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Committee on Public Health

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Final Compromise Amendments 1-10

on the draft Report

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

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1. COMPROMISE AMENDMENT 1 (ART 1-3 AND RECITALS 12, 13, 15 AND 16)

If adopted AMs 7-10, 33-57, 171, 242-257, 270-280, 426-543, ENVI 10, ITRE 10-11, 25-32, IMCO 3, 15 fall

Chapter I
General provisions

Article 1

Objectives and subject matter

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

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

2. To achieve the objectives ***set out*** in paragraphs 1 ***and 1a***, the Regulation sets out a framework to:

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

(b) lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures of critical medicinal products and other medicinal products of common interest;

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

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

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

(da) facilitate investments in critical distribution infrastructure capacity for critical medicinal products ensuring security of supply, availability and accessibility in the Union; and

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

Article 2

Scope

1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products referred to in Article 131 of Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023) 193 final*], ***taking into account the distinctive characteristics of each medicinal product's supply chain***.

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

2. ***Chapter III, Articles 5 to 15,*** Chapter IV ***with the exception of its Section Ia new***, and Article 26(2), point (c) also apply to medicinal products of common interest, ***where the Critical Medicines Coordination Group has issued a positive recommendation pursuant to Article 26(2) (dj (new)).***

Articles 16 and 17 apply, mutatis mutandis, to medicinal products of common interest subject to the condition that the Union funding allocation under Article 16 exceeds EUR 500 million.

Article 3

Definitions

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

~~(1) deleted~~

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

~~(3) deleted~~

~~(4) deleted~~

(4a) 'substance of human origin' or 'SoHO' means 'substance of human origin' or 'SoHO', as defined in Regulation (EU) 2024/1938[1];

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

(5a) 'API starting material' means a raw material, an intermediate product, or an active substance that is used in the production of an active pharmaceutical ingredient (API) and that is incorporated as a significant structural fragment into the structure of the API.

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

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

(7) 'vulnerability evaluation' means the evaluation of the supply chains of critical medicinal products to identify their vulnerabilities performed by the MSSG in accordance with Regulation (EU) …/… of the European Parliament and of the Council[2] *[reference to be added after adoption cf. COM(2023) 193 final]*

(8) 'common name' means a common name as defined in Article 4 point (48) of Directive (EU) …/… of the European Parliament and of the Council [*reference to be added to corresponding Article after adoption of cf. COM(2023)192 final*];

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

(10) 'strategic project' means a ***strategic*** project identified pursuant to the criteria set out in Article 5;

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[1] ***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***

[2] Regulation (EU) …. of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ …) [D.G.: Title according to COM(2023) 193 final. Please check against latest version of this draft Regulation].

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

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

(11 a) 'economic operator' means an economic operator as defined in Directive 2014/24/EU;

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

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

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

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

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

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

(14) 'Member States' cross-border procurement' means a procurement procedure initiated between the contracting authorities from different Member States on the basis of Article 39 of Directive 2014/24/EC;

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

(16) 'joint procurement' means a procurement procedure carried out jointly by the Commission and Member States, as provided for in Article 168(2) of Regulation (EU) 2024/2509;

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

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

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

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

Corresponding recitals

(12) While the primary objective of this Regulation should be to strengthen the security of supply and ensure the availability of critical medicinal products and of medicinal products of common interest, given a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation should also support the Union’s competitiveness by fostering a more stable and predictable market environment, reducing administrative barriers, encouraging investment and supporting innovation in the pharmaceutical sector. ***This should include fostering research and development of innovative treatments, such as alternatives to antimicrobials to address antimicrobial resistance, more targeted cancer therapies, as well as other medicinal products responding to unmet medical needs.*** Ensuring the security of supply and availability of critical medicinal products and the availability and accessibility of other medicinal products of common interest should moreover contribute to the Union’s preparedness, resilience, strategic autonomy and economic and overall security, including when cross-border supply chains risk being disrupted. ***The past health emergencies and crises, like COVID-19, have demonstrated how the presence of critical infrastructures, including hospitals and community pharmacies, has been fundamental in achieving these objectives. Furthermore, in order to strengthen the functioning of the internal market and to ensure the uninterrupted availability of critical medicinal products across the Union, it is necessary to establish a Union coordination mechanism for critical medicinal products. Such a mechanism would enhance the Union capacity to address shortages, strengthen supply chain resilience, and enable coordinated approaches to national stockpiling and contingency stocks.***

