systematic assessment of possible interactions is required to ensure that sustainability goals complement, rather than undermine, resilience.

Finally, the rapporteur supports the establishment of a European preference system, as proposed by the Commission. This instrument must be carefully designed to remain compatible with international obligations and avoid protectionist tendencies. A flexible, incentive-based approach is essential to strengthen European production capacities while maintaining WTO compliance.

Taken together, the proposed changes enhance the Commission's proposal in a balanced way. They provide a more resilient and secure supply of critical medicines, ensure clearer and more coherent rules, and support the successful implementation of the Critical Medicines Act, benefiting patients across Europe.

## AMENDMENTS

The Committee on the Internal Market and Consumer Protection submits the following to the Committee on Public Health, as the committee responsible:

**Amendment 1**

**Proposal for a regulation**
**Recital 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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 ***and lack of transparency of supply chains and stocks result*** in serious harm or risk of serious harm to patients. |

**Amendment 2**

**Proposal for a regulation**
**Recital 10**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 of supply are elements of a solution for ensuring the security of supply, international cooperation should be encouraged. | (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. ***Those instruments should be aligned with Directive 2014/24/EU.*** 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. |

**Amendment 3**

**Proposal for a regulation**
**Recital 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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.

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, ***strategic autonomy*** and economic and overall security, including when cross-border supply chains risk being disrupted.

**Amendment 4**

**Proposal for a regulation**
**Recital 14**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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 ***and pursued with measures that take full advantage of the potential of the internal market and safeguard the free movement of goods***. |

**Amendment 5**

**Proposal for a regulation**
**Recital 18**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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. | 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)***, as well as small mid-cap enterprises as defined in Commission Recommendation (EU) 2025/1099,*** which should have a fair chance to initiate strategic projects, ***and should offer them clear guidance throughout the application, permitting, and regulatory procedures with the aim of reducing the administrative burden on SMEs and small mid-caps***. |

**Amendment 6**

**Proposal for a regulation**
**Recital 19 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(19a) In order to strengthen the Union's capacity to respond effectively and in a coordinated manner to critical shortages of medicinal products, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), as part of its work to ensure Union coordination on the availability of medicines, should contribute to the strengthening and effective implementation of the Solidary Mechanism framework, in particular through communication between Member States and relevant stakeholders, taking into account the principles of solidarity, proportionality, and confidentiality.*** |

**Amendment 7**

**Proposal for a regulation**
**Recital 19 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(19b) Member States should cooperate in good faith and should, where necessary, provide mutual support to any other Member State that has requested assistance through the Solidarity Mechanism, with a view to preventing or mitigating shortages of critical medicinal products.*** |

**Amendment 8**

**Proposal for a regulation**
**Recital 24**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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 ***critical medicines and*** 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 ***a significant weighting of qualitative and non-price criteria, including*** stockholding obligations, ***diversification of supply, efficient and effective*** monitoring of supply chains ***for potential supply bottlenecks***, their transparency to the contracting authority contract performance clauses on timely delivery and measures in case of non-timely delivery. ***Procurement obligations should be applied*** |

***proportionately and adapted to the specific market conditions. Where diversification of supply chains is de facto not possible or not economically feasible, targeted exemptions from certain award criteria may be granted. Contracting authorities should not be precluded from using additional qualitative requirements, where relevant, including sustainability and social factors, in accordance with Directive 2014/24/EU.***

**Amendment 9**

**Proposal for a regulation**
**Recital 26**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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***, taking into account product-specific characteristics***. 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 ***not lead to protectionism and weakened competition and*** be designed and applied in line with the Union's international obligations including the principles of non- |

discrimination and proportionality. ***To safeguard the Union's strategic autonomy and reduce critical dependencies, a significant proportion of the production of critical medicinal products, medicinal products of common interest, or their active pharmaceutical ingredients intended for the Union market should be located within the Union, as defined in this Regulation. While trusted international cooperation and strategic partnerships remain important, ensuring resilience and security of supply means that production capacity needs to meet a certain threshold on Union territory. The assessment of whether this threshold is met should be carried out by the Commission or, where appropriate, by the competent authorities of the Member States, taking into account product-specific characteristics, market conditions, and risk-related considerations. This approach will ensure that the Union retains the capacity to respond effectively to public health needs and future crises.***

**Amendment 10**

**Proposal for a regulation**
**Recital 30**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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.

that critical medicinal products are also relevant for ***the*** 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 ***and non-discriminatory***. 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.

