Council of the European Union

Brussels, 22 June 2026
(OR. en)

10713/26

**Interinstitutional File: 2025/0102 (COD)**

**LIMITE**

**SAN 492**
**PHARM 112**
**MI 656**
**MAP 133**
**POLCOM 223**
**IND 424**
**COMPET 786**
**CODEC 1221**

PUBLIC

**NOTE**

| | |
|---|---|
| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee |
| Subject: | Proposal for a regulation 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 (Critical Medicines Act)<br>*- Analysis of the final compromise text with a view to agreement* |

## I. INTRODUCTION

1. On 11 March 2025, the Commission submitted to the Council and the European Parliament a proposal for 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[1]. This proposal, referred to as the Critical Medicines Act (CMA), was adopted alongside a guidance on the application of state aid rules in the context of the CMA. The proposal was submitted without an Impact Assessment but a Commission staff working document[2] was published on 2 September 2025 summarising the evidence supporting the legislative proposal.

[1] 6872/25
[2] 12444/25

2. The objectives of the proposal, which complements the ongoing revision of the EU pharmaceutical legislation, are to improve the functioning of the internal market by establishing a framework to strengthen the security of supply and the availability of critical medicinal products within the Union. It further aims to improve the availability and accessibility of other medicinal products of common interest where the functioning of the market does not otherwise sufficiently ensure this, whilst giving due consideration to the affordability of those medicinal products.

3. The draft Regulation is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).

4. The European Economic and Social Committee delivered its opinion[3] on 18 June 2025 and the European Committee of the Regions delivered its opinion[4] on 10 December 2025.

5. The Senate of the Parliament of the Czech Republic and the Spanish Parliament, each submitted a positive assessment while raising concerns on certain aspects. The Romanian Senate submitted an opinion raising proportionality concerns and making several recommendations. The Italian Senate submitted two resolutions, being one positive and another raising proportionality concerns. The Italian Chamber of Deputies also submitted an opinion raising proportionality concerns. The Swedish Parliament and the French Senate, each submitted a reasoned opinion raising subsidiarity concerns on parts of the proposal.

6. In the European Parliament, the Committee on Public Health (SANT) has the lead responsibility and MEP Tomislav Sokol (EPP, HR) is the rapporteur. The SANT Committee adopted its report on 15 December 2025, followed by a vote in the Parliament plenary session on 20 January 2026.

7. On 2 December 2025, the Council reached a general approach[5] which constituted the mandate for negotiations with the European Parliament in the context of the ordinary legislative procedure.

---

[3] 10782/25
[4] 5223/26
[5] 15503/25

8. The first trilogue was held on 2 February under the Cyprus Presidency and subsequent trilogues took place on 16 March and 11 May 2026. In total, 24 technical meetings took place as part of the inter-institutional negotiations.

9. At the last trilogue, on which the Cyprus Presidency debriefed Coreper at its meeting of 13 May 2026, the co-legislators provisionally agreed on an overall compromise text as set out in the Annex to this note.

PUBLIC

## II. MAIN ELEMENTS OF THE COMPROMISE TEXT

10. The co-legislators agreed on the following main elements:

    a. Extension of the scope to all orphan medicinal products *(Article 2),* so they would benefit from the provisions on recognition of strategic projects and the permit-granting procedures (Articles 5, 6, 8(1)(c), 12, 13) and of collaborative procurements (articles 21, 22 and 24).
    b. On the recognition of strategic projects *(Article 6)* to centralise the recognition of strategic projects through one or more designated authorities. The assessment of the projects should be done by the designated authority without undue delay and in any event no later than in 20 days after the receipt of the request.
    c. On timelines for environmental assessments and authorisation *(Article 12),* the deadline for adopting a reasoned conclusion has been set to 60 days after receiving all the necessary information. In duly justified exceptional cases, this deadline may be extended by an additional 15 days.
    d. On the financial support by Member States and financial support by Union (*Articles 15 and 16*), a stronger commitment has been included for undertakings benefitting from financial support for strategic projects, within the limits of the undertaking's responsibilities. In addition, in Article 16 a general clause for potential Union funding was added, without prejudice to the current negotiations on the Multi-Annual Financial Framework 2028-2034.

e. On public procurement procedures *(Article 18),* to procure critical medicinal products resilience requirements are set. Contracting authorities may choose between different options to implement these requirements (Article 18(1)). Likewise, for critical medicinal products with a confirmed vulnerability in their supply chain, contracting authorities will be able to choose between two options to implement the 'EU preference' (Article 18(2)) by:

   i. using technical specifications, within the meaning of Article 24 of Directive 2014/24/EU, favouring suppliers that offer 50% of medicinal products or active substances manufactured in the Union, or

   ii. by applying a best price-quality ratio, within the meaning of Article 67 of Directive 2014/24/EU, rewarding the supplier that offers the highest share of medicinal products or active substances manufactured in the Union.

   The agreement also clarifies the concept of manufacturing in the Union for the purpose of the application of "EU preference" and that the "EU preference" shall be applied in compliance with the Union's international commitments (Article 18(2)). Also, contracting authorities may exceptionally not apply these requirements under specific circumstances (Article 18(5)). In addition, the Commission will issue guidelines to support contracting authorities with the implementation of these provisions (Article 18(6)).

f. On collaborative procurements *(Articles 21, 22 and 23),* on Article 22 (Commission procurement on behalf of or in the name of Member States) the threshold of participating countries is set to five Member States, Commission's participation becomes mandatory and the Commission may also, on its own initiative, invite Member States to form a joint request. Moreover, the resilience requirements set in Article 18 should also be used, where relevant, in collaborative procurement procedures. The deletion of Article 23 (joint procurement) has been maintained, in line with the Council mandate.

g. On contingency stocks requirements (*Articles 20 and 20a*), in article 20 (Safeguards related to Member States' contingency stocks requirements and other security of supply measures) wording is added specifying that contingency stock requirements applied by one Member State shall not result in any negative impact in other Member States by respecting the principles of proportionality, transparency and solidarity. On Article 20a (Information sharing and reporting on contingency stocks requirements)

new provisions have been introduced to strengthen transparency, information sharing and reporting between Member States by:

i. sharing information on contingency stock requirements through a digital platform established by the Agency,

ii. reporting, where reasonably possible within national monitoring systems, on up-to-date stock data of critical medicinal products available for voluntary reallocation, provided that they are subject to contingency stock requirements, the Voluntary Solidarity Mechanism (VSM) is activated, and it is requested by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG).

iii. issuance by the MSSG of non-binding recommendations for Member States to consider adapting or suspending contingency stock requirements on a voluntary and temporary basis. These non-binding recommendations would only be issued when the VSM has not resulted in a suitable solution and at the request of the Member State that has activated the VSM.

## III. CONCLUSION

11. The Permanent Representatives Committee is therefore invited to:

- confirm agreement on the final compromise text as set out in the annex to this note with a view to reaching an agreement at first reading with the European Parliament;
- authorise the Chair of the Permanent Representatives Committee to send a letter to inform the Chair of the European Parliament's SANT Committee that, should the European Parliament adopt its position at first reading on the text of the proposal in the exact form as set out in the annex to this note, and subject to revision of that text by the lawyer-linguists of both institutions, the Council will approve the European Parliament's position and the act will be adopted in the wording which corresponds to the European Parliament's position.

PUBLIC

**PE-CONS No/YY - 2025/102(COD)**

PUBLIC

**REGULATION (EU) 2026/…**
**OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of …**

***establishing* a framework *to strengthen the* security of supply *and the availability* of critical medicinal products, as well as the availability ▌ and accessibility of ▌ medicinal products of common interest, and amending Regulation (EU) 2024/795**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

---

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

2 ***Position of the European Parliament of … [(OJ …)/(not yet published in the Official Journal)] and position of the Council at first reading of … [(OJ …)/(not yet published in the Official Journal)]. Position of the European Parliament of … [(OJ …)/(not yet published in the Official Journal)] [and decision of the Council of …].***

Whereas:

(1) ***Availability of critical medicinal products is essential for the Union and the functioning of the internal market.*** 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 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 resilient, secure and reliable supply chains forming the backbone of the supply of medicinal products,*** is vital ***for*** achieving this objective and ▌ safeguarding public health across the Union ***while contributing to the Union's overall security***. ***To safeguard the functioning of the internal market it is therefore necessary to create a common Union framework to collectively address the challenges by strengthening the security of supply and the availability of critical medicinal products.***

(2) In recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages of medicinal products for which insufficient supply ***affects the continuity of care and the operational capacity of health systems and*** results in serious harm or risk of serious harm to patients. ***In addition, the shortages of older antibiotics, whose unavailability results in the necessity to substitute them, can contribute to the increase of antimicrobial resistance. A stable and resilient supply of critical medicines is therefore critical to the health of patients in the Union and the proper functioning of health systems.***

PUBLIC

(3) Shortages of medicinal products can have very different and complex root causes, with challenges identified along the entire pharmaceutical value chain ***which differ depending on the specific characteristics of the supply chains of medicinal products***. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of ***active substances and*** key ***inputs, including starting and raw materials***. 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 ***inputs***. Through diversification of supply sources and investment in local production, the Union can reduce its risk of exposure to shortages of medicinal products. ***In cases of blood-derived and plasma-derived medicinal products, the vulnerabilities can also result from limited collection capacity and unavailability of donors.***

(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 ***starting*** materials and active substances. ***Developing manufacturing capacity throughout the supply chain requires substantial long-term investment in adequate industrial infrastructure, strong research capabilities, regulatory predictability and a skilled workforce.*** Setting up new ***manufacturing capacities in the Union for critical medicinal products***, ***their key inputs and active substances, and expanding*** or modernising existing manufacturing capacities ▌ for ***those*** 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, ***and less*** 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***.