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

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

(15) A well-defined list of critical medicinal products is essential to ensure that the measures are targeted, effective, and proportionate. The critical medicinal products covered by this Regulation should be those for which insufficient supply results in serious harm or risk of serious harm to patients. For this reason this Regulation should apply to critical medicinal products on the Union list of critical medicinal products, as established by Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023) 193 final*]. That list builds upon the experiences of the European Medicines Agency and Member States' Agencies that in 2024, in anticipation of the reform of pharmaceutical legislation, identified a list of 276 critical medicinal products.

(16) To ensure that the measures are applied where justified and proportionate, it is necessary to demonstrate that some measures address a vulnerability in the supply chains of a given critical medicinal product. This Regulation should rely on the vulnerability evaluation performed for the purpose of the application of the general pharmaceutical legislation as per Regulation (EU) No …/… [*reference to be added after adoption cf. COM(2023) 193 final*]. To detect a vulnerability in the supply chains it is necessary to look at aggregated data across all medicinal products authorised in the Union and containing the same active substance, route of administration and formulation. Such an approach allows for the determination whether, for a critical medicinal product with a given active substance, the Union is highly dependent on a single or a limited number of third countries, or a limited number of sites, for active substances, key inputs, or finished dosage forms.

(16a) In order to ensure legal clarity and effective coordination at Union level, it is essential to distinguish between 'contingency stock' and 'national stockpile'. Those two concepts refer to different types of reserves, governed by distinct legal and operational frameworks, and serving different purposes within the supply chain and public health preparedness. Thus, a clear differentiation is necessary to avoid confusion in reporting and management, and to support targeted and proportionate Union-level actions during supply disruptions or emergencies. In the context of contingency stocks and national stockpiles, Member States should be encouraged to explore sustainable measures that contribute to reducing waste and improving the efficient use of available medicinal products in line with national law and national needs.

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

2. COMPROMISE AMENDMENT 2 (ART 4 AND RECITAL 14)

If adopted AMs 58-61, 258-269, 544-570, ITRE 33, IMCO 4, 16-17 fall

Chapter II
Strengthening the Union's security of supply

Article 4

Strategic objective of the Union

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

2. The Member States and the Commission shall work together ***to achieve the strategic objective of the Union referred to in paragraph 1 including by gathering information from healthcare professionals, patient organisations and economic operators including marketing authorisation holders,*** to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures ***provided for in Sections II and III of this Chapter*** that take full advantage of the potential of the internal market, ***reflecting the principles of solidarity and coordination between Member States and reducing dependencies on third countries, while ensuring predictability for project promoter.***

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

Corresponding recital

Recital 14

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

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

3. COMPROMISE AMENDMENT 3 (ART 5-6 AND RECITALS 17-18)

If adopted AMs 11-13, 62-76, 281-290, 571-671, ENVI 3-4, 11, ITRE 12-14, 34-41, IMCO 5, fall

Chapter III
Enabling conditions for investment

SECTION I

CRITERIA AND PROCEDURE FOR THE DETERMINATION OF STRATEGIC PROJECTS

Article 5

Strategic Projects

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

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

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

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

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

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

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

Article 6

Determination *of Strategic Projects*

1. ***Within three months of the entry into force of this Regulation, each*** Member State shall designate an authority ('the designated authority') ***to be in charge of assessing*** and verify***ing*** whether or not a project meets at least one of the criteria set out in Article 5 and ***is therefore to be considered*** a strategic project.

   A promoter may request the designated authority to assess whether a project ***constitutes*** a strategic project.

   Any Member State authority may request the designated authority to verify its determination of a project ***as*** a strategic project.

2. Member States shall communicate to the Commission what is the designated authority for the purposes of paragraph 1.

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

   (a) the contact details and other relevant information on the Member States' designated authorities,

   (b) information on available administrative or financial support from the Union, and

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

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

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

4. Any other Member State authority that receives a request from a promoter concerning Articles 8 to 14 shall assess whether that given project meets the criteria to be considered a strategic project as provided for in Article 5 and where necessary, request the verification of its determination from the designated authority.