**Amendment 11**

**Proposal for a regulation**
**Recital 35**

*Text proposed by the Commission*

(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. For this reason derogations from Article 168 (2) and (3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[12] should be provided.

*Amendment*

(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 ***with defined timelines***. For this reason***, the Commission should assess the proportionality of any collaborative procurement request, taking into account factors such as the necessity and scale of the procurement, the ability of Member States to act individually or collectively, and the potential impact on the internal market, and*** derogations from Article 168 (2) and (3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and

of the Council[12] should be provided. ***The Commission should ensure sufficient resources are allocated to joint procurement procedures in order to guarantee an efficient and robust process.***

[12] 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).

[12] 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).

**Amendment 12**

**Proposal for a regulation**
**Recital 37**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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, the Commission should chair the Critical Medicines Group and perform the functions of its secretariat. | (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 ***Critical Medicines Group may invite representatives from relevant industry associations, patient, consumer and professional healthcare organisations to participate as observers or provide input on specific issues within the group's remit. 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.

**Amendment 13**

**Proposal for a regulation**
**Recital 37 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(37a) Ensuring a reliable supply of critical medicinal products requires coherent coordination between pharmaceutical policy and Union policies on environmental protection and climate change. The Critical Medicines Group may provide opinions and recommendations to the Commission concerning the potential impact of relevant environmental, climate or sustainability legislation on the availability and security of supply of critical medicines in the Union, including with regard to manufacturing sites, supply chains and market availability.*** |

**Amendment 14**

**Proposal for a regulation**
**Recital 39**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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 | (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. ***During accession negotiations, it is important that the Commission promote the gradual harmonisation of candidate*** |

| | |
|---|---|
| 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. | ***countries with the Union acquis in the field of medicinal products, with a view to facilitating their integration into the internal market and to reinforcing the resilience of supply chains for critical medicines.*** 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. |

**Amendment 15**

**Proposal for a regulation**
**Article 3 – paragraph 1 – point 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) 'significant proportion' means that the Commission or, where appropriate, the competent authority of the Member States concerned, has assessed that at least 30% of the annual production volume of a critical medicinal product, a medicinal product of common interest, or their active pharmaceutical ingredient (API), intended for the Union market, is manufactured within the Union;*** |

**Amendment 16**

**Proposal for a regulation**
**Article 4 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union. | 1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union ***and the Member States***. |

**Amendment 17**

**Proposal for a regulation**
**Article 4 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. | 2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market***, while reflecting the principles of solidarity and coordination between Member States and safeguarding the free movement of goods***. |

**Amendment 18**

**Proposal for a regulation**
**Article 18 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union***. Those*** procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, ***the number of diversified suppliers***, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. | 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience***, security and diversification*** of supply in the Union ***and shall base the award of public contracts on the most economically advantageous tender. The*** procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, ***volume or value of manufacturing of the final product or availability of the key ingredients and components within the Union***, monitoring of supply chains ***for potential supply bottlenecks***, their transparency***, including final contract value, upon request*** to the contracting |

authority and***, subject to safeguarding the confidentiality of trade secrets,*** contract performance clauses on timely delivery ***or the number of diversified suppliers***. ***Contracting authorities shall also allow for multi-winner procurements, where appropriate.***

