Council of the European Union

Brussels, 26 November 2026
(OR. en)

15754/26

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

**SAN 791**
**PHARM 202**
**MI 1171**
**MAP 208**
**POLCOM 414**
**IND 687**
**COMPET 1346**
**CODEC 2144**
**PE 133**

**INFORMATION NOTE**

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| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee/Council |
| Subject: | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795<br>- Outcome of the European Parliament's first reading<br>(Strasbourg, 23 to 26 November 2026) |

## I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the Joint declaration on practical arrangements for the codecision procedure[1], a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this proposal at first reading.

[1] OJ C 145, 30.6.2007, p. 5.

In this context, the Chair of the Committee on Public Health (SANT), Adam JARUBAS (EPP, PL) presented on behalf of SANT a compromise amendment (amendment number 261) to the abovementioned proposal for a Regulation, for which the rapporteur Tomislav SOKOL (EPP, HR) had prepared a draft report.

This amendment had been agreed during the informal contacts referred to above.

In addition, the Europe of Sovereign Nations group (ESN) tabled one amendment (amendment number 262).

## II. VOTE

When it voted on 25 November 2026, the plenary adopted the compromise amendment (amendment number 261) to the abovementioned proposal for a Regulation. No other amendments were adopted. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto[2].

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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[2] The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics.*** The symbol " ▌ " indicates deleted text.

**ANNEX**
**(25.11.2026)**

**P10_TA(2026)0395**

# 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

**European Parliament legislative resolution of 25 November 2026 on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (COM(2025)0102 – C10-0048/2025 – 2025/0102(COD))**

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

*The European Parliament*,

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

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

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

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

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

– having regard to the provisional agreement approved by the responsible committee under Rule 75(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 30 June 2026 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

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

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

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

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

1. Adopts its position at first reading hereinafter set out[2];

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

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

[2] This position replaces the amendments adopted on 20 January 2026 (Texts adopted, P10_TA(2026)0001).

**P10_TC1-COD(2025)0102**

**Position of the European Parliament adopted at first reading on 25 November 2026 with a view to the adoption of Regulation (EU) 2026/… of the European Parliament and of the Council *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[5],

Acting in accordance with the ordinary legislative procedure[6],

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

[6] Position of the European Parliament of 25 November 2026.

Whereas:

(1) ***The 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 that 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 establish a common Union framework to collectively address 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, shortages of older antibiotics, whose unavailability results in the necessity to use substitutes, can contribute to an increase in antimicrobial resistance. A stable and resilient supply of critical medicinal products is therefore essential to the health of patients in the Union and the proper functioning of health systems.***

(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 supply chains for 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 materials and raw materials***. Those vulnerabilities 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***. ***In the case of blood-derived and plasma-derived medicinal products, the vulnerabilities can also result from limited collection capacity and unavailability of donors.*** By diversifying supply sources and investing in local manufacturing, the Union can reduce its risk of exposure to shortages of medicinal products.

(4) Industrial challenges and a lack of investment in manufacturing capacity 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.*** Creating new ***manufacturing capacity in the Union, or expanding*** or modernising existing manufacturing capacity ***in the Union, for critical medicinal products***, ***and their active substances and key inputs,*** ▌ 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, in particular in view of lower energy costs, ***and fewer*** environmental requirements 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 capacity in the Union and strengthen the supply chains for critical ***medicinal products***.

***(5) While shortages of medicinal products can occur for any type of medicinal product, they often affect off-patent medicinal products and generic medicinal products, partly due to their low profit margins, which reduce incentives for investment in robust manufacturing capacity. Such medicinal products make up the majority of the medicinal products on the Union list of critical medicinal products established by Regulation (EU) 2026/... of the European Parliament and of the Council[7+]. Many suppliers of off-patent medicinal products and generic medicinal products 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 suppliers of active substances, many located outside its borders.***

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7 Regulation (EU) 2026/… 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 L …, …, ELI: …).

\+ OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Regulation, including its ELI number.

(6) To enhance the security of supply of 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[8] has reinforced the role of the European Medicines Agency (the 'Agency') 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 'Medicine Shortages Steering Group' or 'MSSG'), which brings together representatives from the Agency and Member States to coordinate urgent actions within the Union in relation to the management of existing shortages and issues related to the quality, safety ▌ and efficacy of medicinal products.

[8] 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, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).

(7) In addition, Regulation (EU) 2026/… [+] further strengthens the continuity of supply and availability of medicinal products***, inter alia by*** developing the core tasks already assigned to the Agency under Regulation (EU) 2022/123 and providing 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 a coordinated manner to support the management of shortages and security of supply of medicinal products, including by strengthening the obligations of marketing authorisation holders ***with regard to*** shortage prevention and ***shortage*** reporting ***and by establishing a Voluntary Solidarity Mechanism for medicinal products (the 'Voluntary Solidarity Mechanism') that allows a Member State affected by a critical shortage of a medicinal product to request supplies from other Member States***.

(8) However, despite regulatory obligations on marketing authorisation holders to ensure continuity of supply of medicinal products to meet patients' ***needs*** and the additional regulatory mechanisms introduced by ***Regulations*** (EU) 2022/123 and (EU) 2026/… [+] to mitigate and respond to shortages, the functioning of ***the market*** alone does not always guarantee the availability of medicinal products. That 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 or manufacturing facilities or where there is a high level of dependency on a single third country or a limited number of third countries.

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

(9) As the market for medicinal products remains fragmented in the Union, there is a need for better coordination between Member States to fully leverage the Union's potential to strengthen the security of supply of ***critical*** medicinal ***products and facilitate accessibility to other*** medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. Uncoordinated national measures risk disrupting the internal market, fail to address broader supply chain issues and are insufficient to resolve cross-border issues, including the Union's dependency on a single third country or a limited number of third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions contributing to further harmonisation.

(10) 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 to those medicinal products 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 the product demand market size or the geographical demand market size, which can impact the timely ***accessibility and*** availability of medicinal products in certain Member States. ***This Regulation aims to contribute 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.***

***(11) 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, such medicinal products should qualify for such procurement procedures even where they are not considered medicinal products of common interest. To encourage early accessibility and availability of orphan medicinal products in the Union, certain advantages in the permit-granting process should be also granted to their developers and manufacturers.***

(12) The smooth functioning of the internal market and a high level of human health protection should be ensured as regards medicinal products***. This Regulation aims*** to ***complement*** the Union general pharmaceutical legislation by providing for a harmonised framework that supports Member States' coordinated efforts to encourage investment in new and existing manufacturing capacity for critical medicinal products, to encourage the strategic use of public procurement instruments by the Member States, as well as to leverage aggregated demand through Commission-facilitated collaborative procurement procedures of critical medicinal products and medicinal products of common interest***. This framework also aims to improve 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 the diversification of supply chains and an overall increase in supply contribute to ensuring security of supply, international cooperation should be encouraged.