*(4a)* ***While medicinal products shortages can occur for any type of medicinal product, they often affect older, off-patent, and generic medicinal products, partly 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 established by Regulation (EU) .../...[3+]. Many off-patent and generic medicinal products suppliers have outsourced manufacturing or relocated production of finished medicinal products outside the Union, and frequently source their active substances from third countries. Consequently, the Union relies on a limited number of active substance suppliers and manufacturers, many located outside its borders.***

(5) To enhance the security of supply for medicinal products and thereby contribute to a high level of public health protection, the Union has implemented a range of measures that contribute to building a European Health Union. In particular, Regulation (EU) 2022/123 of the European Parliament and of the Council[4] has reinforced the European Medicines Agency's ('the Agency') mandate by enhancing monitoring, coordination, and reporting mechanisms to prevent and mitigate supply disruptions of critical medicinal products across Member States. That Regulation also established the Agency's Executive Steering Group on Shortages and Safety of Medicinal Products ('the MSSG'), which brings together representatives from the Agency and Member States, to coordinate urgent actions within the Union to manage existing shortages and issues related to the quality, safety and efficacy of medicinal products.

---

*3* ***Regulation (EU) …/… of the European Parliament and of the Council of … laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006.***

*+* ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***

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

(6) In addition, Regulation (EU) …/… [+]further strengthens the continuity of supply and availability of medicinal products***, inter alia by*** developing the core tasks already granted to the Agency by Regulation (EU) 2022/123 and setting out a framework for the activities to be deployed by the Member States and the Agency to improve the Union capacity to react efficiently and in coordinated manner to support the shortages management and security of supply of medicinal products, including by strengthening the obligations of marketing authorisation holders ***with regard to*** shortages prevention and ***shortages*** reporting ***or by establishing a Voluntary Solidarity Mechanism for medicinal products that allows a Member State affected by a critical shortage of a medicinal product to request supplies from other Member States***.

(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 ***Regulations*** (EU) 2022/123 and (EU) …/… [+] to mitigate and respond to shortages, the functioning of ***the market dynamics*** 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.

(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 ***critical*** medicinal ***products and facilitate accessibility to other*** 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.

---

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***

(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, ***might*** still not be available ***and accessible*** to patients in some Member States***, which results in inequalities in access between patients in the Union. This might concern medicinal products for rare diseases, antimicrobials, and other innovative, high-cost, or specialised treatments across various therapeutic areas, such as oncology. Lack of access might*** be caused by a variety of factors, including product or geographical demand market size, which can impact the timely ***accessibility and*** availability of medicinal products in certain Member States. ***This Regulation contributes to reducing inequalities among Member States, and to more equitable access to medicinal products across the Union, so that patients enjoy the same level of access regardless of their country of residence.***

***(9a) Because orphan medicinal products target rare and ultra-rare diseases and limited patient' populations, they would benefit from collaborative procurement that allows for the aggregation of the demand of participating Member States. For this reason, those medicinal products should qualify for such procurement procedures even where they are not considered as medicinal products of common interest. To encourage early access and availability in the Union of those medicinal products, certain advantages in the permit-granting process should be also granted to their developers and manufacturers.***

PUBLIC

(10) The smooth functioning of the internal market and a high level of protection of human health should be ensured as regards medicinal products. ***This Regulation*** should ***aim*** to ***complement*** other Union pharmaceutical legislation by providing for a harmonised framework supporting Member States' coordinated efforts to encourage investments in new***, modernised*** and existing manufacturing capacities for critical medicinal products, ***by*** 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***, as well as by providing a framework to increase coordination between Member States in relation to contingency stock requirements***. 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.

(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 [5+], Regulation (EU) …/… [++] 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.

---

[5] ***Directive (EU) 2026/… of the European Parliament and of the Council of … on the Union code relating to medicinal products for human use, and repealing Directives 2001/83/EC and 2009/35/EC.***

[+] ***OJ: please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).***

[++] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***

***(11a) Data made available to competent authorities in accordance with Regulation (EU) 2025/327 of the European Parliament and of the Council[6] on the European Health Data Space (EHDS) can contribute to the implementation of this Regulation.***

(12) While the primary objective of this Regulation should be to ***improve the functioning of the internal market by establishing a framework to*** strengthen the security of supply and ▌ the availability of critical medicinal products***, as well as the availability and accessibility*** of medicinal products of common interest, given ***that*** 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. Ensuring the security of supply and availability of critical medicinal products and the availability and accessibility of ▌ 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***, therefore supporting the Union's strategic autonomy***.

(13) Taking into account the different root causes of the availability issues affecting critical medicinal products and medicinal products of common interest, some measures should apply to critical medicinal products only.

---

***[6] 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).***

(14) ***Ensuring*** the security of supply ***and the availability*** of critical medicinal products ***for patients in the Union*** to safeguard public health***, patients' safety*** and the economic and overall security of the Union ***is a*** strategic ***objective*** of the Union. ***To achieve this, it is important that the Member States and the Commission 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 this effort, the Commission has an important role to support the coordinated efforts of the Members States.***

(15) A well-defined list of critical medicinal products is essential to ensure that the measures are targeted, effective ▌ and proportionate. The ▌ medicinal products covered by this Regulation ***are*** those for which insufficient supply results in serious harm or risk of serious harm to patients. For this reason this Regulation should apply to critical medicinal products on the Union list of critical medicinal products, as established by Regulation (EU) …/… [+]. That list builds upon the experiences of the ▌ Agency and Member States' agencies that in 2024 ▌ identified a list of 276 critical medicinal products.

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***

(16) To ensure that the measures are applied where justified and proportionate, it is necessary to demonstrate that some measures address a vulnerability in the supply chains of ***critical medicinal products while taking into account the distinctive characteristics of each category of*** critical medicinal ***products' supply chain***. This Regulation should rely on the vulnerability evaluation performed for the purpose of the application of the general pharmaceutical legislation ***pursuant to*** Regulation (EU) No …/… [+]. To detect a vulnerability in the supply chains it is necessary to look at aggregated data across all medicinal products authorised in the Union and containing the same active substance, route of administration and formulation. Such an approach allows for the determination whether, for a critical medicinal product with a given active substance, the Union is highly dependent on a single or a limited number of third countries, or a limited number of sites, for active substances, key inputs, or finished dosage forms.

(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 ***and contribution to the objectives of preserving public health and protection of patients' interests***, the relevant ***permit-granting*** 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 ***without delay,*** 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.

(18) ***The*** designated authority should ***assess*** whether a given project is a strategic project***. To offer real advantage to strategic projects as regards shortened permitting timelines, such assessments should be provided swiftly, without undue delay. When justified by the complexity of the project being the subject of an assessment, the timeline for an assessment can take up to 20 days***. 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, ***where such processes, status and procedures already exist in national law,*** as well as ▌ be offered targeted ▌ support. ***It is necessary that the strategic project relies on continuous supply of energy and gas to be able to produce the critical medicinal products. For this reason the Member States could consider the strategic projects as 'protected customer' in accordance with Regulation 2017/1938 of the European Parliament and of the Council [7] concerning measures to safeguard the security of gas supply.*** The Member States should ***also*** give particular attention to small and ***medium-sized*** enterprises (SMEs) which should have a fair chance to initiate strategic projects. ***This Regulation should be applied in a manner that guarantees fair and equal competition among all market players, regardless of their size and ownership structure. In order to ensure uniform conditions for the implementation of this Regulation in the Member States, a standard template for a request for recognition of a strategic project should be provided for by means of implementing acts. 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[8].***

---

*7* ***Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010 (OJ L 280, 28.10.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/1938/oj).***

*8* ***Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).***

***(18a) A project promoter should be able to request that their application for a permit is granted the status of the highest national significance, if such a status exists in national law, and be treated accordingly. National authorities are to grant the status of the highest national significance to an application for a permit without prejudice to obligations provided for in Union law.***

***(18b) A project promoter should be able to request that any dispute resolution procedure, litigation, appeal and proceedings on judicial remedies related to the permit-granting process, and the issuance of permits for a strategic project in the Union, is treated as urgent if and to the extent to which national law provides for such an urgency procedure.***

(19) The production of medicinal products has environmental implications and ***might*** 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 ***that*** negative environmental impacts***, including of a transboundary nature,*** 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 ***nor neglecting steps necessary for a proper assessment of transboundary impacts in accordance with applicable law***.

***(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).***

PUBLIC

(20) Land use conflicts can create barriers to the deployment of strategic projects. The relevant national, regional or local authority responsible for preparing zoning, spatial and land use plans should consider whether to introduce in these plans***, where appropriate,*** certain provisions related to strategic projects. Those plans have the potential to help balance the public interest and common good, decreasing the potential for conflict and accelerating the sustainable deployment of strategic projects in the Union.

(21) Given the capital-intensive nature of pharmaceutical production, including the establishment or expansion ***or modernisation*** of manufacturing sites for critical medicinal products, active substances, and key inputs, targeted financial support can play a crucial role in incentivising production within the Union. To strengthen the security of supply of critical medicinal products, and where private investment alone is not sufficient, financial support of investments in manufacturing capacity within the Union may be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of ***Union*** State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary.

***(21a) In order to enforce the supply commitments from the manufacturing sites that have received public support, it is important that all available legal instruments and tools are used. This, in particular, includes enforcement of related clauses in grants or award agreements, or activation, when justified, of funding recovery mechanisms in accordance with the applicable law and contractual terms.***

***(21b) Where the export of critical medicinal products manufactured in the Union leads to a critical shortage or a risk of a critical shortage, all available legal instruments are to be considered to ensure availability of these products to patients in the Union. This includes Regulation (EU) 2015/479 of the European Parliament and the Council[9].***

---

***9 Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports (OJ L 83, 27.3.2015, p. 34, ELI: http://data.europa.eu/eli/reg/2015/479/oj).***

(22) ***Financial Support for*** strategic projects ***could be provided by the Union under Union programmes in line with the objectives and provisions set out in the respective regulations establishing those programmes. In particular, strategic projects should be able to*** benefit from access to existing ***Union*** funding instruments, ***including*** the EU4Health Programme[10], ***the*** Digital Europe Programme[11] and Horizon Europe[12] (relevant, for example, for active substances referred to in [redacted] 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[13] (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.

***(22a) The strategic projects that received public financial support specifically to strengthen the security of supply of critical medicinal products should prioritise supplies to the Union market and ensure, within the limits of their responsibilities, supplies that cover needs of patients in the Member States where those critical medicinal products have been placed on the market.***

---

[10] 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).

[11] 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 L 166, 11.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/694/oj).

[12] 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 L 170, 12.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/695/oj).

[13] 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 (OJ L, 2024/795, 29.2.2024, ELI: http://data.europa.eu/eli/reg/2024/795/oj).