***Contracting authorities may take into account the views of economic operators and other relevant stakeholders when defining procurement requirements as set out in the first subparagraph. In particular with regard to supplier diversification, procurement requirements shall be proportionate and adapted to the specific characteristics of the relevant market segment. Where diversification of supply chains is demonstrably not technically possible or not economically feasible, targeted exemptions from certain criteria may be granted, so as not to jeopardise the availability of critical medicinal products on the market.***

**Amendment 19**

**Proposal for a regulation**
**Article 18 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. ***With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the*** contracting authorities shall***, where justified,*** apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments. | 2. Contracting authorities shall apply procurement requirements***, for critical medicinal products*** that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union***, the European Economic Area (EEA) or the European Free Trade Association (EFTA) area, in order to ensure security of supply, and, when feasible, shall apply multi-winner procurements***. These requirements shall be applied in compliance with the Union's international commitments. |

**Amendment 20**

**Proposal for a regulation**
**Article 18 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. The Commission shall, by ... [18 months from the date of entry into force of this Regulation], adopt guidelines to support public procurement practices in the field of medicinal products covered by this Regulation. The guidelines adopted by the Commission shall illustrate the effective application of the criteria for the most economically advantageous tender, in particular on the application of non-price criteria, ensuring that such criteria shall be allocated a significant weighting in order to promote resilience and diversification of the supply in the Union. The guidelines shall also provide guidance on the assessment and practical application of the concept of significant proportion as defined in Article 3 of this Regulation including its implementation in specific market situations and the methodology for verifying compliance. They shall ensure a common understanding and legal certainty, while balancing the promotion of Union production with the need to avoid protectionism and weakened competition.*** |

**Amendment 21**

**Proposal for a regulation**
**Article 18 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. With regard to **other** medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities ***may*** apply procurement requirements that favour suppliers that | 3. With regard to medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities ***shall*** apply procurement requirements that favour suppliers that manufacture at least a |

manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments.

significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments.

**Amendment 22**

**Proposal for a regulation**
**Article 18 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. This Article shall not preclude contracting authorities from using additional qualitative requirements, ***including in relation to environmental*** sustainability and social ***rights***. | 4. This Article shall not preclude contracting authorities from using additional qualitative requirements, ***in accordance with Directive 2014/24/EU, that aim to contribute to improving supply chain security and the availability of critical medicinal products or medicinal products of common interest, which may take into account, where relevant, considerations related to*** sustainability and social ***factors***. |

**Amendment 23**

**Proposal for a regulation**
**Article 18 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2 and 3 ***where justified by*** market analysis or ***considerations related to the financing of health services***. | 5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2 and 3***,*** market analysis ***where they can demonstrate that the application of these provisions would lead to a disproportionately high price in the procurement concerned or impact negatively affordability of critical medical products for patients***. ***That derogation shall be clearly justified in writing and specify the circumstances relied upon. It shall be subject to ex-post review by the supervisory authority designated by the Member State.*** |

**Amendment 24**

**Proposal for a regulation**
**Article 20 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for ***companies*** to hold contingency stocks. | Measures on security of supply applied in one Member State shall not result in any negative impact ***on security of supply*** in other Member States. Member States shall, in particular, ***aim to*** avoid such an impact when proposing and defining the scope and timing of any form of requirements for ***public or private entities*** to hold contingency stocks. |

**Amendment 25**

**Proposal for a regulation**
**Article 20 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. To facilitate a coordinated approach between Union and national authorities as well as marketing authorisation holders, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), as part of its work to ensure Union coordination on the availability of medicines, shall contribute to the strengthening and effective implementation of the Solidary Mechanism framework, in particular the communication between Member States, marketing authorisation holders on the movement of stocks including, where appropriate, for medicinal products other than critical medicines, in cases of identified or imminent risk of shortage.*** |