(13) This Regulation is without prejudice to the obligations of marketing authorisation holders, in particular under Regulations (EU) 2022/123 and (EU) 2026/…[+] and Directive (EU) 2026/… of the European Parliament and of the Council[9++], including the obligation to ensure sufficient supplies of medicinal products, within the limits of their responsibility. It is aligned with the principles of the internal market and is without prejudice to Union competition law, including antitrust, merger and State aid rules.

***(14) Data made available to competent authorities in accordance with Regulation (EU) 2025/327 of the European Parliament and of the Council[10] can contribute to the implementation of this Regulation.***

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[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

[9] 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 PE-CONS 66/26 (2023/0132(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Directive, including its ELI number.

[10] 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).

(15) The primary 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, as well as ***the availability and accessibility*** of medicinal products of common interest. However, given ***that*** a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation also supports 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 can also contribute to the Union's preparedness, resilience, and economic and overall security, including when cross-border supply chains risk being disrupted***,*** ***thereby supporting the Union's strategic autonomy***.

(16) 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.

(17) A well-defined list of critical medicinal products is essential to ensure that the measures provided for by this Regulation 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) 2026/… [+]. That list builds upon the experiences of the ▌ Agency and competent authorities of the Member States responsible for medicinal products that in 2024 ▌ identified a list of 276 critical medicinal products.

(18) To ensure that the measures provided for by this Regulation 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 the supply chain of each category of*** critical medicinal ***products***. This Regulation makes use of the vulnerability evaluation carried out for the purpose of Regulation (EU) 2026/… [+]. 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 third country or a limited number of third countries, or a limited number of manufacturing sites, for active substances, key inputs, or finished dosage forms.

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

(19) ***Ensuring*** the security of supply ***and the availability*** of critical medicinal products ***for patients in the Union*** to safeguard public health***, patient safety*** and the economic and overall security of the Union ***is a*** strategic ***objective*** of the Union. ***To achieve this, Member States and the Commission should cooperate to strengthen the security of supply and to support the continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. In that regard, the Commission should support the coordinated efforts of the Member States.***

(20) 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 of critical medicinal products ***and their contribution to the objectives of preserving public health and protection of patients' interests***, strategic projects should be considered to be in the public interest. In order to ensure their swift implementation, competent authorities of the Member States should ensure that the relevant ***permit-granting*** processes are carried out ***without delay,*** in particular by making available any form of accelerated procedures that exists in applicable Union and national law***, whilst upholding the highest social, health and environmental standards***. To that end, it is important that those competent authorities be provided with adequate resources. Competent authorities of the Member States should consider the streamlining of permit-granting processes, for example by enabling the digital submission of required information.

(21) ***The*** designated authority should ***assess*** whether an industrial project is a strategic project***. In order to offer a real advantage to strategic projects as regards shortened permit-granting timelines, such assessments should be provided swiftly, without undue delay. When justified by the complexity of the project, the 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*** processes and related dispute resolution procedures, ***where such processes, status and procedures already exist in national law. They should also*** ▌ be provided with targeted ▌ administrative support and, upon request, advice and regulatory support, where relevant. ***To allow for the production of critical medicinal products, strategic projects require continuity of supply of energy and gas. For this reason, Member States are able to consider a strategic project to be a 'protected customer' as defined in Regulation (EU) 2017/1938 of the European Parliament and of the Council[11].*** It is important that Member States have particular regard to small and ***medium-sized*** enterprises (SMEs) to give them a fair chance to initiate strategic projects. ***This Regulation should be applied in a manner that guarantees fair and equal competition among all market actors, regardless of their size and ownership structure***.

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[11] 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).

***(22)*** ***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[12].***

***(23)*** ***A strategic project promoter should be able to request that an application for a permit*** for that strategic project ***be granted the status of the highest national significance, where such a status exists in national law, and be treated accordingly. Competent authorities of the Member States should grant the status of the highest national significance to an application for a permit subject to obligations provided for in Union law.***

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**12** 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).

***(24) A strategic project promoter should be able to request that any dispute resolution procedure, litigation, appeals or judicial remedies, related to the permit-granting process or to the issuance of permits for strategic projects in the Union, be treated as urgent if and to the extent that national law provides for such an urgency procedure.***

(25) 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***.

(26) Land use conflicts can create barriers to the deployment of strategic projects. The relevant national, regional or local authority responsible for preparing zoning, spatial plans and land use plans should consider including in those 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.

***(27) 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).***

(28) Given the capital-intensive nature of pharmaceutical production, including the establishment or the expansion ***or modernisation*** of manufacturing sites for critical medicinal products and their active substances and key inputs, targeted financial support can play a crucial role in incentivising production within the Union. In order to strengthen the security of supply of critical medicinal products, and where private investment alone is not sufficient, financial support in the form of investment in manufacturing capacity within the Union might be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in supply chains, while ensuring that such support complies with Union 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 and will be updated as necessary.

***(29)*** ***In order to enforce the supply commitments from the manufacturing sites that have received public financial 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.***

***(30)*** ***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 those products to patients in the Union, including Regulation (EU) 2015/479 of the European Parliament and the Council[13].***

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*13* 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).

(31) ***Financial support for*** strategic projects can be provided by the Union ***from 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[14], ***the*** Digital Europe Programme[15] and Horizon Europe[16] (relevant, for example, for active substances referred to in ▌ Regulation (EU) 2021/695 of the European Parliament and of the Council), as well as the Strategic Technologies for Europe Platform (STEP), when they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 of the European Parliament and of the Council[17] (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.

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14 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).

15 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).

16 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).

17 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).

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

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

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

(35) 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***[18] ***through the integration of resilience*** requirements***, as appropriate, in the process of public procurement in accordance with that Directive, in particular through the 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, it is important that*** procurement ***procedures under this Regulation*** include ***predictable quantities. That can serve as an incentive for manufacturers to maintain or scale up manufacturing capacity, particularly for medicinal products that are essential for public health but might not be commercially attractive under standard market conditions***.

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**18** 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).