(23) To allow for a more coordinated approach to financial support, it is appropriate that Member States and the Commission exchange ▌ information on financial support to strategic projects. As regards the strategic projects that have ***received Union*** funding, ***it is important that*** the beneficiaries ▌ follow the relevant communication and visibility rules.

***(23a) Since the strategic projects are located in the territory of the Union, any public financial support provided to establish, increase, modernise the manufacturing capacity for critical medicinal products, their active substances or key inputs, should be spent within the Union.***

(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 ▌, it is necessary to establish rules that ***promote resilience of supply in public*** procurement ***procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council[15] through integration of resilience*** requirements***, as appropriate, in the process of public procurement in accordance with this Directive, in particular through application of award criteria favouring the*** most economically advantageous tender (MEAT) that take into account the supply security and availability considerations. ***In addition, to provide market predictability and support investment in the production of medicinal products,*** procurement ***procedures under this Regulation are to, where justified,*** include ***predictable quantities. 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 might not be commercially attractive under standard market conditions***.

---

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

***(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 medicinal 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.***

***(24b) The resilience of supply is strengthened if diversified supply sources are available, as diversification reduces a concentration of risk. Any dependence on only one supplier, irrespective of whether established in the Union or outside the Union, threatens the security of supply. Resilience requirements should therefore aim to support the availability of alternative suppliers of active substances, but also should be able to relate, inter alia, to stockholding obligations, timeliness of the delivery or management of the supply chains. Contracting authorities in the Member States should retain flexibility to decide the most relevant approach, given the market situation and their specific needs. The resilience can be promoted throughout the procurement procedures, by integrating those resilience requirements either in the selection criteria, technical specifications, award criteria or in the contract performance clauses, depending on the market situation and public health considerations. Active use of award criteria acknowledging quality alongside price are essential levers.***

(25) ***Across Member States, contracting authorities differ in their introduction and*** use of ***resilience*** requirements in public procurement procedures***, which lead to differentiated practices. This could*** have ***a*** 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 ***resilience requirements*** should be mandatory ***and a more streamlined practice supported***.

PUBLIC

(26) ***Where dependency on a single or a limited number of countries outside the Union is threatening the*** security of supply, it is necessary to procure in a way that promotes ***alternative supply options to ensure a high level of public health protection. For this reason, and in order to support the*** diversification of suppliers, where ***a vulnerability evaluation of critical medicinal product performed by the MSSG points to the vulnerability resulting from a high level of*** dependency on a single or ▌ limited number of third countries, ▌ ***the*** contracting authorities ▌ should ***apply the*** procurement requirements that***, while preserving competition, incentivise manufacturing in the Union. To ensure flexibility necessary to accommodate different national procurement practices*** in the ***Member States***, the contracting authorities ***should be able to choose at least one from the tools offered in this Regulation. Such*** procurement requirements ***could take the form of award criteria relying on a scoring system that rewards the*** suppliers ***proportionally to the volume of Union manufactured*** products ***offered and weighting attributed to manufacturing in the Union that effectively incentivises it, with the possibility to provide an extra reward for suppliers that offer more than 50 % of the contract volume manufactured in the Union. In case contracting authorities consider several lots in the procurement procedure, such requirements could also take form of technical specifications reserving at least one lot, representing*** a significant ***percentage*** of ***the total volume of the contract, to*** products ***manufactured*** in the ***Union***. ▌

(***26a***) ▌ Member States' responsibilities for the definition of their health policy and for the organisation and delivery of health services and medical care, including the allocation of financial resources, are to be respected***, as referred to in Article 168(7) TFEU***. The contracting authorities should therefore retain the ability ***in exceptional cases***, where justified by ▌ considerations related to ▌ market ***circumstances*** or considerations related to financing of health services, to adopt procurement approaches that differ from those set out in this Regulation as long as they are in line with the Union's international obligations.

*(26b) Considering the complexity of the pharmaceutical value chain, the contracting authorities, when assessing whether medicinal products and active pharmaceutical substances have been manufactured in the Union, should be able to rely on claims and evidence provided by the tenderers and should take into account manufacturing steps that add the most value.*

*(26c) In order to incentivise investments in modernisation or establishment of new manufacturing capacity in the Union for critical medicinal products for which a vulnerability evaluation indicated a vulnerability resulting from the high level of dependency on third countries, it is necessary that the industry operators have predictable market conditions that would encourage investments. For this reason it is important that the procurement requirements favouring manufacturing in the Union apply as long as the medicinal product remains on the Union list of critical medicinal products and is designated as vulnerable due to the high level of dependency and for a minimum period of 5 years from the day of entry into force of the last implementing act by which the medicinal product in question is specified as vulnerable due to the high level of dependency.*

*(26d) The continuous availability of critical medicinal products is essential to preserve human life and can be seriously threatened by the existence of a confirmed vulnerability of supply to the Union, consisting of a high level of dependency on one or a few number of third countries. The resilience requirements in procurement procedures aiming to safeguard the availability of critical medicinal products should be applied subject to the Union's international commitments including the Government Procurement Agreement in WTO and other relevant international agreements to which the Union is bound.*

PUBLIC

(27) The application of procurement requirements ***in public procurement procedures*** should take into account the specific market conditions and public health needs of each procurement procedure, whilst bearing in mind the considerations related to affordability of medicinal products. Certain procurement requirements ***might*** not be justified if they result in disproportionate cost for procurers or discourage participation, leading to no bids***, or if no suitable tender or no requests to participate have been submitted in response to a similar public procurement procedure launched by the same contracting authority in the two years prior to the commencement of the planned new procurement procedure***. ***Contracting authorities can presume tenders whose price exceeds the contracting authority's budget, as determined and documented prior to the launching of the procurement procedure, to be considered as tenders with disproportionate costs. Similarly, certain requirements might not be justified where it is strictly necessary due to reasons of extreme urgency brought about by events unforeseeable by the contracting authority and where the circumstances invoked to justify extreme urgency are not attributable to the contracting authority and make it impossible to comply with those requirements in the specific context of a negotiated procedure without prior publication. Such extreme urgency events can include major natural or public-health emergencies requiring immediate action to protect patients' life and health. In all such cases, the non-application of those requirements should be duly justified and exceptional.***

▌

(29) The Commission ***should*** issue guidelines designed to support Member States ***and contracting authorities*** in implementing ***and applying the resilience requirements in public procurement, including the*** obligations to use ***resilience*** requirements ***and requirements that favour critical medicinal products, or their active substances, manufactured in the Union*** with a view to strengthening the security of supply***. The Commission should consult relevant stakeholders such as patients and consumer organisations, healthcare professionals,*** public ***healthcare*** payers and ***marketing authorisation holders, in the process of preparation of those guidelines***.

(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 ***requirements in public*** procurement ***procedures*** by contracting authorities within their territory***. Such national programmes could also promote the consistent use*** of multi-winner approaches where beneficial, based on ***a*** thorough market analysis. To ensure a comprehensive approach, and considering that critical medicinal products are also relevant for ***the*** outpatient sector where they are often not purchased through public procurement, ***those national*** programmes ***can*** also encompass ***other*** 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 ***(CMCG)***, 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.

***(30a) In order to ensure legal clarity and effective coordination at Union level, it is essential to distinguish between the concepts of contingency stocks 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 In the context of contingency stocks, Member States should be encouraged to require that the economic actors requested to hold contingency stocks apply sustainable measures that contribute to reducing waste and improving the efficient use of available medicinal products in line with national law and national needs.***

PUBLIC

(31) ***Some*** Member States ***impose obligations on marketing authorisation holders and other economic operators*** in the pharmaceutical supply chain to ***healthcare providers and patients to*** hold contingency stocks ***for the purpose of safeguarding the security of supply of medicinal products within their territory. Contingency stocks are to be distinguished from publicly owned national, regional or local stockpiling in order to anticipate and manage a specific crisis. Contingency stocks requirements imposed by a Member State can potentially*** have a ▌ negative impact on the internal market and ***result in unavailability of the medicinal products concerned in*** other Member States. ***Any such contingency stocks requirements are to take into account that any restriction to the free movement of goods has to be justified, in accordance with the TFEU as interpreted by the Court of Justice of the European Union.*** To avoid ***a negative*** impact ***on availability of medicinal products, Member States*** should ***also, when introducing or changing existing contingency stock requirements for any medicinal products, including when determining the medicinal products covered, the size of required stocks and the timeline for establishment of the stocks, take*** into consideration the principles of proportionality, transparency and solidarity. ▌ Member States should give due consideration to forthcoming Commission guidelines designed to facilitate the fulfilment of Member States' obligations as regards ***compliance with*** the internal market ***and the free movement of goods*** when proposing and defining ***contingency stock*** requirements ▌ .

***(31a) To support the identification of potential negative impacts of the national contingency stock requirements, any Member State should notify the CMCG of its intention to impose such requirements, as well as inform the CMCG of those requirements once adopted. Such obligation should be without prejudice to the notification requirement under Directive (EU) 2015/1535 of the European Parliament and of the Council[16]. To support transparency of Member States contingency stock requirements, the Agency should provide an overview of the imposed contingency stock requirements.***

---

***16 Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, ELI: http://data.europa.eu/eli/dir/2015/1535/oj).***

*(31b)* ***It is important to fully leverage the Voluntary Solidarity Mechanism for medicinal products to allow preventing negative consequences of critical shortages of critical medicines to patients. Once the Voluntary Solidarity Mechanism for medicinal products is activated, the MSSG should be able to request the data on the available stock of critical medicinal products concerned, and if the Voluntary Solidarity Mechanism for medicinal products does not result in a suitable option to address the request of a Member State facing a shortage, the MSSG could issue recommendations.***

(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. ***The participation of the economic operators in collaborative procurement procedures conducted pursuant to this Regulation should be voluntary.***

(33) Directive 2014/24/EU ▌ provides for the possibility of procurement involving contracting authorities from different Member States. Whereas it has been found helpful to make small markets attractive for suppliers, thereby achieving better availability of medicinal products, ***the*** implementation ***of that possibility*** is time- and resource-intensive, especially in the ***procurement*** starting phase, and considered a limiting factor. To facilitate the deployment of procurement initiatives involving contracting authorities from different Member States, the Commission, when requested, should provide its assistance during the preliminary phase of setting up such a procurement initiative. ***The Commission assistance should be limited in time and should not concern the choices of procurement procedures, or of the procurement requirements, selection of tenders or decision on inclusion of specific contract elements. The involved Member States are able to agree to continue the procedure without the Commission's facilitation, including by agreement on another facilitator in accordance with Directive 2014/24/EU. Any involved Member State can withdraw from the procedure at any stage before the signature of the procurement contract. Withdrawal by one Member State would not in itself affect the continuation of the procedure by the remaining participating Member States, provided that the minimum requirements under this Regulation are still met. Member States could specify that they wish to conduct the cross-border procurement with candidate countries.***

PUBLIC

(34) Taking into account experiences resulting from the implementation of joint procurement of medical countermeasures pursuant to Regulation (EU) 2022/2371 of the European Parliament and of the Council[18]**,** and of COVID-19 vaccines ▌ pursuant to Council Regulation (EU) 2016/369[19] in the context of the EU Vaccines Strategy**,** and acknowledging potential benefits that leveraging of several Member States demand in one procurement procedure ***might*** have, Member States should be able to consider ▌ requesting the Commission to procure on their behalf, or in their name, where such procurement could contribute to the achievement of the objectives of this Regulation.