5. Where the verification whether a project ***constitutes*** a strategic project has been performed by ***a designated*** authority in accordance with this Article, any other authority shall rely on that verification.

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

5b. ***The guidelines referred to in paragraph 5a shall, in particular, specify:***

(a) ***measurable criteria for the assessment of strategic relevance, including the project's potential to address supply vulnerabilities, enhance manufacturing capacity or resilience, ensure security of supply, or contribute to Union-wide public health preparedness;***

(b) ***indicative timelines for operational readiness, transparency requirements, and steps for submission and assessment of requests;***

(c) ***available mechanisms for cooperation and exchange of information between the Commission and the designated authority to allow for consistent application of the guidelines.***

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

5d. ***Prior to the determination of a project as strategic, the designated authority shall notify the Critical Medicines Coordination Group of its intention to make such a determination. Within one month of receipt of such notification, the Critical Medicines Coordination Group shall assess whether the project would result in a significant duplication of existing or planned manufacturing capacities within the Union. Where the Critical Medicines Coordination Group does not complete the assessment within that period, the project shall be presumed not to result in significant duplication.***

Where the Critical Medicines Coordination Group considers that the project would result in a significant duplication of existing or planned manufacturing capacities within the Union, it shall inform the designated authority thereof. Such projects shall not be eligible to receive financial support from the Union pursuant to Article 16.

Corresponding recitals

(17) Certain projects ***and technology*** can have a positive impact on security of supply as they increase the Union's manufacturing capacity for critical medicinal products, ***improve efficiencies in the production of those products,*** and strengthen the resilience of the Union's supply chains. In order to encourage private investments in these projects, the concept of strategic projects, ***including cross-border strategic projects*** should be introduced. Given their role in ensuring the Union's security of supply for critical medicinal products, the relevant permitting authority should consider strategic projects to be in the public interest. To ensure their expedient implementation, national authorities should ***be provided with adequate resources to*** ensure that the relevant permit granting processes are carried out in the fastest way possible making available,

in particular any form of accelerated procedures that exists in applicable Union and national law, ***whilst upholding the highest social, health and environmental standards***. National authorities should consider their streamlining as well as enab***ling*** digital submission of required information. ***To ensure the efficient use of resources and strategic coherence at Union level, the designation of strategic projects should avoid unnecessary duplication of existing or planned manufacturing capacities for the same medicinal product, its active substances, or key inputs, unless such duplication is justified by clearly demonstrated needs.***

(17 a) In order to safeguard the Union's strategic interests and the resilience of its industrial base, strategic projects for manufacturing critical medicines must operate without interruption, including during crises or supply chain disruptions. Member States should take all necessary measures to prevent or mitigate unplanned disruptions to essential supplies and to ensure the continued availability of key personnel.

(18) To avoid unnecessary delays and the creation of additional administrative layers, the verification of whether a project fulfils the strategic project criteria should be performed by any Member State authority requested to provide advantages offered in this Regulation. A designated authority should, when solicited, verify whether a given project is a strategic project. In order to accelerate and facilitate their deployment, strategic projects should benefit from streamlined administrative processes, priority status in the context of permit granting procedures and related dispute resolution procedures, as well as, be offered targeted regulatory support. In this context, the Member States should give particular attention to small and medium sized enterprises (SMEs) ***and small mid-cap enterprises (SMCs), as well as entities not engaged in an economic activity, with a view to ensuring that they*** have a fair chance to initiate strategic projects. ***Member States and designated authorities should pay particular attention to minimising the administrative burden on SMEs and SMCs and should provide support and clear guidance through the application, permitting and regulatory processes. Furthermore, requirements should be applied in a manner that guarantees fair and equal competition among all market players, regardless of their ownership structure. To support the effective implementation of this Regulation, the Commission should provide guidance to national authorities and project promoters, intended as a practical support tool. Such guidance should assist in the preparation, determination and support of strategic projects.***

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

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

4. COMPROMISE AMENDMENT 4 (ART 7-14 AND RECITALS 19-20)

If adopted AMs 14, 77-88, 291-303, 672-726 ENVI 5, 12-18, ITRE 42-52, IMCO 6-7 fall

SECTION II

FACILITATING ADMINISTRATIVE AND PERMIT-GRANTING PROCESSES

Article 7

Priority status of strategic projects

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

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

Article 8

*Administrative **and technical** support*

1. Upon request of a project promoter, a Member State shall provide to a strategic project located on its territory all the administrative support necessary to facilitate its timely and effective implementation, including assistance:

   (a) with regard to 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 required consultations of local communities, organisations and social partners***;

   (c) along the permit-granting process.