**Amendment 26**

**Proposal for a regulation**
**Article 20 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Member States shall ensure that any requirements they impose on ***companies*** in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. | Member States shall ensure that any requirements they impose on ***public or private entities*** in the supply chain to hold contingency stocks***, or any restrictions they establish on the free movement of medicines,*** are proportionate and respect the principles of transparency and solidarity. ***Member States shall, in cases where such requirements may have an impact on other Member States, without undue delay, notify the European Medicines Agency and inform other Member States of their intentions in the Critical Medicines Group, as specified in Article 26, using a common notification mechanism established for this purpose.*** |

**Amendment 27**

**Proposal for a regulation**
**Article 20 – paragraph 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2a. The European Medicines Agency shall assess the notified measures in light of their potential impact on the availability of medicinal products in other Member States and on the functioning of the internal market and shall report its findings to the Commission and the Critical Medicines Coordination Group.*** |

**Amendment 28**

**Proposal for a regulation**
**Article 20 – paragraph 2 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***2b. Any Member State that considers itself negatively affected by measures adopted by another Member State may submit an opinion describing the negative*** |

***impacts to the Critical Medicines Group and the Commission. The Commission shall, without delay, engage with the Member State concerned and other affected Member States to promote coordinated solutions.***

**Amendment 29**

**Proposal for a regulation**
**Article 21 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Having received the request, the Commission shall inform all other Member States of the initiative and set an appropriate deadline for them to declare interest. Such a deadline shall not exceed three weeks. | 2. Having received the request, the Commission shall inform all other Member States of the initiative and set an appropriate deadline for them to declare interest***, provided the product qualifies as a medicinal product of common interest in their jurisdiction***. Such a deadline shall not exceed three weeks. |

**Amendment 30**

**Proposal for a regulation**
**Article 21 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The Commission shall assess the request in light of the objectives of this Regulation***. The Commission shall communicate to the interested Member States its decision on whether it agrees, or not, to facilitate the proposed initiative within three weeks of receiving the request***. | 3. The Commission shall assess the ***necessity and proportionality of the*** request ***in light of the actual access hurdles in the Member States and*** in light of the objectives of this Regulation***, taking into account, where necessary, the views of relevant stakeholders, including market authorisation holders***. |

**Amendment 31**

**Proposal for a regulation**
**Article 21 – paragraph 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 4. ***If*** the Commission declines the | 4. ***The Commission shall*** |

| | |
|---|---|
| request, it shall provide reasons for the refusal. | ***communicate to the interested Member States its decision on whether it agrees, or not, to facilitate the proposed initiative within three weeks of receiving the request. Where*** the Commission declines the request, it shall provide reasons for the refusal. |

**Amendment 32**

**Proposal for a regulation**
**Article 21 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the interested Member States. The Commission shall facilitate communication and cooperation between the involved Member States and provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products. | 5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the interested Member States. The Commission shall facilitate communication and cooperation between the involved Member States and provide advice on applicable Union public procurement rules and on regulatory ***and intellectual property*** matters related to medicinal products. |

**Amendment 33**

**Proposal for a regulation**
**Article 22**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***[...]*** | ***deleted*** |

**Amendment 34**

**Proposal for a regulation**
**Article 23 – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Joint Procurement | Joint Procurement ***and procurement on behalf of Member States*** |

**Amendment 35**

**Proposal for a regulation**
**Article 23 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Under conditions laid down in this Article and by way of derogation from Article 168(2) of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least nine Member States may engage, as contracting parties, in a joint procurement procedure. | 1. Under ***the*** conditions laid down in this Article and by way of derogation from Article 168(2) ***and (3)*** of Regulation (EU, Euratom) 2024/2509, if a contract is necessary for the implementation of the joint action between the Commission and Member States, the Commission and at least nine Member States may engage, as contracting parties, in a joint procurement procedure***, or the Commission may procure, on behalf of, or in the name of nine or more Member States, in accordance with paragraphs 2 to 8 of this Article***. |

**Amendment 36**

**Proposal for a regulation**
**Article 23 – paragraph 2 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. A ***joint*** procurement procedure may be organised following a request by the Member States or at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below: | 2. A procurement procedure ***as referred to in paragraph 1*** may be organised following a request by the Member States or at the Commission's initiative***, provided that,*** when the procurement relates to medicinal products belonging to one of the categories below: |

**Amendment 37**

**Proposal for a regulation**
**Article 23 – paragraph 2 – point b**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (b) medicinal products of common interest, for which a joint clinical assessment report has been published | (b) medicinal products of common interest, for which a joint clinical assessment report has been published |

pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council[31] , or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.