(35) To ensure that the collaborative procurement ***on behalf or in name of the Member States*** contribute to the achievement of the objectives of this Regulation, while fully respecting the principle of subsidiarity, the Commission's involvement ▌ should be limited to ▌ cases ***where the conditions set out in the relevant Articles are met***. For this reason***, derogation*** from Article ***168(3)*** of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[20] should be provided.

---

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

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

[20] 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).

*(35a) It is not appropriate that the Commission conducts a collaborative procurement on behalf of, or in the name of, the requesting Member States where it has substantiated grounds to expect that the procedure will not contribute to the improvement of the security of supply of critical medicinal products or the accessibility of medicinal products of common interest, while at the same time contributing to their affordability, or where there are substantiated concerns that the procedure could result in a restriction of competition, a distortion of trade or discrimination against Member States that do not participate in the initiative, or where the involvement of the Commission cannot be justified in the light of the principles of utility, necessity and proportionality, and in this context, concerns related to the efficient use of the Commission resources. The Commission should therefore be able to refuse to conduct the procurement procedure on these grounds.*

PUBLIC

(36) ***In accordance with Article 168 of Regulation (EU, Euratom) 2024/2509, the Commission, when procuring on behalf or in the name of the Member States, is to act only within the limits of the mandate given by the participating Member States.*** To ensure transparency, legal clarity, and effective coordination, ***a*** structured agreement between the Member States and the Commission should govern procurement procedures under this Regulation that rely on an active Commission involvement. Such ***an*** agreement should set out the division of responsibilities, decision-making processes, the information to be shared as relevant to the procurement procedure, including information on Member States' participation in parallel negotiations through different channels in relation to the same medicinal products or the same active substances as appropriate, and liability provisions, ensuring a fair and efficient framework for participating Member States while preventing market distortions and supply disruptions. This Regulation is without prejudice to**,** and does not prevent the use of**,** joint procurement procedures established under Regulation (EU) 2022/2371 ▌ for those critical medicinal products and other medicinal products that also fall within the definition of medical countermeasures as set out in that Regulation. ▌ This Regulation is without prejudice to Council Regulation (EU) 2022/2372***[21]*** setting the framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

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

(37) ***In order to ensure*** a structured and coordinated approach***, as well as a coherent information exchange, to strengthen*** the security of supply of critical medicinal products***,*** collaboration ***between the Member States, as well as*** between the Member States and the Commission***, is required. To that end, the CMCG*** should be established to facilitate effective coordination across the relevant policy areas. The ***CMCG*** should be composed of ***a permanent representative with strategic*** expertise in medicinal ***products*** procurement policies, industrial policy related to pharmaceuticals and public health. ***As necessary, Member States should be able to appoint additional expert representatives to accompany the permanent Member State representative in order to support the different tasks of the CMCG.*** The Commission should be a member of the ***CMCG***. To ensure structured discussions, ***a representative of the Member States and a representative of*** the Commission should ***co-chair. The Agency should have an observer status. The representatives of relevant stakeholders, including industry and patients' representatives, could, at the discretion of the CMCG, be invited by the CMCG to meetings to provide expertise or participate as observers, where this is relevant and appropriate. The Commission should*** perform the functions of ***the*** secretariat ***of the CMCG***.

PUBLIC

(38) To ensure coordinated implementation of this Regulation, the ***CMCG*** should enable exchanges of information related to funding of strategic projects***. The CMCG*** should also facilitate the exchange of information on national programmes ***to promote best practices and, where appropriate, voluntary cooperation on Member States*** public procurement ***policies with regard to*** critical ***medicinal products. The CMCG*** should furthermore facilitate discussions on ▌ collaborative procurement ***initiatives, exchanges on guiding principles on contingency stock requirements, discussions on*** the need to prioritise the vulnerability evaluation for specific critical medicinal products ***and serve as a forum for discussion on other possible collaborative initiatives, such as reserving jointly a manufacturing capacity for critical medicinal products, their active substances or key inputs***. ***The coordination work of the CMCG should be distinct from the work of the MSSG established under Article 3 of Regulation (EU) 2022/123 and whose tasks are set out in that Regulation (EU) 2022/123 and Regulation (EU) No …/…*** [+]***. Whereas the main tasks of the MSSG are to coordinate Union-level responses to actual or potential shortages of medicinal products during public health emergencies or major events, to monitor the supply and demand of critical medicines and to provide recommendations to prevent or mitigate shortages and support the strengthening of security of supply of critical medicinal products, the focus of the CMCG should be to facilitate coordination of the measures envisaged in this Regulation creating the necessary conditions on investments and public procurement coordination and collaboration to proactively reduce dependencies and strengthen Union manufacturing capacity.***

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***

*(38a) In order to ensure the efficient use of resources and their sound management, as well as the impact of public funding to support strategic projects, it is important that Member States and the Commission establish channels for exchanging and coordinating on relevant information. The CMCG should play a central role in facilitating such exchanges between the Member States. The Commission should also provide the CMCG with information on open calls intended to support the strategic projects under Union funding instruments. Where applicable, further synergies should be ensured through increased coordination at national level between CMCG members and Member States representatives involved in the management of potentially relevant Union funding*

*(38b) The CMCG should facilitate discussions between interested Member States to explore their interest in concluding joint reservation contracts of specific manufacturing capacities. Whenever a joint reservation contract results in a necessity to increase or modernise manufacturing capacity, such initiative should be recognised as a strategic project and benefit from the advantages offered by this Regulation.*

(39) The ▌ availability and security of supply of critical medicinal products ***is to be enhanced through diversification of supply sources, including through*** access to alternative sources of supply in third countries***. Such access could be supported by existing*** international ▌ agreements***. In view of exploring the potential of mutually beneficial*** cooperation ***in the area of critical medicinal products, the Commission*** could ▌ pursue ***new*** strategic partnerships with third countries ▌, especially with candidate countries. In this context, the Commission should assess ▌ 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 ***under*** the Treaties.

(40) To ensure the application of this Regulation, it is necessary that ***market actors*** make available information ***to the competent*** authorities ▌ and the Commission***. The national competent authorities, the Commission or the Agency, as relevant,*** must therefore be able to request, when necessary and ***avoiding*** duplication of information requests, the information necessary for the application of this Regulation***. Furthermore, existing data infrastructures and databases should be fully leveraged in order to reduce reporting burdens, and improve the efficiency of data exchanges between competent authorities and stakeholders. Market actors should be able to indicate that the information has already been provided and is available to the requesting authority. Information acquired*** in the ***course of implementing this Regulation should be protected by the relevant Union and national law. An appropriate level of confidentiality of sensitive business information and data obtained should be ensured in accordance with applicable Union and national law. In particular, the staff of the Commission and the national competent authorities 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 CMCG. Any obligations on sharing information pursuant to this Regulation should not apply to data that concern the essential interests of the Member States' security or defence.***

PUBLIC

(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 ***at the latest*** five years after its application and every five years thereafter. ***That*** evaluation should include an assessment of the extent to which the objectives ***of this Regulation***, as set out in Article 1, have been achieved, including its impact on stakeholders, regulatory procedures, and market dynamics. ***The evaluation should also include an assessment of the scope, functioning and efficiency of Article 18, as well as of the coherence of the Regulation with developments within the field of public procurement.*** In particular, the Commission's evaluation should take into account the views of Member States, ***market actors***, ***contracting authorities*** and other relevant stakeholders, ensuring that their feedback contributes to the continuous improvement of the regulatory framework. The results of ***the*** 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 ***that*** evaluation, national authorities***, market actors, contracting authorities and other relevant stakeholders*** should provide relevant data and information upon request to support the Commission's assessment.

(42) Since the objectives of this Regulation***, namely to improve the functioning of the internal market by establishing*** a framework to strengthen the availability and security of supply of critical medicinal products within the Union and to improve the availability and accessibility of medicinal products of common interest through coordinated and targeted action of Member States***,*** cannot be sufficiently achieved by the Member States acting alone, but can rather, by reason of ***the*** scale ***of the action needed***, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the TFEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve ***those*** objectives.

HAVE ADOPTED THIS REGULATION:

# Chapter I

# General provisions

Article 1

Objectives and subject matter

1. The objective of this Regulation is ***to improve the functioning of the internal market by establishing a framework*** 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***,*** supporting the security of the Union ***and strategic autonomy and contributing to patients' safety***. The objective of this Regulation is also to improve the availability and accessibility of ▌ medicinal products ***of common interest*** where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the ▌ affordability of ***those*** medicinal products.

2. To achieve the objectives referred to in paragraph 1, ***this*** Regulation ***establishes*** a framework to:

   (a) facilitate***, support and incentivise*** investments in ***new*** manufacturing capacity ***and strengthen existing manufacturing capacity*** for critical medicinal products, ***as well as*** their active substances and other key inputs in the Union***, to increase the resilience of the supply chains and to facilitate their sustainable availability to the critical medicinal product producers***;

   (b) lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification***, reducing dependencies, in particular on third countries, where these put the supply of critical medicinal products at risk, and by fostering*** resilience in the public procurement procedures ▌;

PUBLIC

***(ba) address shortages and strengthen availability of critical medicinal products by facilitating coordination, transparency and solidarity among Member States with regard to contingency stocks requirements;***

(c) leverage the aggregated demand of participating Member States through collaborative procurement procedures, and

(d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.