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

2a. Member States shall ensure that a strategic project located within its territory is provided with the administrative and technical support necessary to prevent or

mitigate unplanned interruptions in the supply of energy, gas or heat required for the establishment or expansion of manufacturing capacity, including facilitating timely access to relevant network connections and capacity, and coordinating with the competent network operators to ensure the stability and continuity of supply.

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

Article 9

Request for granting the status of highest national significance

1. A project promoter may request that their application for a permit is granted the status of the highest national significance, when such a status exists in national law, and be treated accordingly.

2. National authorities shall grant the status of the highest national significance to an application for a permit without prejudice to obligations provided for in Union law.

Article 10

Procedures relating to dispute resolution

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

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

Article 11

Regulatory and scientific support from medicines agencies and pharmaceutical inspectorates

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

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

Article 12

Environmental assessments and authorisation

1. A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[3], Directive 2000/60/EC of the European Parliament and of the Council[4], Directive 2001/42/EC of the European Parliament and of the Council[5], Directive 2008/98/EC of the European Parliament and of the Council[6], Directive 2009/147/EC of the European Parliament and of the Council[7], Directive 2010/75/EU of the European Parliament and of the Council[8], Directive 2011/92/EU of the European Parliament and of the Council[9] or Directive 2012/18/EU of the European Parliament and of the Council[10], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts ***is*** applied. ***The application of the joint or coordinated procedure shall not affect the content or quality of the environmental impact assessment.***

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

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

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

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

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3 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).

4 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).

5 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).

6 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).

7 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).

8 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).

9 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).

10 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).

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, Articles 6(4) and 16(1) of Directive 92/43/EEC and for the purposes of Article 4(14) and (15) and Article 5(11) and (12) of Regulation (EU) 2024/1991 strategic projects in the Union may be considered to have an overriding public interest and to serve the interests of public health and safety provided that all the conditions set out in those acts are fulfilled.

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

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

2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[11], the combined assessment shall also cover those impacts ***The fact that assessments are combined pursuant to this paragraph shall not affect their content, or quality or robustness of the assessment.***

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

[11] Directive 2014/89/EU of the European Parliament and of the Council of 23 ELI: http://data.europa.eu/eli/dir/2014/89/oj July 2014 establishing a framework for maritime spatial planning (OJ L 257, 28.8.2014, p. 135, ELI: http://data.europa.eu/eli/dir/2014/89/oj).

Article 14

Applicability of UNECE Conventions

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

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

Corresponding recitals

(19) The production of medicinal products has environmental implications and may negatively impact not only the environment itself but also human health. The environmental assessments and authorisations required under Union law are an integral part of the permit-granting process for strategic projects and an essential safeguard to ensure negative environmental impacts are prevented or minimised. However, to ensure that permit-granting processes for strategic projects are predictable and timely, it should be possible to streamline the required assessments and authorisations by the relevant authority, while not lowering the level of environmental protection.

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

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

5. COMPROMISE AMENDMENT 5 (ART 15-17 AND RECITALS 21-23)

If adopted AMs 15-16, 89-100, 304-324, 727-849, ITRE 15-17, 53-59 fall

SECTION III

FINANCIAL INCENTIVES

Article 15

Financial support by Member States

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

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

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

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

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

3. The Member State that provided financial support to a strategic project may request such ***project promoter*** to ***prioritise and*** provide the necessary supplies of a critical medicinal product ***or, where applicable, medicinal product of common interest***,

active substance or key inputs, as applicable, to the Union market ***as a priority*** to avoid shortages in one or several Member States.

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

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

3b. Where there is a substantiated risk that export of a critical medicinal product or, where applicable, medicinal product of common interest, would undermine supply within the Union, and upon request by at least one Member State, the Commission may require the project promoter benefiting from financial support to obtain an export authorisation before transferring such products outside the Union. This measure shall be proportionate, time-limited and targeted to safeguard public health within the Union.