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

pursuant to Article 12(4) ***of*** Regulation (EU) 2021/2282 of the European Parliament and the Council[31] , or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation***, where such products have been identified as being subject to clearly defined supply risks under the mechanisms set out in this Regulation***; ***procurement procedures shall be designed with the objective of facilitating timely patient access to such products.***

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

**Amendment 38**

**Proposal for a regulation**
**Article 23 – paragraph 3**

*Text proposed by the Commission*

3. The Commission ***may decide to conduct the joint procurement procedure if*** the procurement procedure ***helps to improve*** the security of supply and availability of critical medicinal products in the Union or ***ensure*** the availability and accessibility of medicinal products of common interest, as applicable.

*Amendment*

3. The Commission ***shall assess the necessity and proportionality of*** the procurement procedure ***referred to in paragraph 1. It shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition and only launch it if it assesses that the procedure contributes to improving*** the security of supply and availability of critical medicinal products in the Union or ***ensuring*** the availability and accessibility of medicinal products of common interest, as applicable. ***That assessment shall be based on objective criteria, including market conditions, risk assessments, and product-specific characteristics, and may also be***

***conducted on the basis of a consultation with the marketing authorisation holder and relevant stakeholders.***

**Amendment 39**

**Proposal for a regulation**
**Article 23 – paragraph 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***4a. The procurement procedure set out in this Article shall be preceded by a joint procurement agreement between the Commission and the participating Member States in order to determine the practical arrangements governing the procurement, the duration of the procedure and the award criteria, in accordance with relevant Union law.*** |

**Amendment 40**

**Proposal for a regulation**
**Article 23 – paragraph 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.*** | ***deleted*** |

**Amendment 41**

**Proposal for a regulation**
**Article 23 – paragraph 6**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 6. If in light of the Commission ***assessment***, it is necessary, in order to achieve the objectives of this Regulation, | 6. If***,*** in light of the Commission ***assessments referred to in paragraph 3***, it is necessary, in order to achieve the |

***to conduct*** the procurement ***as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the*** procedure may be ***conditioned*** upon ***acceptance of these conditions by*** interested Member States.

objectives of this Regulation, the procurement procedure may be ***conditional*** upon interested Member States ***accepting specific requirements, including conducting the procurement as exclusive to those Member States or agreeing to minimum binding quantities***.

**Amendment 42**

**Proposal for a regulation**
**Article 23 – paragraph 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***7a. In order to promote the resilience, availability, and diversification of the supply chain, the Commission shall ensure that any procurement procedure under this Article applies the award criteria and requirements referred to in Article 18.*** |

**Amendment 43**

**Proposal for a regulation**
**Article 23 – paragraph 8**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509. | 8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) ***and (3)*** of Regulation (EU, Euratom) 2024/2509. |

**Amendment 44**

**Proposal for a regulation**
**Article 23 – paragraph 8 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***8a. The Commission shall inform the European Parliament about any procurement procedures conducted in*** |

***accordance with this Article and, upon request, grant access to the contracts that are concluded as a result of those procedures, subject to the adequate protection of commercially sensitive information, including business secrets, commercial relations and the interests of the Union.***

**Amendment 45**

**Proposal for a regulation**
**Article 23 – paragraph 8 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***8b. Where the Commission cancels the procurement procedure in accordance with Article 174 of Regulation (EU, Euratom) 2024/2509, it shall immediately inform the participating Member States thereof, so that they can initiate their own procurement procedures without delay.*** |