***(36) 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. It should also be possible for resilience requirements 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. Resilience of supply can be promoted throughout the procurement procedures, by integrating those resilience requirements either in the technical specifications, selection criteria, contract award criteria or in the contract performance clauses, depending on the market situation and public health considerations. The active use of award criteria acknowledging quality alongside price is essential.***

(37) ***Across Member States, contracting authorities differ in their introduction and*** use of ***resilience*** requirements in public procurement procedures***. Those differences 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 tenderers. In order to avoid such negative outcomes and support ***a more streamlined practice***, the use of ***resilience requirements*** should be mandatory.

(38) ***Where dependency on a single third country or a limited number of third countries is threatening the*** security of supply of a critical medicinal product, it is necessary to procure that critical medicinal product 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 a critical medicinal product carried out by the MSSG establishes a vulnerability in the supply chain due to a high level of*** dependency on a single third country or ▌ a limited number of third countries, ▌ ***the*** contracting authorities ▌ should ***apply the*** procurement requirements that***, while preserving competition, incentivise manufacturing in the Union. To ensure the flexibility necessary to accommodate different national procurement practices*** in the ***Member States***, the contracting authorities ***should apply at least one of the mechanisms provided for in this Regulation.***

***Such*** procurement requirements ***could take the form of award criteria relying on a scoring system that rewards the*** tenderers ***proportionately to the volume of Union manufactured*** critical medicinal products and their active substances ***offered and on a weighting attributed to manufacturing in the Union that effectively incentivises it, with the possibility to provide an extra reward for tenderers that offer more than 50 % of the contract volume manufactured in the Union. Where contracting authorities consider several lots in the procurement procedure, such procurement requirements could also take form of technical specifications requiring that at least one lot representing*** a significant ***percentage*** of ***the total volume of the contract is reserved for*** critical medicinal products and their active substances ***manufactured*** in the ***Union***.

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

***(40) The continuous availability of critical medicinal products is essential to preserve human life and can be seriously threatened by a vulnerability in the supply chains due to a high level of dependency on a single third country or a limited 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 the World Trade Organization and other relevant international agreements to which the Union is bound.***

***(41) In order to incentivise investments in modernisation, increase or creation of new manufacturing capacity in the Union for critical medicinal products for which a vulnerability evaluation established a vulnerability in the supply chains due to a high level of dependency on a single third country or a limited number of third countries, it is necessary that market conditions be predictable. For this reason the procurement requirements favouring manufacturing in the Union should apply for as long as a medicinal product remains on the Union list of critical medicinal products and is specified as vulnerable due to that high level of dependency on a single third country or a limited number of third countries and for a minimum period of five years from the date of entry into force of the last implementing act by which that critical medicinal product is specified as vulnerable due to that high level of dependency.***

***(42) In order to strengthen the resilience of supply of 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 tenderers for the same medicinal product. Such multi-winner approaches in procurement procedures can promote diversification of supply, enhance security of supply, and ensure that manufacturing capacity is distributed across different manufacturers and geographical locations within the Union.***

(***43***) ▌ 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.

(44) 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 costs for procurers or discourage participation, leading to no bids***, or if no suitable tenders 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 launching of the planned new procurement procedure***.

***Contracting authorities can presume that tenders whose price exceeds the contracting authority's budget, as determined and documented prior to the launching of the procurement procedure, are tenders with disproportionate costs. In addition, it should be possible for contracting authorities not to apply certain procurement requirements where, for 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, it is not possible to comply with those requirements in the specific context of a negotiated procedure without prior publication. Such 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.***

▌

(45) 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 patient and consumer organisations, healthcare professional organisations,*** public ***healthcare*** payers and ***industry representatives, in the process of preparation of those guidelines***.

(46) 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 should 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 ***should*** also be able to encompass ***other*** measures related to pricing and reimbursement in order to strengthen the sustainability and the resilience of supply, where appropriate. National 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. That 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.

***(47)*** ***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 stockpiles. Those two concepts refer to different types of reserves which are governed by distinct legal and operational frameworks, and which serve different purposes in the supply chain and in the context of public health preparedness.***

(48) ***Some*** Member States ***impose obligations on marketing authorisation holders, and other economic operators in the supply chain of medicinal products*** that are supplied 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 stockpiles in order to anticipate and manage a specific crisis. Contingency stock requirements imposed by a Member State could potentially*** have a ▌ negative impact on the internal market and ***result in the unavailability of the medicinal products concerned in*** other Member States.

***When imposing any such contingency stock requirements, Member States 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.*** In order 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. ***Contingency stock requirements and other security of supply measures should be implemented in a way that aims to minimise waste thereby improving the efficient use of available medicinal products in line with national law and national needs.*** ▌ It is important that Member States give due consideration to 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 ▌ .

***(49) 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 imposed. Such obligation should be without prejudice to the notification requirement under Directive (EU) 2015/1535 of the European Parliament and of the Council[19]. To support transparency of Member State contingency stock requirements, the Agency should provide an overview of the imposed contingency stock requirements.***

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**19** 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, p. 1, ELI: http://data.europa.eu/eli/dir/2015/1535/oj).

***(50)*** ***It is important to fully leverage the Voluntary Solidarity Mechanism to prevent the negative consequences for patients of critical shortages of critical medicinal products. Once the Voluntary Solidarity Mechanism has been 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 does not result in a suitable option to address the request of a Member State facing a shortage, the MSSG should be able to issue recommendations.***

(51) 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 economic operators in collaborative procurement procedures conducted pursuant to this Regulation is voluntary.***

(52) Directive 2014/24/EU ▌ provides for the possibility of procurement procedures involving contracting authorities from different Member States. Although 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 is considered a limiting factor. To facilitate the deployment of collaborative procurement initiatives involving contracting authorities from different Member States, the Commission, when requested, should provide assistance during the preliminary phase of setting up such a procurement initiative. ***Such facilitation 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 the inclusion of specific contract elements. It should be possible for participating Member States to continue the procedure without the Commission's facilitation, including by agreement on another facilitator in accordance with Directive 2014/24/EU. Any participating Member State can withdraw from the procedure at any stage before the signature of the procurement contract. Withdrawal by one Member State does not in itself affect the continuation of the procedure by the remaining participating Member States, provided that the requirements under this Regulation are still met. Member States should be able to specify that they wish to conduct cross-border procurement with candidate countries.***

(53) 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[20], and of COVID-19 vaccines ▌ pursuant to Council Regulation (EU) 2016/369[21] 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.

(54) To ensure that the collaborative procurement ***on behalf of or in name of the Member States*** contributes 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 this Regulation are met***. For this reason, ***a derogation*** from Article ***168(3)*** of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[22] should be provided.

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20 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).

21 Council Regulation (EU) ***2016/369*** of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/369/oj).

22 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).