Article 2

Scope

1. This Regulation applies***, with the exception of Article 21,*** to the critical medicinal products listed in the Union list of critical medicinal products referred to in Article ***137*** of Regulation (EU) …/… [+]. ▌

2. ***Articles 1, 21, 22 and 24, Article 26(2), point (c), and Article 26(5)*** also apply to medicinal products of common interest. ▌

***2a. Articles 1, 5 and 6, Article 8(1), point (c), Articles 12, 13 and 21, Article 22(1), point (b), Article 22(1a) to (7), Article 24, Article 26(2), point (c), and Article 26(5) of this Regulation also apply mutatis mutandis to orphan medicinal products and designated orphan medicinal products, irrespectively of whether a given product is a critical medicinal product as defined in Article 2, point (…), of Regulation (EU) …/… [+] or a medicinal product of common interest as defined in Article 3, point (5), of this Regulation, as applicable.***

---

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Regulation, including its ELI number.***

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***

Article 3

Definitions

For the ***purposes*** of this Regulation, ***relevant definitions laid down in Article 4 of Directive (EU) …/… [++] and in Article 2 of Regulation (EU) …/… [+] shall apply.*** The following definitions shall ***also*** apply:

[redacted]

(2) ‘key input’ means ***an*** input material other than an active substance required in the manufacturing process of a given medicinal product, including ***immediate*** packaging materials, excipients, solvents***,*** reagents ***and starting materials***;

[redacted]

***(3a) ‘collecting’ means collection of substances of human origin, as defined in Article 3, point (1), of Regulation (EU) 2024/1938 of the European Parliament and of the Council[22], or of substances of animal origin for the purpose of being used as a starting material for critical medicinal products;***

[redacted]

(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;

---

[++] ***OJ: please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).***

[22] ***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 (OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).***

(6) 'vulnerability in the supply chains' means risks and weaknesses within the supply chains of critical medicinal products ***as evaluated in accordance with Article 136(1), point (b), and Article 138(2), of Regulation (EU) …/…*** [+]***;***

(7) 'vulnerability evaluation' means the evaluation of the supply chains of critical medicinal products ***as carried out*** in accordance with ***Article 136 and Article 138(2) of*** Regulation (EU) …/… [+]

▌

(9) 'contracting authorities' means contracting authorities as defined in Article 2(1)**,** point (1)**,** of Directive 2014/24/EU;

(10) 'strategic project' means an industrial project ***recognised as a strategic project by a designated authority as referred to in Article 6*** pursuant to the criteria set out in Article 5;

(11) 'project promoter' means any undertaking or consortium of undertakings developing a strategic project;

(12) '***permit-granting*** process' means a process covering all relevant permits to build***, 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;

(13) 'innovative manufacturing process' means a novel manufacturing process ***or manufacturing*** technology**,** or novel application of an existing ***manufacturing*** technology, including ▌ decentralised manufacturing, continuous manufacturing, ***yield improvements or chemistry or biotechnology processes that contribute to the environmental performance of the production, and use of*** Artificial Intelligence, platform ***technologies or 3D technologies in*** manufacturing;

---

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***

***(13a) 'contingency stocks requirement' means an obligation to hold stocks of certain medicinal products, imposed by a Member State, by law, regulations or administrative provisions, on marketing authorisation holders and other economic operators in the supply chain of medicinal products to healthcare providers and patients, including stockholding obligations in public procurement procedures;***

(***14***) 'Member States' cross-border procurement' means a procurement procedure initiated ***at the request of Member States and involving*** contracting authorities from different Member States ***pursuant to*** Article 39 of Directive ***2014/24/EU***;

(15) 'procurement on behalf of or in the name of the Member States' means a procurement procedure initiated at the request of Member States and mandating the Commission to act as a central purchasing body on behalf of, or in the name of, the requesting Member States, as provided for in Article 168(3) of Regulation (EU***, Euratom***) 2024/2509 ***of the European Parliament and of the Council***;

▌

(17) 'supplier' means the manufacturer or marketing authorisation holder of finished dosage forms, or manufacturer of key inputs or active substances;

(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 ▌ critical medicinal products ***and their supply chains,*** 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***;***

***(18a) 'resilience of supply' means the ability of the supply chain to maintain a continuous and demand-oriented supply of medicinal products, active substances and key inputs in the Union, even during disruptions or external shocks.***

PUBLIC

# Chapter II

# Strengthening the Union's security of supply

Article 4

***Cooperation between Member States and the Commission***

I

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.

3. The Commission shall support the coordinated efforts of the Members States.

# Chapter III

# Enabling conditions for investment

## SECTION I

## CRITERIA AND PROCEDURE FOR THE RECOGNITION OF STRATEGIC PROJECTS

Article 5

Strategic Projects

A project located in the Union and related to creating***, modernising*** or increasing manufacturing capacity shall be ***recognised*** as a strategic project if it meets at least one of the following criteria:

(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;

PUBLIC

(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;

(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;

(d) it contributes to the roll-out ***in the Union*** 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.

Article 6

Recognition of Strategic Projects

1. Each Member State shall designate an authority ('the designated authority') that shall assess ▌ whether ***an industrial*** project meets at least one of the criteria set out in Article 5 and ***is*** therefore ***recognised as*** a strategic project.

***A Member State may designate more than one authority.***

***1a. In order for a project to be recognised as a strategic project,*** a promoter ***of an industrial project shall*** request the designated authority to assess whether ***the*** project is a strategic project. ***The request shall contain justification and relevant evidence related to the fulfilment of at least one of the criteria set out in Article 5. The designated authority shall provide its conclusion to the project promoter without undue delay and in any event no later than 20 days after the receipt of the request.***

***1b. The submission of a*** request ***for*** a project ***to be recognised as*** a strategic project ***as provided for in paragraph 1a does not preclude the promoter of the project from simultaneously initiating application procedures with other authorities for the permits needed for the project***.

2. Member States shall communicate to the Commission ▌ the designated ***authorities*** for the purposes of paragraph 1 ***of this Article and Article 16(2)***.

3. The Commission shall provide a simple, accessible***, and user-friendly*** webpage ***for project promoters*** on which ***at least the following elements*** shall be clearly listed***:***

***(a) the contact details and other relevant information on the tasks of Member States' designated authorities;***

***(b) information on dedicated Union support for strategic projects; and***

***(c) a standard template for the project promoter's request referred in paragraph 1a available in all official languages of the Union.***

***3a. The Commission shall adopt implementing acts to provide for the standard template referred to in paragraph 3, point (c), of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30a.***

4. Any other ***authority in the*** Member State ▌ that receives a request from a promoter concerning Articles 8 to 14 shall ***rely on the decision of the designated authority pursuant to paragraph 1 as to*** whether that given project ***is recognised as*** a strategic project ▌.

▌

## SECTION II

## FACILITATING ADMINISTRATIVE AND PERMIT-GRANTING PROCESSES

### Article 7

### Priority status of strategic projects

***1.*** 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.

PUBLIC

***2.*** The Member States' authorities shall ensure that the relevant ***permit-granting*** processes related to strategic projects are carried out ***without delay, in particular by*** making available ▌ any form of accelerated procedures that exists in applicable Union and national law ***while ensuring the quality and robustness of assessments***.

***2a. Member States shall take into account paragraph 1 for the purposes of identifying 'protected customers' as defined in Article 2, point (5), of Regulation 2017/1938 of the European Parliament and of the Council [23].***

Article 8

Administrative ***and technical*** support

1. Upon request of a project promoter, ▌ Member ***States' authorities*** shall provide to a strategic project located on its territory ▌ the administrative support necessary to facilitate its timely and effective implementation, including assistance ***in accordance with national law***:

   (a) with regard to ***the project promoter's*** compliance with applicable administrative and reporting obligations;

   (b) with regard to informing the public, with the aim of increasing public acceptance of the strategic project ***and, where relevant, facilitating the consultation of local communities, organisations and social partners***;

   (c) ***to the project promoter*** along the permit-granting process.

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) and not-for-profit entities*** and, where ***necessary***, establish a dedicated channel for communication with ***them*** to provide guidance and respond to queries related to the implementation of this Regulation.

---

***[23] Regulation 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010 ELI: http://data.europa.eu/eli/reg/2017/1938/oj.***

Article 9

Request for granting the status of highest national significance

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.

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.

Article 10

Procedures relating to dispute resolution

A project promoter may request that any dispute resolution procedure, litigation, appeal and proceedings on judicial remedies related to the permit-granting process and the issuance of permits for a strategic project in the Union before any national courts, tribunals or panels, including with regard to mediation or arbitration, where they exist in national law, is treated as urgent if and to the extent to which national law provides for such an urgency procedure. The applicable rights of defence of individuals or of local communities shall be respected during such urgency procedure.

The project promoter shall participate in such urgency procedures, where applicable.

Article 11

Regulatory and scientific support from ***competent authorities for medicinal products***

1. Upon request of a project promoter, a Member ***State's competent authority for medicinal products*** shall provide regulatory support to a strategic project located on its territory, ***where relevant. Such support shall include administrative support for obtaining the necessary authorisations from the competent authority.***

PUBLIC

***The Member State's competent authority shall prioritise inspections to verify compliance with*** Good Manufacturing Practices ▌ for ***the*** approval of new and extended manufacturing sites and for the ***modernisation of the*** manufacturing sites ▌ in the context of the concerned strategic project. ***Where appropriate a Member State may refer the promoter to request the dedicated advice and assistance by the European Medicines Agency ('the Agency') in accordance with paragraph 2.***

2. Upon request of a project promoter, the ▌ Agency ▌ shall provide dedicated advice to assist project promoters developing projects relying on innovative manufacturing processes. ***Where this advice includes aspects related to Good Manufacturing Practices, the Agency shall involve the relevant national competent authority for medicinal products in the provision of this advice.***

PUBLIC

Article 12

Environmental assessments and authorisation

1. 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[24], Directive 2000/60/EC of the European Parliament and of the Council[25], Directive 2001/42/EC of the European Parliament and of the Council[26], Directive 2008/98/EC of the European Parliament and of the Council[27], Directive 2009/147/EC of the European Parliament and of the Council[28], Directive 2010/75/EU of the European Parliament and of the Council[29], Directive 2011/92/EU of the European Parliament and of the Council[30] or Directive 2012/18/EU of the European Parliament and of the Council[31], 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.***

---

*24* 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).