**Amendment 46**

**Proposal for a regulation**
**Article 24 – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Agreement concerning procedures under ***Articles 22 and*** 23 | Agreement concerning procedures under ***Article*** 23 |

**Amendment 47**

**Proposal for a regulation**
**Article 24 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Member States participating in the procurement procedures covered by ***Articles 22 and*** 23 shall share with the Commission any information relevant for the procurement procedure. Member States shall provide resources necessary for the | 1. Member States participating in the procurement procedures covered by ***Article*** 23 shall share with the Commission any information relevant for the procurement procedure. Member States shall provide resources necessary for the successful |

| | |
|---|---|
| successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge. | conclusion of the procedure, in particular through involvement of staff with expertise and knowledge. |

**Amendment 48**

**Proposal for a regulation**
**Article 24 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. | 2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. ***It shall, where appropriate, also include safeguards to ensure transparency of award criteria and the prevention of discriminatory practices.*** |

**Amendment 49**

**Proposal for a regulation**
**Article 24 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 24a*** |
| | ***During accession negotiations, the Commission shall promote the gradual harmonisation of candidate countries with the Union acquis in the field of medicinal products, with a view to facilitating their integration into the internal market and to reinforcing the resilience of supply chains for critical medicines.*** |

**Amendment 50**

**Proposal for a regulation**
**Article 26 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission, so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market. | 1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission, ***including with regard to the assessment of the impact of other Union legal acts on the availability of critical medicines and the development of appropriate countermeasures,*** so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market. |

**Amendment 51**

**Proposal for a regulation**
**Article 26 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. To ensure the views of relevant stakeholders are taken into account, the Critical Medicines Group may invite representatives from relevant industry associations, pharmaceutical organisations, manufacturers, patient, consumer and professional healthcare organisations or market authorisation holders to participate as observers or provide input on specific issues within the group's remit.*** |

**Amendment 52**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point a a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(aa) monitor the availability and distribution of critical medicinal products and medicinal products of common interest across the Union;*** |

**Amendment 53**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(da) issue guidelines and exchange best practices on the use of resilience criteria in the framework of public procurement and on the use of qualitative criteria in the context of public procurement;*** |

**Amendment 54**

**Proposal for a regulation**
**Article 26 – paragraph 2 – point d b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(db) support the Commission in its dialogue with Member States on national security of supply measures, where relevant and feasible, with the aim of identifying coordinated solutions that make full use of, and protect, the proper functioning of the internal market.*** |

**Amendment 55**

**Proposal for a regulation**
**Article 26 – paragraph 5 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***5a. The Critical Medicines Group may provide recommendations to the Commission on regulatory exemptions that are necessary for the short-term redistribution of critical medicinal products, such as modifications to packaging, language or labelling requirements. The Critical Medicines Group may also provide opinions and recommendations to the Commission concerning the potential impact of relevant legislation on the availability and*** |

***security of supply of critical medicines in the Union, including with regard to manufacturing sites, supply chains and market availability.***

## ANNEX: DECLARATION OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur for opinion declares that she included in her opinion input on matters pertaining to the subject of the file that she received, in the preparation of the opinion, prior to the adoption thereof in committee, from the following interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register[5], or from the following representatives of public authorities of third countries, including their diplomatic missions and embassies:

| **1. Interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register** |
|---|
| European Commission, Directorate-General for Health and Food Safety |
| Bundesärztekammer |
| CSL Behring |
| European Federation of Pharmaceutical Industries and Associations (EFPIA) |
| Medicines for Europe |
| Kassenärztliche Bundesvereinigung |
| Pharma Deutschland e.V. |
| Permanent Representation of Germany to the EU |
| Deutsche Sozialversicherung |
| Merck |
| Bristol-Myers Squibb Company |
| Johnson & Johnson |
| Pfizer Inc. |
| Pharmaceutical Group of the European Union (PGEU) |
| Viatris |
| GSK |
| Bundesverband Medizintechnologie e.V. |
| **2. Representatives of public authorities of third countries, including their diplomatic missions and embassies** |

The list above is drawn up under the exclusive responsibility of the rapporteur for opinion.