***(55) It is not appropriate for the Commission to conduct a collaborative procurement procedure on behalf of or in the name of Member States where it has substantiated grounds to believe 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 not participating in the initiative, or where the involvement of the Commission cannot be justified in light of the principles of utility, necessity and proportionality, and in that context, there are concerns related to the efficient use of the Commission resources. The Commission should therefore be able to refuse to conduct the procurement procedure on those grounds.***

(56) ***In accordance with Article 168 of Regulation (EU, Euratom) 2024/2509, the Commission, when procuring on behalf of or in the name of 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 active Commission involvement. Such ***an*** agreement should set out the division of responsibilities, decision-making processes, the information relevant for the procurement procedure to be shared, 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[23].

[23] 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, 6.12.2022, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj).

(57) ***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 from each Member State with strategic*** expertise in medicinal ***product*** procurement policies, in industrial policy related to pharmaceuticals and in public health. ***As necessary, Member States should be able to appoint additional expert representatives to accompany the permanent 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 observer status. It should be possible for the CMCG to invite, at its discretion, the representatives of relevant stakeholders, including industry and patients' representatives, 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***.

(58) 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 and 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 by Article 3 of Regulation (EU) 2022/123 and whose tasks are set out in that Regulation and in Regulation (EU) No 2026/…*** [+]***. 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 of and demand for critical medicinal products and to provide recommendations to prevent or mitigate shortages and support the strengthening of security of supply of critical medicinal products. However, the focus of the CMCG should be to facilitate the coordination of the measures under this Regulation that create the necessary conditions on investments and to facilitate coordination of and collaboration on public procurement, in order to proactively reduce dependencies and strengthen Union manufacturing capacity.***

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

***(59) 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.***

***(60) The CMCG should facilitate discussions between interested Member States to explore their interest in concluding joint contracts to reserve specific manufacturing capacity. Where such a joint contract results in a need to increase or modernise manufacturing capacity, the resulting industrial project could be recognised as a strategic project and benefit from the advantages offered by this Regulation.***

(61) The ▌ security of supply and availability of critical medicinal products ***are to be enhanced through, inter alia, the diversification of supply sources, including through*** access to alternative supply sources 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.

(62) To ensure the application of this Regulation, it is necessary that information be made available ***to the competent*** authorities ▌ and the Commission***. The competent authorities of the Member States, the Commission or the Agency, as relevant,*** should be able to request, when necessary and ***avoiding*** duplication of information requests, the information necessary for the application of this Regulation***. Furthermore, it is important to fully leverage existing data infrastructures and databases in order to reduce reporting burdens, and improve the efficiency of data exchanges between competent authorities and stakeholders. It should be possible 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 applicable 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 competent authorities of the Member States should not disclose information acquired or exchanged by them pursuant to this Regulation where such information is covered by the obligation of professional secrecy. This should also apply to the 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.***

(63) 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 date of application and every five years thereafter. ***That*** evaluation should include an assessment of the extent to which the ▌ objectives ***of this Regulation*** have been achieved, including its impact on stakeholders and on 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 this Regulation with developments within the field of public procurement.*** In particular, the evaluation should take into account the views of Member States, ***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, competent authorities of the Member States***, contracting authorities and other relevant stakeholders*** should, upon request, provide relevant data and information to support the Commission's assessment.

(64) Since the objective of this Regulation***, namely to improve the functioning of the internal market by establishing*** a framework to strengthen the security of supply and availability 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, 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 Treaty on European Union. 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 ***that*** objective,

HAVE ADOPTED THIS REGULATION:

## Chapter I
## General provisions

### Article 1
### Objective and subject matter

1. The objective of this Regulation is ***to improve the functioning of the internal market by establishing a framework*** to:

   (a) 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 ***and strategic autonomy*** of the Union ***and contributing to patients' safety; and***

   (b) 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 objective referred to in paragraph 1, ***this*** Regulation provides for measures 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 key inputs in the Union***, in order to facilitate the sustainable availability of those active substances and key inputs to manufacturers of critical medicinal products, thereby increasing the resilience of the supply chains***;

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

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

(d) leverage the aggregated demand of participating Member States through collaborative procurement procedures; and

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

Article 2

Scope

1. This Regulation***, with the exception of Article 22,*** applies to the critical medicinal products on the Union list of critical medicinal products referred to in Article ***137*** of Regulation (EU) 2026/…[+]. ▌

2. Article 22 applies to medicinal products of common interest. ***Articles 1, 23 and 24, Article 26(2), point (e), and Article 26(3)*** also apply to medicinal products of common interest. ▌

***3. Articles 1, 5 and 6, Article 8(1), point (c), Articles 12, 13 and 22, Article 23(1), point (b), Article 23(2) to (9), Article 24, Article 26(2), point (e), Article 26(3) and Article 29 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 (25), of Regulation (EU) 2026/…[+] or a medicinal product of common interest as defined in Article 3, point (10), of this Regulation, as applicable.***

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

Article 3

Definitions

For the ***purposes*** of this Regulation, the following definitions apply:

(1) ‘medicinal product’ means a medicinal product as defined in Article ***5(1)***, point (1), of Directive (EU) 2026/…[+];

(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***;

(3) ‘active substance’ means an active substance as defined in Article ***5(1)***, point (3), of Directive (EU) 2026/…[+];

***(4) ‘starting material’ means a starting material as defined in Article 5(1), point (4), of Directive (EU) 2026/…[+];***

[+] OJ: please insert in the text the number of the Directive in document PE-CONS 66/26 (2023/0132(COD)).

***(5) 'collection' means the 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[24], or of substances of animal origin for the purpose of being used as a starting material for critical medicinal products;***

***(6) 'excipient' means an excipient as defined in Article 5(1), point (6), of Directive (EU) 2026/…[+];***

***(7) 'immediate packaging' means an immediate packaging as defined in Article 5(1), point (51), of Directive (EU) 2026/…[+];***

***(8) 'labelling' means labelling as defined in Article 5(1), point (52), of Directive (EU) 2026/…[+];***

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**24** 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).

\+ OJ: please insert in the text the number of the Directive in document PE-CONS 66/26 (2023/0132(COD)).