*25* 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).

*26* 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).

*27* 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).

*28* 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).

*29* 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).

*30* 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).

*31* 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).

Under the coordinated procedure referred to in the first subparagraph, a competent authority shall coordinate the various individual assessments of the environmental impact of a particular project required by the relevant Directive.

Under the joint procedure referred to in the first subparagraph, a competent authority shall provide for a single assessment of the environmental impact of a particular project required by the relevant Directive.

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 ***60*** days of receiving all necessary information.

3. In exceptional cases, where the nature, complexity, location or size of the proposed project so requires, Member States may extend the time limit referred to in paragraph 2 once by a maximum of 15 days, before its expiry and on a case-by-case basis. In that event, the competent authority shall inform the project promoter in writing of the reasons justifying the extension and of the deadline for its reasoned conclusion.

4. The deadlines for consulting the public concerned as referred to in Article 1(2), point (e), of Directive 2011/92/EU and the authorities referred to in Article 6(1) of that Directive on the environmental impact assessment report referred to in Article 5(1) of that Directive shall not be longer than 85 days and not shorter than the 30 day period referred to in Article 6(7) of that Directive.

5. With regard to the environmental impacts or obligations referred to in Article 4(7) of Directive 2000/60/EC, Article 9(1), point (a), of Directive 2009/147/EC ***and*** Articles 6(4) and 16(1) of Directive 92/43/EEC**,** and for the purposes of Article 4(14) and (15) and Article 5(11) and (12) of Regulation (EU) 2024/1991**,** strategic projects in the Union may be considered to have an overriding public interest and to serve the interests of public health and safety provided that all the conditions set out in those acts are fulfilled.

PUBLIC

Article 13

Planning

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 ***are*** available ***and accessible***.

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[32], 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.***

---

***32*** Directive 2014/89/EU of the European Parliament and of the Council of 23 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).

Article 14

Applicability of UNECE Conventions

1. This Regulation is without prejudice to the obligations under the United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, signed at Aarhus on 25 June 1998, and under the UNECE Convention on environmental impact assessment in a transboundary context, signed at Espoo on 25 February 1991 and its Protocol on Strategic Environmental Assessment, signed in Kyiv on 21 May 2003.

2. All decisions adopted pursuant to the Articles in this Section***, to which the obligations under the UNECE Convention apply,*** shall be made publicly available.

## SECTION III

## FINANCIAL INCENTIVES

Article 15

Financial support by Member States

1. Without prejudice to Articles 107 and 108 ***of the Treaty on the Functioning of the European Union (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 ***Coordination*** Group ***('CMCG')*** referred to in Article 26(2)**,** point (a).

***1a. 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.***

PUBLIC

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 ▌ the Union market ▌ to ensure***, within the limits of its responsibilities, appropriate and continued supply so that the needs of patients are covered and*** the critical medicinal product remains available in the Member States ***on whose market it has been made available.***

Where ***appropriate, the terms of the financial support shall stipulate for how long the obligation to prioritise the Union market shall continue to apply in case the critical medicinal product is removed from the Union list of critical medicinal products***.

3. The Member State that provided financial support to a strategic project may ***require the beneficiary*** undertaking to ***prioritise supply and*** 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 ***more*** Member States.

Any ***other*** 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. ***The beneficiary undertaking shall make best efforts to supply such products in the requesting Member State.***

Article 16

Financial support from the Union

1. ***Financial support for strategic projects under*** the Multiannual Financial Framework 2021-2027[33] may be ***provided by the*** Union ***from Union programmes***, including***,*** but not limited to***,*** the EU4Health Programme ***established by Regulation (EU) 2021/522***, Horizon Europe ***established by Regulation (EU) 2021/695***, and the Digital Europe Programme ***established by Regulation (EU) 2021/694,*** provided that such ***financial*** support is in line with the objectives set out in the ***respective*** regulations establishing those programmes.

---

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

***1a. Where a project promoter receives financial support for a strategic project from a Union financial instrument which provides that funding may be made available under the condition of strengthening the availability of critical medicinal products consistent with the objectives of this Regulation, it shall prioritise supply to the Union market and shall ensure, within the limits of its responsibilities, that the critical medicinal product remains available in the Member States in whose market it has been made available.***

2. ***Where the strategic project relates to critical medicinal products for which the vulnerability evaluation has been concluded,*** at the request of a project promoter, justified by ***the*** necessity to ***demonstrate that a strategic project addresses a*** vulnerability ***in the supply chains as necessary*** for the purpose of an application ***of*** Union funding, the designated authority shall ***verify*** whether a strategic project addresses a vulnerability in the supply chains identified following the vulnerability evaluation. The designated authority shall provide ***the verification to the*** project promoter within 15 working days of ***receiving the*** request. The designated authority shall inform the Commission about the strategic projects identified as addressing an existing vulnerability in the supply chains without delay.

***Where the designated authority considers that the submitted particulars and documents accompanying the request referred to in the first subparagraph are incomplete, it shall inform the project promoter accordingly and shall set a time-limit for providing the missing information and documents. In case the designated authority sets such a time-limit, the time-limit referred to in the first subparagraph shall be suspended until the missing information and documents required have been provided.***

***2a. A financial allocation may also be made available from the general budget of the Union.***

PUBLIC

Article 17

Exchange of information on ***financial support for strategic*** projects

1. Member States shall***, without prejudice to their right to decide whether*** to provide financial support to strategic projects***, inform the CMCG, referred to in Article 25, of the intention to provide such financial support*** sufficiently in advance to ***enable the CMCG*** to carry out its coordination task as set out in Article ***26***.

2. The Commission ***and Member States*** shall ***regularly*** inform ***the CMCG*** of the strategic projects ***receiving*** financial support from the Union ***and Member States respectively to enable the CMCG to carry out its coordination task***.

***2a. When informing the Critical Medicines Group pursuant to paragraphs 1 and 2, Member States shall include information on how the strategic projects concerned meet one or more of the criteria listed in Article 5.***

***3.*** The Commission ***shall inform the CMCG about all open calls to support strategic projects. It*** may inform the ***CMCG of its*** intention to propose the establishment of funding possibilities ***and*** any other ***Union funding*** programmes that ***could*** benefit the availability of critical medicinal products, under specific rules and conditions of ***those*** Union funding programmes.

PUBLIC

# Chapter IV

# Demand side measures

## SECTION I

## *REQUIREMENTS FOR PUBLIC* PROCUREMENT *PROCEDURES* AND RELATED MEASURES

Article 18

Incentivising resilience, sustainability and positive social impacts in public procurement procedures

1. For ***public procurement*** procedures of critical medicinal products falling within the scope of Directive 2014/24/EU ▌, contracting authorities ▌ shall apply ▌ requirements that ***effectively*** promote the resilience of supply in the Union ***for*** those ***critical medicinal products ('resilience requirements').***

   ***The resilience*** requirements shall ***support the diversification of supply sources of active substances and, where applicable, medicinal products, including within the Union, and reward reliable and compliant suppliers. In addition, the resilience requirements may, inter alia,*** relate to stockholding ▌, ▌ timely delivery ***and management of the supply chains***.

   ***The resilience requirements shall be implemented by at least one of the following:***

   ***(a) selection criteria within the meaning of Article 58 of Directive 2014/24/EU; or***

   ***(b) technical specifications within the meaning of Article 42 of Directive 2014/24/EU; or***

   ***(c) best price-quality ratio as contract award criteria within the meaning of Article 67 of Directive 2014/24/EU; or***

   ***(d) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU.***

PUBLIC

2. ***For public procurement procedures of*** critical medicinal products for which a vulnerability in the supply chains has been ***identified*** 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 ▌ favour ***manufacturing of such*** medicinal products in the Union. ▌

***To favour manufacturing of critical medicinal products in accordance with the first subparagraph, the contracting authorities shall apply at least one of the following mechanisms:***

***(a) use technical specifications within the meaning of Article 42 of Directive 2014/24/EU requiring that at least one lot representing at least 50 % percent of the total volume covered by all lots is reserved for the suppliers offering the critical medicinal product and its active substance manufactured in the Union when applying multi-winner approaches in procurement procedures; or***

***(b) apply the best price-quality ratio as award criterion within the meaning of Article 67 of Directive 2014/24/EU and favour suppliers of critical medicinal products and their active substances manufactured in the Union by applying a scoring that proportionately rewards the share of manufacturing in the Union and by applying a weighting that effectively achieves this objective. In this context, the contracting authority may allocate additional points to the manufacturer who offers 50% or more of the critical medicinal products and their active substances manufactured in the Union.***

***The procurement requirements shall be applied in compliance with the Union's international commitments.***

***For the purpose of applying this paragraph, manufacturing in the Union shall include manufacturing steps that are carried out within the Union other than import, repackaging, packaging other than immediate packaging, labelling, quality testing and, where applicable, certification.***

PUBLIC

***Evidence supporting the claim in tenders that the manufacturing is taking place in the Union shall be provided where required by the tenderers, and supported by documents facilitating the independent verification by the contracting authority.***

***2a. The procurement requirements referred to in paragraph 2 shall apply for as long as the medicinal product remains on the Union list of critical medicinal products and is designated as vulnerable due to the high level dependency and for a minimum period of 5 years from the date of entry into force of the last implementing act by which the medicinal product in question is specified by the Commission as being vulnerable due to the high level of dependency in accordance with Article 137(3) of Regulation (EU) …/…[+].***

3. ***For the purposes of paragraphs 1 and 2***, the contracting authorities ▌ shall ***consider, where appropriate, multi-winner approaches***.

4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including ***requirements related*** to environmental sustainability and social rights.