Where natural persons are identified in the list by their name, by their function or by both, the rapporteur for opinion declares that she has submitted to the natural persons concerned the European Parliament's Data Protection Notice No 484 (https://www.europarl.europa.eu/data-protect/index.do), which sets out the conditions applicable to the processing of their personal data and the rights linked to that processing.

[5] Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register (OJ L 207, 11.6.2021, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2021/611/oj).

## PROCEDURE – COMMITTEE RESPONSIBLE

| | |
|---|---|
| **Title** | Laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 |
| **References** | COM(2025)0102 – C10-0048/2025 – 2025/0102(COD) |
| **Committee(s) responsible**<br>Date announced in plenary | SANT<br>21.5.2025 |
| **Opinion by**<br>Date announced in plenary | IMCO<br>21.5.2025 |
| **Rapporteur for the opinion**<br>Date appointed | Marion Walsmann<br>23.6.2025 |
| **Discussed in committee** | 15.7.2025 25.9.2025 16.10.2025 |
| **Date adopted** | 11.11.2025 |
| **Result of final vote** | +: 44<br>–: 2<br>0: 1 |
| **Members present for the final vote** | Alex Agius Saliba, Pablo Arias Echeverría, Jeannette Baljeu, Arno Bausemer, Biljana Borzan, Anna Cavazzini, Stefano Cavedagna, David Cormand, Henrik Dahl, Dóra Dávid, Adnan Dibrani, Klara Dostalova, Hanna Gedin, Sandro Gozi, Maria Grapini, Elisabeth Grossmann, Maria Guzenina, Svenja Hahn, Anna-Maja Henriksson, Virginie Joron, Pierre Jouvet, Arba Kokalari, Nikola Minchev, Piotr Müller, Reinis Pozņaks, Christel Schaldemose, Andreas Schwab, Tomislav Sokol, Dimitris Tsiodras, Inese Vaidere, Adina Vălean, Kim Van Sparrentak, Marion Walsmann |
| **Substitutes present for the final vote** | Marc Angel, José Cepeda, Veronika Cifrová Ostrihoňová, Salvatore De Meo, Dirk Gotink, Sophia Kircher, Alice Kuhnke, Marlena Maląg, Gaetano Pedulla', Joanna Scheuring-Wielgus, Tomáš Zdechovský, Kosma Złotowski |
| **Members under Rule 216(7) present for the final vote** | Siegbert Frank Droese, Pál Szekeres |

## FINAL VOTE BY ROLL CALL
## BY THE COMMITTEE ASKED FOR OPINION

| 44 | + |
|---|---|
| ECR | Stefano Cavedagna, Marlena Maląg, Piotr Müller, Reinis Pozņaks, Kosma Złotowski |
| PPE | Pablo Arias Echeverría, Henrik Dahl, Dóra Dávid, Salvatore De Meo, Dirk Gotink, Sophia Kircher, Arba Kokalari, Andreas Schwab, Tomislav Sokol, Dimitris Tsiodras, Inese Vaidere, Adina Vălean, Marion Walsmann, Tomáš Zdechovský |
| PfE | Klara Dostalova, Virginie Joron |
| Renew | Jeannette Baljeu, Veronika Cifrová Ostrihoňová, Sandro Gozi, Svenja Hahn, Anna-Maja Henriksson, Nikola Minchev |
| S&D | Alex Agius Saliba, Marc Angel, Biljana Borzan, José Cepeda, Adnan Dibrani, Maria Grapini, Elisabeth Grossmann, Maria Guzenina, Pierre Jouvet, Christel Schaldemose, Joanna Scheuring-Wielgus |
| The Left | Hanna Gedin, Gaetano Pedulla' |
| Verts/ALE | Anna Cavazzini, David Cormand, Alice Kuhnke, Kim Van Sparrentak |