(9) ‘critical medicinal product’ means ***a critical medicinal product as defined in Article 2, point (25), of Regulation (EU) 2026/…[+];***

(10) ‘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;

***(11) ‘designated orphan medicinal product’ means a designated orphan medicinal product as defined in Article 2, point (34), of Regulation (EU) 2026/…[+];***

***(12) ‘orphan medicinal product’ means an orphan medicinal product as defined in Article 2, point (35), of Regulation (EU) 2026/…[+];***

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+ OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

(13) ‘vulnerability in the supply chains’ means risks and weaknesses in the supply chains of critical medicinal products ***as evaluated in accordance with Article 136(1), first subparagraph, point (b), and Article 138(2), of Regulation (EU) 2026/… [+];***

(14) ‘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) 2026/…[+];

▌

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

(16) ‘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;

(17) ‘strategic project promoter’ means any undertaking or consortium of undertakings developing a strategic project;

(18) ‘***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;

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

(19) ‘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;

***(20) ‘platform technology’ means a platform technology as defined in Article 5(1), point (34), of Directive (EU) 2026/…[+];***

[+] OJ: please insert in the text the number of the Directive in document PE-CONS 66/26 (2023/0132(COD)).

*(21) 'contingency stock requirement' means an obligation to hold stocks of certain medicinal products, imposed by a Member State, by provisions laid down by law, regulation or administrative action, on marketing authorisation holders and other economic operators involved in supplying medicinal products to healthcare providers and patients, including stockholding obligations in public procurement procedures;*

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

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

(24) ‘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**.**

## Chapter II

## Strengthening the Union's security of supply

### Article 4

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

▌

The Member States and the Commission shall cooperate to strengthen the security of supply and to support the continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. In that regard, the Commission shall support the coordinated efforts of the Member States.

## Chapter III

## Enabling conditions for investment

### SECTION I

### STRATEGIC PROJECTS

Article 5

Criteria for the recognition of strategic projects

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

(a) it creates or increases capacity***, including through new technologies and innovative manufacturing processes,*** for manufacturing one or more critical medicinal products or their active substances, or for collection;

(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

Procedure for the 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.***

***2.*** ***In order for an industrial project to be recognised as a strategic project,*** the promoter ***of that project shall*** request the relevant designated authority to assess whether ***the*** project is a strategic project. ***The request shall contain justifications 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 decision to the project promoter without undue delay and in any event no later than 20 days from the receipt of the request.***

***3.*** ***The submission of a*** request ***for*** an industrial project ***to be recognised as*** a strategic project ***as provided for in paragraph 2 does not preclude the project promoter from simultaneously initiating application procedures with other authorities involved in the permit-granting process***.

4. Member States shall communicate to the Commission ▌ the designated ***authorities*** for the purposes of paragraph 1 ***of this Article and Article 16(3)***.

5. 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 the 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 2 available in all official languages of the institutions of the Union.***

***6. The Commission shall adopt implementing acts to provide for the standard template referred to in paragraph 5, point (c), of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32.***

7. Any other ***authority in the*** Member State ▌ that receives a request from a project promoter concerning Articles 8 to 14 shall ***rely on the decision of the designated authority referred to in paragraph 2 of this Article 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 to contribute to the security of supply of critical medicinal products in the Union and, therefore, to be in the public interest.

***2.*** Competent authorities of the Member States 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 relevant assessments***.

***3.*** ***Member States shall take paragraph 1 of this Article into account*** when considering whether an undertaking in charge of a strategic project is a ***'protected customer', as defined in Article 2, point (5), of Regulation (EU) 2017/1938 of the European Parliament and of the Council***[25]***,*** subject to the requirements of that Regulation***.***

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[25] 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).

Article 8

Administrative support

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

(a) with regard to ***the strategic 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) throughout the permit-granting process.

2. When providing the administrative support referred to in paragraph 1, competent authorities of the Member States shall pay particular attention to small and medium size enterprises (SMEs)***, small mid-cap enterprises 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.

Article 9

Request for granting the status of highest national significance

Where such a status exists in national law, a strategic project promoter may request that an application for a permit for that strategic project be granted the status of the highest national significance and treated accordingly. Subject to other obligations provided for in Union law, competent authorities of the Member States shall grant such a status.

Article 10

Procedures relating to dispute resolution

A strategic project promoter may request that any dispute resolution procedure, litigation, appeals or judicial remedies, related to the permit-granting process or to the issuance of permits for strategic projects in the Union before any national courts, tribunals or panels, including any mediation or arbitration procedure, where they exist in national law, be treated as urgent if and to the extent that 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.

Where applicable, the strategic project promoter shall participate in the urgency procedure referred to in the first subparagraph.

Article 11

Regulatory support from ***competent authorities of Member States responsible for medicinal products and advice from the Agency***

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

***A competent authority of a Member State responsible for medicinal products 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 strategic project promoter to the dedicated advice and assistance provided by the European Medicines Agency (the 'Agency') in accordance with paragraph 2.***

2. Upon request of a strategic project promoter, the ▌ Agency ▌ shall provide dedicated advice and assistance to strategic project promoters developing strategic projects relying on innovative manufacturing processes. ***Where such advice includes aspects related to Good Manufacturing Practices, the Agency shall involve the relevant competent authority of a Member State responsible for medicinal products in the provision of that advice.***

Article 12

Environmental impact assessments and authorisations

1. Where the obligation to assess the effects on the environment arises simultaneously from two or more of the following Directives, a strategic project promoter may request that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts ***be*** applied:

a) Council Directive 92/43/EEC[26];

b) Directive 2000/60/EC of the European Parliament and of the Council[27];

c) Directive 2001/42/EC of the European Parliament and of the Council[28];

d) Directive 2008/98/EC of the European Parliament and of the Council[29];

e) Directive 2009/147/EC of the European Parliament and of the Council[30];

f) Directive 2010/75/EU of the European Parliament and of the Council[31];

g) Directive 2011/92/EU of the European Parliament and of the Council[32];

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26 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).

27 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).

28 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).

29 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).

30 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).

31 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).

32 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).

h) Directive 2012/18/EU of the European Parliament and of the Council[33].

***The application of the coordinated or joint procedure referred to in the first subparagraph shall not affect the content or quality of the environmental impact assessment.*** Under the coordinated procedure, a competent authority of a Member State shall coordinate the various individual assessments of the environmental impact of a particular strategic project required by the relevant Directive. Under the joint procedure, a competent authority of a Member State shall provide for a single assessment of the environmental impact of a particular strategic project required by the relevant Directive.

2. The competent authorities of the Member States shall 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.

[33] 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).

3. In exceptional cases, where the nature, complexity, location or size of the strategic project so requires, competent authorities of the 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 such a case, the competent authority of the Member State shall inform the strategic 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 of the European Parliament and of the Council[34]**,** 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.