5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2***, 2a*** and 3 where ***it is duly*** justified by market ***circumstances*** or considerations related to the financing of health services***, where:***

   ***(a) the required critical medicinal product can only be supplied by a specific economic operator as defined in Article 2(1), point (10), of Directive 2014/24/EU and no reasonable alternative or substitute exists, and the absence of competition is not the result of an artificial narrowing down of the parameters of the public procurement procedure;***

---

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***

***(b) no suitable tenders or no suitable requests to participate have been submitted in response to a similar public procurement procedure launched by the same contracting authority in the two years prior to the commencement of the planned new procurement procedure;***

***(c) the application of paragraphs 1, 2, 2a and 3 would oblige the contracting authority to acquire critical medicinal products having disproportionate costs; or***

***(d) in the context of a negotiated procedure without prior publication pursuant to Article 32(2), point (c), of Directive 2014/24/EU.***

***5a. The justification for the exceptions referred to in paragraph 5 specifying the relevant circumstances or considerations shall be documented in writing by the contracting authority and be subject to verification and redress where relevant.***

***6. By ... [12 months from the date of entry into force of this Regulation], the Commission shall issue guidelines designed to support Member States in implementing the obligations of this Article and to facilitate the compliance with those obligations by contracting authorities.***

Article 19

***National*** programmes supporting ▌ resilience in public procurement procedures

1. By ***... [12*** months ***from the date of*** entry into force of this Regulation***],*** each Member State shall***, with due respect to the organisation of the procurement of medicinal products within the Member State,*** 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. ***Member States may involve their national pricing and reimbursement authorities in the planning and evaluation of such programmes.***

PUBLIC

2. Member States shall ***inform*** the Commission in its role of the secretariat of the ***CMCG about their programmes***. The Commission shall ensure the distribution to all members of the ***CMCG*** forthwith. The ***CMCG*** shall facilitate a discussion***,*** aiming to ensure coordination of national programmes including as regards the application of ***the procurement requirements referred to*** in Article 18(2) and may issue opinions. Where the ***CMCG*** issues an opinion concerning the national programmes, Member States ▌ may take it into account when revising their programmes.

Article 20

Safeguards related to Member States' contingency ***stock*** requirements and other security of supply measures

***1.*** ***Contingency stock requirements*** applied in one Member State shall not result in any negative impact in other Member States ***by respecting the principles referred to in paragraph 2 of this Article.***

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.

***2.*** Member States shall ensure that any ***contingency stock*** requirements***, including the implementation timeline,*** they impose on ***economic operators*** in the supply chain***, are targeted*** and respect the principles of ***proportionality,*** transparency and solidarity.

***2a. This Article is without prejudice to obligations under Union law for the notification of technical regulations and technical barriers to the internal market, including those laid down in Directive (EU) 2015/1535.***

***2b. All contingency stock requirements and other security of supply measures shall be implemented in a way that aims to minimise waste of medicinal products through effective stock rotation based on the 'first expired, first out' system to prevent the destruction of medicinal products.***

PUBLIC

*2c. The Commission shall, following a consultation with relevant stakeholders, including patient and consumer organisations, healthcare professional organisations, public healthcare payers, and industry representatives, issue Union guidelines for contingency stocks. Those guidelines may include:*

*(a) best practices, reviewed regularly, for the setting of contingency stocks;*

*(b) recommended strategies for timely deployment of contingency stocks, including labelling and packaging arrangements;*

*(c) best practices on sustainable contingency stock management and disposal of medicinal products.*

*Article 20a*

*Information sharing and reporting on contingency stock requirements*

*1. Member States shall, without prejudice to their right to decide to impose contingency stock requirements, inform the CMCG of their intention to impose such requirements or make significant changes to such existing requirements, and inform of any such requirements once imposed or of any such changes once made, for the purpose of transparency and to enable exchanges on the guiding principles of proportionality and solidarity referred to in Article 20(2).*

*2. This Article is without prejudice to obligations under Union law for the notification of technical regulations and technical barriers to the internal market, including those laid down in Directive (EU) 2015/1535.*

*3. The Agency shall establish and maintain a digital platform which provides an overview of contingency stock requirements imposed by national law including which critical medicinal products are covered and the size of required stocks.*

PUBLIC

*4. Where The European Voluntary Solidarity Mechanism for medicinal products is activated in accordance with Article 131 of Regulation (EU) …/… [+], Member States shall, where reasonably possible within their national monitoring systems, upon request from the MSSG, provide up-to-date stock data relating to critical medicinal products subject to contingency stock requirements, which a Member State identifies as available for reallocation.*

*5. Where the activation of the Voluntary Solidarity Mechanism for medicinal products has not resulted in a suitable option to address that request, the MSSG may, at the request of the Member State that activated that Mechanism, issue a recommendation to Member States with the aim of facilitating contributions by marketing authorisation holders to that Mechanism.*

*Such recommendation may, where appropriate, invite Member States to consider suspending or adapting contingency stock requirements and related enforcement measures, in order to enable the supply of the concerned critical medicinal product to Member States facing a shortage and ensuring an optimal allocation of critical medicinal products between the Member States.*

*6. Article 29a(4) shall apply to any information sharing and reporting under this Article.*

---

[+] *OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Regulation, including its ELI number.*

## SECTION II

## *VOLUNTARY* COLLABORATIVE PROCUREMENTS

Article 21

Commission facilitated Member States' cross-border procurement

1. Upon a reasoned request ***from*** 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 ***2014/24/EU[34] where the procurement concerns*** medicinal products of common interest.

2. Having received the request, the Commission shall inform all other Member States of the ***request, through the CMCG,*** and set ▌ a deadline ***of 4*** weeks ***for Member States to declare their interest in participating in the procedure***.

3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall ***inform*** the interested Member States ***of*** its decision on whether it agrees ▌ to facilitate the proposed ***request*** within ***15 working days following expiry of the deadline specified in paragraph 2***.

4. ***Where*** the Commission declines the request, it shall ***state its*** reasons for the refusal.

5. ***Where*** the Commission accepts the request, the Commission shall provide secretarial and logistical support to the ***participating*** Member States. The Commission shall facilitate communication and cooperation between the ▌ Member States and provide advice on applicable Union public procurement rules***, including on the use of procurement requirements as set out in Article 18*** and on regulatory matters related to medicinal products.

---

***34*** 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 ).3

6. The facilitation offered by the Commission shall be limited in time and ***shall*** end at the latest upon signature of the procurement contract by the participating contracting authorities. ***Member States participating in the cross-border procurement shall procure at their cost only.***

7. The Commission shall not be responsible, nor held liable, for any breaches of Union or national procurement laws by the participating contracting authorities. The Commission shall ***bear no*** liability associated with the conduct of the procurement procedure by ***participating*** Member States ***or for the*** implementation of the contract resulting from the procedure.

***7a. Member States may specify that they wish to conduct the cross-border procurement as referred to in paragraph 1 with those candidate countries that choose to participate in the procedures established herein and with which the Union has entered into a bilateral agreement thereof, 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.***

Article 22

Commission procurement on behalf of or in the name of Member States

1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509***,*** where ***five*** or more Member States jointly request the Commission to procure on their behalf ▌ or in their name ***and at their costs (`the joint request`)***, the Commission ***shall, unless it provides substantiated reasons not to*** initiate ***the*** procurement ***procedure, initiate such a*** procedure under the conditions ***laid down*** in this Article when the procurement ***concerns*** medicinal products belonging to one of the following categories***:***

   (a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;

(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation ***2021/2282/EU*** [18], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States ***pursuant to*** Article 23(1)**,** point (e)**,** of that Regulation.

***1a. The Commission may, on its own initiative, invite Member States to submit a joint request in accordance with paragraph 1.***

2. The joint request referred to in paragraph 1 shall only be ***submitted*** where the medicinal product concerned fulfils one of the criteria ***laid down*** in that paragraph and ***where*** the requested procurement procedure ***is expected*** to improve the security of supply and availability of critical medicinal products in the Union or ***to*** ensure the availability and accessibility ***and contribute to affordability*** of medicinal products of common interest, as applicable.

3. The participation in the procurement procedure shall be open to all Member States. ***Having received the joint request,*** the Commission shall inform all ***other*** Member States of the ***joint*** request, through the ***CMCG, and set a deadline of four weeks for Member States to express their interest in participating in*** the procedure.

4. The Commission shall assess ▌ whether the ***joint*** request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could ***result in*** discrimination or restriction ***on*** trade or a distortion ***of*** competition ***taking into account the utility, necessity and proportionality of the joint request***.

5. ***Within 15 working days following expiry of the deadline in paragraph 3,*** the Commission shall ***communicate to*** the interested Member States ▌ its decision and state its reasons in case of a refusal.

PUBLIC

***5a. The procurement procedures under this Article shall apply, where relevant, resilience requirements equivalent to those set out in Article 18. Those requirements shall be specified in accordance with Regulation (EU, Euratom) 2024/2509 and specified in the mandate given by the participating Member States to the Commission within the meaning of Article 168(3) of that Regulation.***

6. ***The initiation of the procurement procedure by*** the Commission ***shall be conditional upon the interested Member States accepting binding minimum quantities, in accordance with their national need, and may be conditional, if*** necessary ▌ in order to achieve the objectives of this Regulation, ***upon the interested*** Member States ***refraining from participating in competing subsequent procurement processes. Such a procurement*** procedure may ***only be initiated once*** these conditions ***have been accepted by the*** interested Member States.

7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article ***168(3)*** of Regulation (EU, Euratom) 2024/2509[35].

▌

Article 24

Agreement concerning procedures under ***Article 22***

1. Member States participating in the procurement procedures ***under Article 22*** shall share with the Commission any information relevant for the procurement procedure. ***The participating*** Member States shall provide ***the*** resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge.

---

[35] ***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 (recast) (OJ L, 26.9.2024, p. 1, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).***

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. ***The procedure shall be carried out in accordance with the mandate given by the Member States to the Commission as required by Article 168(3) of Regulation (EU, Euratom) 2024/2509.***

# Chapter V
# Critical Medicines Coordination Group

Article 25

Establishment of Critical Medicines Coordination Group

1. A Critical Medicines Coordination Group (‘***CMCG***’) is hereby established.

2. The Member States and the Commission are Members of the ***CMCG***. Each Member State shall appoint ***one*** permanent ***representative, with strategic*** expertise relevant for implementing ▌ the different measures set out in this Regulation. ***As necessary***, Member States may appoint ***an alternate permanent representative and additional expert*** representatives ***to accompany the permanent Member State representative in order to support the*** different tasks of the ***CMCG***. The Agency shall have an observer status.