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|---|---|
| ESN | Arno Bausemer, Siegbert Frank Droese |

| 1 | 0 |
|---|---|
| PfE | Pál Szekeres |

Key to symbols:
+ : in favour
- : against
0 : abstention

## PROCEDURE – COMMITTEE RESPONSIBLE

| | | | | |
|---|---|---|---|---|
| **Title** | Laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 | | | |
| **References** | COM(2025)0102 – C10-0048/2025 – 2025/0102(COD) | | | |
| **Date submitted to Parliament** | 12.3.2025 | | | |
| **Committee(s) responsible**<br>Date announced in plenary | SANT<br>21.5.2025 | | | |
| **Committees asked for opinions**<br>Date announced in plenary | BUDG<br>21.5.2025 | ENVI<br>21.5.2025 | ITRE<br>21.5.2025 | IMCO<br>21.5.2025 |
| **Not delivering opinions**<br>Date of decision | BUDG<br>20.3.2025 | | | |
| **Rapporteurs**<br>Date appointed | Tomislav Sokol<br>2.5.2025 | | | |
| **Discussed in committee** | 1.9.2025 | 5.11.2025 | | |
| **Date adopted** | 15.12.2025 | | | |
| **Result of final vote** | +:<br>–:<br>0: | 27<br>1<br>8 | | |
| **Members present for the final vote** | Vytenis Povilas Andriukaitis, Bartosz Arłukowicz, Marie-Luce Brasier-Clain, Laurent Castillo, Christophe Clergeau, Margarita de la Pisa Carrión, Ondřej Dostál, Viktória Ferenc, Nicolás González Casares, Michalis Hadjipantela, Adam Jarubas, Ondřej Knotek, András Tivadar Kulja, Peter Liese, Ignazio Roberto Marino, Tilly Metz, Alessandra Moretti, Elena Nevado del Campo, Nikos Papandreou, Michele Picaro, Jessica Polfjärd, Ruggero Razza, Tomislav Sokol, Dario Tamburrano, Vlad Vasile-Voiculescu, Tiemo Wölken | | | |
| **Substitutes present for the final vote** | Ivan David, Valérie Deloge, Sérgio Humberto, Billy Kelleher, Dan-Ștefan Motreanu, Marta Temido, Aurelijus Veryga | | | |
| **Members under Rule 216(7) present for the final vote** | Benoit Cassart, Nils Ušakovs, Michal Wiezik | | | |
| **Date tabled** | 19.12.2025 | | | |

## FINAL VOTE BY ROLL CALL BY THE COMMITTEE RESPONSIBLE

| 27 | + |
|---|---|
| ECR | Aurelijus Veryga |
| PPE | Bartosz Arłukowicz, Laurent Castillo, Michalis Hadjipantela, Sérgio Humberto, Adam Jarubas, András Tivadar Kulja, Peter Liese, Dan-Ştefan Motreanu, Elena Nevado del Campo, Tomislav Sokol |
| PfE | Viktória Ferenc |
| Renew | Benoit Cassart, Billy Kelleher, Vlad Vasile-Voiculescu, Michal Wiezik |
| S&D | Vytenis Povilas Andriukaitis, Christophe Clergeau, Nicolás González Casares, Alessandra Moretti, Nikos Papandreou, Marta Temido, Nils Ušakovs, Tiemo Wölken |
| The Left | Dario Tamburrano |
| Verts/ALE | Ignazio Roberto Marino, Tilly Metz |

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|---|---|
| ESN | Ivan David |

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|---|---|
| ECR | Michele Picaro, Ruggero Razza |
| NI | Ondřej Dostál |
| PPE | Jessica Polfjärd |
| PfE | Marie-Luce Brasier-Clain, Valérie Deloge, Ondřej Knotek, Margarita de la Pisa Carrión |

Key to symbols:
+ : in favour
- : against
0 : abstention