[34] Regulation (EU) 2024/1991 of the European Parliament and of the Council of 24 June 2024 on nature restoration and amending Regulation (EU) 2022/869 (OJ L, 2024/1991, 29.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1991/oj).

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 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, as referred to in Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[35], those impacts shall also be covered in the combined assessment. ***The fact that assessments are combined pursuant to this paragraph shall not affect their content, quality or robustness.***

[35] 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 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***, Member States may prioritise financial support for strategic projects that address a vulnerability in the supply chains of critical medicinal products established following a vulnerability evaluation, giving due consideration to the strategic orientations, referred to in Article 26(2)***,*** point (a), of this Regulation, of the Critical Medicines ***Coordination*** Group ***(CMCG) established pursuant to Article 25*** of this Regulation.

***2. The Commission shall facilitate the consistent application of this Article by providing guidance to Member States on the possibilities offered under existing Union State aid rules for the granting of State aid to strategic projects.***

3. 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 the event that the medicinal product is removed from the Union list of critical medicinal products***.

4. 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 the related critical medicinal product, active substance or key input, as applicable, to the Union market to avoid shortages in one or ***more*** Member States.

5. Where a Member State encounters a threat of shortages of a critical medicinal product, it may ***request*** the Member State that provided financial support to the related strategic project to request on its behalf that the beneficiary undertaking supply that critical medicinal product to it. ***The beneficiary undertaking shall make best efforts to supply such critical medicinal product to the Member State that is encountering a threat of shortages of that critical medicinal product.***

Article 16

Financial support from the Union

1. ***Financial support for strategic projects under*** the Multiannual Financial Framework 2021-2027[36] may be ***provided by the*** Union ***from Union programmes,*** including 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.

***2. Where an undertaking receives financial support for a strategic project from a Union funding instrument which allows for funding to be made available under the condition of strengthening the availability of critical medicinal products in accordance with the objective 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 to which the strategic project relates remains available in the Member States on whose market it has been made available.***

[36] Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the multiannual financial framework for the years 2021 to 2027 (OJ L 433 I, 22.12.2020, p. 11, ELI: http://data.europa.eu/eli/reg/2020/2093/oj).

3. ***Where a strategic project relates to a critical medicinal product for which the vulnerability evaluation has been concluded and has established a vulnerability in the supply chains,*** the designated authority shall, at the request of the strategic project promoter, verify whether that strategic project addresses that vulnerability. Such a request shall only be made where there is a need to ***demonstrate,*** for the purpose of an application ***of*** Union funding***, that a strategic project addresses an established*** vulnerability ***in the supply chains***.

The designated authority shall provide ***the verification to the*** strategic project promoter within 15 working days of ***receiving the*** request. The designated authority shall inform the Commission without delay about the strategic projects that it has confirmed as addressing an existing vulnerability in the supply chains .

***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 strategic project promoter accordingly and shall set a time-limit for providing the missing information and documents. Where 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.***

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

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***.

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

***4.*** 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.

## 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, critical 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) technical specifications within the meaning of Article 42 of Directive 2014/24/EU;***

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

***(c) best price-quality ratio assessed on the basis of 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.***

2. ***For public procurement procedures of*** critical medicinal products for which a vulnerability in the supply chains has been ***established*** through a vulnerability evaluation pointing to a high level of dependency on a single third country or a limited number of third countries, the contracting authorities shall ▌ favour ***manufacturing of such*** critical medicinal products in the Union. ▌

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

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

***(b)*** the ***application of the best price-quality ratio assessed on the basis of contract award criteria within the meaning of Article 67 of Directive 2014/24/EU, favouring tenderers offering 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 the context of the second subparagraph, point (b), the contracting authorities may allocate additional points to tenderers offering critical medicinal products and their active substances, 50 % or more of which are manufactured in the Union.***

***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.***

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

***3. The procurement requirements referred to in paragraph 2 of this Article shall apply for as long as the medicinal product remains on the Union list of critical medicinal products and is specified as vulnerable due to a high level of dependency on a single third country or a limited number of third countries and for a minimum period of five years from the date of entry into force of the last implementing act by which that critical medicinal product is specified by the Commission as vulnerable due to that high level of dependency in accordance with Article 137(3) of Regulation (EU) 2026/…[+].***

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

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

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

6. Contracting authorities may exceptionally decide not to apply paragraphs 1 to 4 where ***it is duly*** justified by market ***circumstances*** or considerations related to the financing of health services***, namely 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;***

***(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 launching of the planned new procurement procedure;***

***(c) the application of paragraphs 1 to 4 would oblige the contracting authority to acquire critical medicinal products having disproportionate costs; or***

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

***7. The justification for the exceptions referred to in paragraph 6 specifying the relevant circumstances or considerations shall be documented in writing by the contracting authority and be subject to verification and redress where relevant.***

***8. 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.***

***9. This Article shall be applied in compliance with the Union's international commitments.***

Article 19

***National*** programmes supporting ▌ security of supply 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 national 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 national programmes may also include measures related to 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 national programmes.***

2. Member States shall ***inform*** the Commission in its role as secretariat of the ***CMCG about their programmes***. The Commission shall ensure the distribution of that information without delay to all members of the ***CMCG***. The ***CMCG*** shall facilitate a discussion aiming to ensure coordination of such 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 .***

Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of contingency stock requirements.

***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.

***3.*** ***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.***

*4. 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.*

*5. 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 stock requirements. Those guidelines may include:*

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

*(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 21*

*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, transparency and solidarity as 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 contingency stocks.*

***4. Where the Voluntary Solidarity Mechanism for medicinal products (the 'Voluntary Solidarity Mechanism') is activated to mitigate a critical shortage in a Member State in accordance with Article 131 of Regulation (EU) 2026/…[+], Member States shall, where reasonably possible within their national monitoring systems, upon request from the Medicine Shortages Steering Group (MSSG), provide up-to-date data relating to stocks of critical medicinal products that are subject to contingency stock requirements which a Member State identifies as available for reallocation.***

***5. Where the activation of the Voluntary Solidarity Mechanism has not resulted in a suitable option to mitigate the critical shortage referred to in paragraph 4, the MSSG may, upon request from the Member State that activated the Voluntary Solidarity Mechanism, issue a recommendation to Member States with the aim of facilitating contributions by marketing authorisation holders to the Voluntary Solidarity 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 30(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 PE-CONS 65/26 (2023/0131(COD)).