***The representatives of relevant stakeholders, including industry and patients' representatives, may, at the discretion of the CMCG, be invited to meetings to provide expertise or participate as observers, where this is relevant and appropriate.***

***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.***

PUBLIC

3. The ***CMCG*** shall work closely with the MSSG, the Agency ▌ and national ***competent*** authorities ▌ for medicinal products. For discussions where input from ***national*** regulatory authorities ***responsible for medicinal products*** is necessary, the ***CMCG and the MSSG*** may organise joint meetings***. To fulfil its tasks, the CMCG shall, where relevant, also consult through joint meetings with patient and consumer organisations, healthcare professional organisations and industry representatives***.

4. The Commission***, acting as the Secretariat of the CMCG,*** shall organise ***regular meetings*** and coordinate the work of the ***CMCG. The CMCG shall establish its rules of procedure, including procedures relating to the working*** group ***referred to in paragraph 6***.

5. ***The CMCG shall be co-chaired by*** a representative of the Commission ***and by a representative*** of the ***Member States, who shall be elected by and from among the representatives of the Member States***.

6. The ***CMCG***, at the proposal of the ***co-chair*** or any ***of*** its members, may***, on a case-by-case basis,*** decide to establish ***one or more*** working ***groups***.

7. The ***CMCG*** shall use its best endeavours to reach consensus, where possible***, when providing advice as referred to in Article 26(1), when providing recommendations as referred to in Article 26(2), point (d), and when providing an opinion as referred to in Article 26(5). If such consensus cannot be reached, the CMCG shall issue its position by a majority of two-thirds of its members. Each Member State shall have one vote***. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the ***CMCG***'s position.

PUBLIC

Article 26

Tasks of the Critical Medicines Coordination Group

1. The ***CMCG*** shall facilitate coordination in the implementation of this Regulation***, including***, where appropriate, ***by providing advice to*** the Commission ***or Member States at their request***, 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***.

2. In order to attain the objectives referred to in paragraph 1, the ***CMCG*** shall perform the following tasks:

   (a) facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information***, where available,*** on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States***,*** and facilitate discussion on the capacity needed in the Union to strengthen its supply security and availability of critical medicinal products***, their active substances and key inputs*** within the Union;

   ***(aa) enable the exchanges of information between the Member States and the Commission as referred to in Article 17 and, where necessary, facilitate coordination of respective actions aiming to attain the objectives of this Regulation;***

   (b) facilitate exchanges on the national programmes referred to in Article 19***, promote best practices*** and enable cooperation on***,*** and coordination of***,*** Member States public procurement policies with regard to critical medicinal products;

   ***(ba) facilitate exchanges of information on contingency stock requirements as referred to in Article 20a(1);***

   (c) facilitate discussion ***on*** collaborative procurement ***initiatives***;

PUBLIC

(d) ***provide recommendations to*** the MSSG ***on*** the order of priority of critical medicinal products for vulnerability evaluation ***as set out in Regulation (EU) …/…*** [+], and propose a review or an update of existing evaluations where necessary***;***

***(da) regularly*** discuss the potential contribution of strategic partnerships to the objectives of this Regulation ▌ and the consistency and potential synergies between Member States' cooperation with relevant third countries and the actions carried out by the Union***;***

***(db) facilitate exchanges among Member States in order to explore interest in joint reservation contracts;***

***(dc) enable strategic foresight discussions among Member States and stakeholders taking into account long-term trends, vulnerabilities, opportunities for enhancing the resilience and sustainability of supply chains of critical medicines within the Union.***

5. The ***CMCG***, at the Commission'***s or Member State'***s request, may provide an opinion on matters related to the application of this Regulation in the context of performing tasks as referred to in this Article.

---

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Regulation, including its ELI number.***

# Chapter VI
# International cooperation

Article 27

Strategic partnerships

Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to ***support the diversification of sources of supply*** of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. ***Such potential strategic partnerships may take the form of dialogues on industrial, regulatory and policy matters, arrangements for stakeholders' meetings or for experts' exchanges.***

The Commission shall also explore the possibility of building on existing forms of cooperation, ***such as free trade agreements or association agreements, and in particular with candidate countries where*** possible ***and appropriate***, ***in order*** to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union ***or diversification of the supply sources***. ***The Commission shall regularly inform the CMCG about their ongoing considerations and assessments.***

PUBLIC

# Chapter VII

# Amendments to Regulation (EU) 2024/795

Article 28

Regulation (EU) 2024/795 is amended as follows:

(a) in Article ***2(1)***, point (a)▌(iii)***,*** is replaced by the following:

'(iii) biotechnologies, and any other technologies relevant for manufacturing of critical medicinal products as defined in ***Article 2, point (...), of Regulation (EU) .../…***[+]*;

_____

* Regulation (EU) ***…/***… of the European Parliament and of the Council laying down ***Union procedures for the authorisation and supervision of*** medicinal products ***for human use and establishing rules governing the European Medicines Agency***,▌amending ***Regulations (EC) No 1394/2007 and*** Regulation (EU) ***No 536/2014 and repealing Regulations (EC) No 141/2000 , (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.'***

(b) in Article 2, the following subparagraph is added in paragraph 3:

'By way of derogation from the first subparagraph of this paragraph, the value chain for the development or manufacturing of medicinal products that fall within the scope of the [Critical Medicines Act] and that are referred to in paragraph 1, point (a)(iii)***,*** of this Article,▌relates to finished dosage forms, as well as to active pharmaceutical ingredients and other key inputs necessary for the production of the finished dosage forms of critical medicinal products as defined in ***that*** Regulation.;'

---

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***



PUBLIC

(c) in Article 2, paragraph 8 is added:

‘8. Strategic projects designated in accordance with the [Critical Medicines Act] that address a vulnerability in the supply chains of critical medicinal products shall be deemed to contribute to the STEP objective referred to in paragraph 1, point (a)(iii).;’

(d) in Article 4, paragraph 7 is replaced by the following:

‘7. Strategic projects recognised in accordance with the relevant provisions of the Net-Zero Industry Act, the Critical Raw Materials Act [and the Critical Medicines Act] that fall within the scope of Article 2 of this Regulation and that receive a contribution under the programmes referred to in Article 3 of this Regulation may also receive a contribution from any other Union programme, including funds under shared management, provided that those contributions do not cover the same costs. The rules of the relevant Union programme shall apply to the corresponding contribution to the strategic project. The cumulative funding shall not exceed the total eligible costs of the strategic project. The support from the different Union programmes may be calculated on a pro rata basis in accordance with the documents setting out the conditions for support.;’

(e) in Article 6, paragraph 1, point c is replaced by the following:

‘(c) details of projects that have been ***recognised*** as strategic projects under the Net-Zero Industry Act, the Critical Raw Materials Act and the [Critical Medicines Act], to the extent that they fall within the scope of Article 2 of this Regulation.’

PUBLIC

# Chapter VIII
# Final provisions

Article 29

Obligation of the market actors to provide information

1. ***For the purposes of Articles 6 and 8, Article 11(1), Articles 12 and 15, Article 16(2) and Article 26(2), point (a), the national competent authorities concerned may request information from promoters of industrial projects, project promoters,*** marketing authorisation holders and other ***actors*** in the supply and distribution chains of critical medicinal products***,*** their ▌ active substances or ***key inputs, including from importers and manufacturers of medicinal products, active substances or key inputs and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other natural or legal persons or legal entities that are authorised or otherwise entitled to supply*** medicinal products ***to the public.***

***For the purposes of Article 30, the national competent authorities and*** the Commission ***may request*** information ***from the market actors referred to in paragraph 1, contracting authorities and other stakeholders.***

For the ***purposes of Article 11(2), the Agency may request information from project promoters, marketing authorisation holders, manufacturers of medicinal products and manufacturers or suppliers of active substances or key inputs***.

2. ***Where information is requested by*** national ***competent*** authorities ***or the Agency, as relevant, pursuant to paragraph 1, an actor may indicate that*** the information requested ***has already been provided to the national competent authority concerned or the Agency pursuant to other relevant Union legal acts. In such cases, the national competent authority concerned or the Agency shall take due account of the information already provided in so far as this information has been provided and may be used also for the purposes of this Regulation***.

PUBLIC

3. ***Where a market actor submits information pursuant to paragraph 1, that actor shall indicate whether the information provided contains any commercially confidential information, identify the relevant parts of that information having a commercially confidential nature and explain why that information is of such nature.*** The Commission***, the*** national ***competent authority or the Agency, as relevant,*** shall assess the merits of ***each*** confidentiality ***claim*** made by ***the actors*** and shall protect any information that is commercially confidential against unjustified disclosure ***in accordance with Article 29a***.

***Article 29a***

***Handling of confidential information***

***1. Information acquired in the course of implementing this Regulation shall be protected by the relevant Union and national law.***

***2. Member States, the Commission and the Agency shall ensure the protection of trade and business secrets and other commercially confidential information obtained and processed in application of this Regulation, in accordance with relevant Union and national law.***

***3. The Commission, the Agency and the national competent authorities, their officials, employees and other persons working under the supervision of those authorities shall ensure, in accordance with relevant Union or national law, the confidentiality of information obtained while carrying out their tasks and activities pursuant to this Regulation. This obligation also applies to all representatives of Member States, observers, experts and other participants attending meetings of the CMCG pursuant to Article 25.***

***4. A Member State may refuse to share information where it concerns the essential interests of its security and defence.***

PUBLIC

Article 30

Evaluation

1. By **… /**five years ***from*** the date of application of this Regulation**/** and every five years thereafter, the Commission shall evaluate this Regulation***, including its impact on the security of supply of medicinal products and the use of collaborative procurement and submit*** a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.

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 include an assessment of the scope, functioning and efficiency of Article 18, as well as of the coherence of this Regulation with the developments in the field of public procurement.***

3. The national authorities and ***other actors*** shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to ***paragraphs 1 and 2***.

***3a. The report referred to in paragraph 1 shall, where appropriate, be accompanied by legislative proposals.***

***Article 30a***

***Committee Procedure***

***1. The Commission shall be assisted by a committee. 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.***

PUBLIC

Article 31

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ***the date of the first publication in the Official Journal of the Union list of critical medicinal products established in accordance with Article 137 of Regulation (EU) …/…***[+]. ***The requirements in Article 18(1) and (2) shall apply to public procurement procedures launched after that date.***

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

| | |
|---|---|
| *For the European Parliament* | *For the Council* |
| *The President* | *The President* |

[+] ***OJ: please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).***