## SECTION II

## *VOLUNTARY* COLLABORATIVE PROCUREMENTS

### Article 22

### Commission-facilitated Member State cross-border procurement

1. Upon a reasoned request ***from*** three or more Member States (the 'request'), the Commission may act as facilitator for cross-border procurement, as laid down in Article 39 of Directive ***2014/24/EU,*** involving those requesting Member States, ***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 four*** 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. Within ***15 working days of the expiry of the deadline specified in paragraph 2,*** the Commission shall ***inform*** the interested Member States ***of*** its decision.

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

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 ▌ participating 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.

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 do so at their own cost.***

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 procurement contract.

***8. Member States may specify that they wish to conduct the cross-border procurement as referred to in paragraph 1 with candidate countries that choose to participate in the procedure laid down in this Article and with which the Union has entered into a bilateral agreement in respect 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 request.***

Article 23

Commission procurement procedure 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 (a 'joint request')***, the Commission ***shall, unless it provides substantiated reasons not to*** launch ***the*** procurement ***procedure, launch such a*** procedure, where the procurement ***concerns*** a medicinal product that***:***

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

(b) is a medicinal product of common interest for which a joint clinical assessment report has been published pursuant to Article 12(4) of Regulation ***(EU) 2021/2282 of the European Parliament and of the Council***[37] or which has undergone a clinical assessment carried out under the voluntary cooperation among Member States ***pursuant to*** Article 23(1)**,** point (e)**,** of that Regulation.

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[37] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/2282/oj).

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

4. Participation in the procurement procedure referred to in paragraph 1 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.

5. The Commission shall assess ▌ the ***joint*** request in light of the objectives of this Regulation. The Commission shall in particular assess 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***.

6. ***Within 15 working days of the expiry of the deadline specified in paragraph 4,*** the Commission shall ***inform*** the interested Member States ▌ of its decision on whether it agrees to launch the procurement procedure referred to in paragraph 1 and, in the event of a refusal, state its reasons.

***7.*** Resilience requirements equivalent to those set out in Article 18 ***shall apply, where relevant***, to procurement procedures under this Article. Those requireme***nts 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.***

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

9. With the exception of 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.

I

Article 24

Agreement concerning procurement procedures under ***Article 23***

1. Member States participating in a procurement procedure ***under Article 23*** 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.

2. ***The procurement procedures under Article 23 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.*** A mandate 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.

## Chapter V
## Critical Medicines Coordination Group

Article 25

Establishment of the Critical Medicines Coordination Group

1. The Critical Medicines Coordination Group (CMCG) is hereby established.

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

3. 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 representative in order to support the*** different tasks of the ***CMCG***. The Agency shall have observer status.

***The representatives of relevant stakeholders, including industry and patient 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.***

4. The ***CMCG***, upon a proposal from the ***co-chairs*** or any ***of*** its members, may***, on a case-by-case basis,*** decide to establish ***one or more*** working ***groups***.

***5. The representatives appointed to the CMCG and, where relevant, to its working group or working groups shall make a declaration of their financial and other interests and update it whenever necessary and at least annually.***

6. The ***CMCG*** shall work closely with the MSSG, the Agency ▌ and the ***competent*** authorities of the Member States ▌ responsible for medicinal products. For discussions where input from ***competent*** authorities of the Member States ***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, patient and consumer organisations, healthcare professional organisations and industry representatives***.

7. 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, where relevant, procedures relating to the working*** group or working groups ***referred to in paragraph 4***.

8. The ***CMCG*** shall use its best endeavours to reach consensus, where possible***, including when providing advice as referred to in Article 26(1), when providing recommendations as referred to in Article 26(2), point (f), and when providing an opinion as referred to in Article 26(3). 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.

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***, in order 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 achieve the objectives referred to in paragraph 1, the ***CMCG*** shall perform the following tasks:

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

***(b) enable exchanges of information as referred to in Article 17 and, where necessary, facilitate the coordination of actions aiming to achieve the objective of this Regulation;***

(c) 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;

***(d) facilitate exchanges of information on contingency stock requirements as referred to in Article 21(1);***

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

(f) ***provide recommendations to*** the MSSG ***on*** the order in which critical medicinal products are to be prioritised for the vulnerability evaluation ***as set out in Regulation (EU) 2026/…***[+], and propose a review or an update of existing vulnerability evaluations where necessary***;***

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

***(g)*** ***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***;***

***(h)*** ***facilitate exchanges among Member States in order to explore interest in joint contracts to reserve specific manufacturing capacity;***

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

3. The ***CMCG***, at the Commission'***s or Member States'*** 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.

## 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 supply sources*** 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 or 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 its ongoing considerations and assessments.***

## Chapter VII

## Amendments to Regulation (EU) 2024/795

Article 28

Amendments to Regulation (EU) 2024/795

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

(1) Article 2 is replaced by the following:

‘*Article 2*

**STEP objectives**

1. In order to ensure Union sovereignty and security, reduce the Union’s strategic dependencies in strategic sectors, strengthen the Union’s competitiveness by strengthening its resilience and productivity and by mobilising financing, favour a level playing field for investments in the internal market, foster cross-border participation, including of SMEs, strengthen economic, social and territorial cohesion and solidarity among Member States and regions and promote inclusive access to attractive quality jobs by investing in the skills of the future and making its economic, industrial and technological base fit for the green and digital transitions, the STEP shall pursue the following objectives:

(a) supporting the development or manufacturing of critical technologies throughout the Union, or safeguarding and strengthening their respective value chains as referred to in paragraph 3, in the following sectors:

(i) digital technologies, including those contributing to the targets and objectives of the Digital Decade Policy Programme 2030, multi-country projects as defined in Article 2, point (2), of Decision (EU) 2022/2481, and deep tech innovation;

(ii) clean and resource efficient technologies, including net-zero technologies as defined in Regulation (EU) 2024/1735 of the European Parliament and of the Council*;

(iii) biotechnologies, and any other technologies relevant for manufacturing of critical medicinal products as defined in ***Article 2, point (25), of Regulation (EU) 2026/… of the European Parliament and of the Council***+;

(iv) defence technologies;

+ OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

(b) addressing shortages of labour and skills critical to all kinds of quality jobs in support of the objective set out in point (a), in particular through life-long learning, education and training projects, including the European Net-Zero Industry Academies established pursuant to Article 30 of Regulation (EU) 2024/1735, and in close cooperation with social partners and education and training initiatives already in place.

2. The technologies referred to in paragraph 1, point (a), shall be deemed critical where they meet either of the following conditions:

(a) they bring to the internal market an innovative, emerging and cutting-edge element with significant economic potential;

(b) they contribute to reducing or preventing strategic dependencies and vulnerabilities of the Union.

3. The value chain for the development or manufacturing of critical technologies referred to in paragraph 1, point (a), of this Article relates to final products, as well as to specific components and specific machinery primarily used for the production of the final products and critical raw materials set out in Annex II to Regulation (EU) 2024/1252 of the European Parliament and of the Council[***], and to associated services critical for and specific to the development or manufacturing of those final products.

By way of derogation from the first subparagraph of this paragraph, the value chain for the development or manufacturing of technologies that fall within the scope of Regulation (EU) 2024/1735 and that are technologies referred to in paragraph 1, point (a)(ii) of this Article, relates to final products, as well as to specific components and specific machinery primarily used for the production of the final products, as defined in Regulation (EU) 2024/1735 and to associated services critical for and specific to the development or manufacturing of those final products.

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 ***Regulation (EU) 2026/… of the European Parliament and of the Council****[+] and that are referred to in paragraph 1, point (a)(iii)**,** of this Article ▌ shall relate to finished dosage forms, as well as to active substances and key inputs necessary for the production of the finished dosage forms of critical medicinal products as defined in Article 2, point (25), of Regulation (***EU) 2026/…***[++].

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 53/26 (2025/0102(COD)).

[++] OJ: please insert in the text the number of the Regulation in document PE-CONS 65/26 (2023/0131(COD)).

4. Strategic projects recognised in accordance with Article 14 of Regulation (EU) 2024/1735 that comply with the criteria on resilience or the criteria on competitiveness of Regulation (EU) 2024/1735 shall be deemed to contribute to the STEP objective referred to in paragraph 1, point (a)(ii).

5. Strategic projects recognised in accordance with Article 7 of Regulation (EU) 2024/1252 shall be deemed to contribute to the STEP objective referred to in paragraph 1, point (a).

6. Where an important project of common European interest (IPCEI) approved by the Commission pursuant to Article 107(3), point (b), TFEU relates to any of the technology referred to in paragraph 1, point (a), of this Article, the relevant technologies shall be deemed critical.

7. By 2 May 2024, the Commission shall issue guidance on how the technologies in the sectors referred to in paragraph 1, point (a), of this Article can be considered critical as well as on how to meet the conditions set out in paragraph 2 of this Article. In that guidance, the Commission shall clarify the notion of value chain and associated services critical for and specific to the development or manufacturing of the final products referred to in paragraph 3 of this Article. By 24 February 2026, the Commission shall update that guidance to cover the sector set out in Article 2(1), point (a)(iv). That guidance shall be reviewed, where appropriate, in light of the interim evaluation report referred to in Article 8.

8. Strategic projects recognised in accordance with ***Regulation (EU) 2026/…***[+] 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).

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* Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (OJ L, 2024/1735, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1735/oj).

** Regulation (EU) 2026/…[++] 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 Regulation (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004, and (EC) No 1901/2006 (OJ L, …, …, ELI:…).

*** Regulation (EU) 2024/1252 of the European Parliament and of the Council of 11 April 2024 establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1724 and (EU) 2019/1020 (OJ L, 2024/1252, 3.5.2024, ELI: http://data.europa.eu/eli/reg/2024/1252/oj).

**** 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 (OJ L, …, …, ELI: …).';

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[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 53/26 (2025/0102(COD)).

[++] OJ: please insert in the footnote the number, date of adoption and publication reference of the Regulation in document PE-CONS 65/2026 (2023/0131(COD)).

[+++] OJ: please insert in the footnote the number, date of adoption and publication reference of the Regulation in document PE-CONS 53/2026 (2025/0102(COD)).

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

‘7. Strategic projects recognised in accordance with the relevant provisions of Regulations (EU) 2024/1252, (EU) 2024/1735 and (EU) 2026/…[+] 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.’;

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 53/26 (2025/0102(COD)).

(3) in Article 5, point d) is replaced by the following:

‘(d) foster contacts across the sectors of the technologies referred to in Article 2, making particular use of existing industrial alliances, networks and structures, including the Net-Zero Europe Platform established by Regulation (EU) 2024/1735 and the European Critical Raw Materials Board established by Regulation (EU) 2024/1252;’;

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

‘(c) details of projects that have been ***recognised*** as strategic projects under Regulations (EU) 2024/1252, (EU) 2024/1735 and ***(EU) 2026/…***[+], to the extent that they fall within the scope of Article 2 of this Regulation.’.

[+] OJ: please insert in the text the number of the Regulation in document PE-CONS 53/26 (2025/0102(COD)).

## Chapter VIII
## Final provisions

Article 29

Obligation to provide information

1. ***For the purposes of Articles 6 and 8, Article 11(1), Articles 12 and 15, Article 16(3) and Article 26(2), point (a), the competent authorities of the Member States concerned may request information from project promoters, strategic 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 and wholesale distributors, as well as stakeholder representative associations or other natural or legal persons that are authorised or entitled to supply*** medicinal products ***to the public.***

***For the purposes of Article 31, the competent authorities of the Member States and*** the Commission ***may request*** information ***from the actors referred to in the first subparagraph of this paragraph, contracting authorities and other stakeholders.***

For the ***purposes of Article 11(2), the Agency may request information from strategic 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 competent*** authorities of the Member States ***or the Agency, as relevant, pursuant to paragraph 1, an actor as referred to in the first subparagraph of paragraph 1 may indicate that*** the information requested ***has already been provided to the competent authority of the Member State concerned or the Agency pursuant to other relevant Union legal acts. In such cases, the competent authority of the Member State concerned or the Agency shall take due account of the information already provided in so far as that information has been provided and may be used also for the purposes of this Regulation***.

3. ***Where an actor as referred to in the first subparagraph of paragraph 1 of this Article submits information pursuant to paragraph 1 of this Article, 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 competent authority of the Member State or the Agency, as relevant,*** shall assess the merits of ***each*** confidentiality ***claim*** made by ***that actor*** and shall protect any information that is commercially confidential against unjustified disclosure ***in accordance with Article 30***.

*Article 30*

*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 competent authorities of the Member States, 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.***

Article 31

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 critical 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 objective as established in Article 1 has 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 competent authorities of Member States 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***.

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

***Article 32***

***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.***

Article 33

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 application of the implementing act establishing the Union list of critical medicinal products pursuant to Article 137 of Regulation (EU) 2026/…***[+] or from … [OJ: please insert the day following that of the entry into force of this Regulation], whichever is later. ***The requirements in Article 18(1) and (2) of this Regulation shall apply to public procurement procedures launched after the date of application of this Regulation.***

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

Done at…,

| | |
|---|---|
| *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 PE-CONS 65/26 (2023/0131(COD)).