3c. Where financial support has been granted, the project promoter shall demonstrate that the funds have been used within the territory of the Union.

Article 16

Financial support from the Union

1. ***All the Union funding under the current and future*** Multiannual Financial ***Frameworks***, including to ***regional policy funding*** programmes***, may support strategic projects unless explicitly excluded by the legal basis or the scope of relevant programmes and*** provided that such support is in line with the objectives set out in the regulations establishing those programmes.

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

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

2. At the request of a project promoter, justified by necessity to provide results of vulnerability evaluation for the purpose of an application for Union funding, the designated authority shall assess whether a strategic project addresses a vulnerability

in the supply chains identified following the vulnerability evaluation. The designated authority shall provide its assessment to a project promoter within 15 working days of its request. The designated authority shall inform the Commission about the strategic projects identified as addressing an existing vulnerability in the supply chains without delay.

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

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

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

2d. ***Where financial support has been granted, the project promoter shall demonstrate that the funds have been used within the territory of the Union.***

Article 17

Exchange of information on funded projects

1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article 2***5*** of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article ***26***. ***This information shall include a description of how the project meets one or more of the criteria listed in Article 5.***

2. The Commission shall ***regularly*** inform the Critical Medicines Group of the strategic projects that benefited from financial support from the Union ***including information on how these projects meet the criteria listed in Article 5.***

   The Commission ***shall*** inform the Critical Medicines Group of ***its*** intention to propose the establishment of funding possibilities ***to support strategic projects. It shall also*** inform ***the Critical Medicines Group*** of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes.

Corresponding recitals

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

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

(23) To allow for a more coordinated approach to financial support, it is appropriate that Member States and the Commission exchange the information on financial support to strategic projects. ***In doing so, an appropriate level of confidentiality of sensitive business information and data obtained should be respected and protected, such as details of value chains, the disclosure of which could harm the competitive position of the companies involved. The Commission and the national competent authorities, their officials, employees and other persons working under the supervision of those authorities as well as officials and employees of other authorities of the Member States should not disclose information acquired or exchanged by them pursuant to this Regulation where such information is covered by the obligation of professional secrecy. This should also apply to the Critical Medicines Coordination Group. The data collated pursuant to this Regulation should be handled and stored in a secure environment.*** As regards the strategic projects that have benefitted from EU funding, the beneficiaries should follow the relevant communication and visibility rules[12].

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

6. COMPROMISE AMENDMENT 6 (ART 18-20 AND RECITALS 24-31)

If adopted AMs 17-25, 101-113, 325-374, 850-1015, ENVI 6, 19-22, ITRE 18, 60-64, IMCO 8-10, 18-28 fall

Chapter IV
Demand side measures

SECTION I

AWARD CRITERIA AND OTHER PROCUREMENT REQUIREMENTS AND RELATED MEASURES

Article 18

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

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

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

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

For the purposes of this paragraph, a 'significant proportion' of the manufacture of a critical medicinal product shall be considered to take place within the Union if at least one of the following conditions is met:

(a) at least 50% of the active substance used in the manufacture of the product is produced within the Union or, where appropriate, the EFTA countries;

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

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

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

For the purposes of this paragraph, a 'significant proportion' of the manufacture of a medicinal product of common interest shall be considered to take place within the Union if at least one of the following conditions is met:

(a) at least 50 % of the active substance used in the manufacture of the product is produced within the Union or, where appropriate, the EFTA countries; or, in the case of medicinal products of common interest for which no relevant substitute is produced within the Union, any third country with which the Union has established a strategic partnership within the meaning of Article 27 of this Regulation;

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

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

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

4. ***Procurement procedures under this Chapter shall, include*** additional qualitative ***criteria***, ***in particular criteria relating*** to environmental sustainability and ***the promotion of*** social rights.

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

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

Article 19

Programmes supporting sustainability and resilience in public procurement procedures

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

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

Article 20

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

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

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

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

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

2. The Commission shall, following a consultation with relevant stakeholders, including patient and consumer organisations, healthcare professional organisations, public healthcare payers, and marketing authorisation holders, issue Union guidelines recommending the establishment of common standards for contingency stocks and national stockpiles to support Member State activities, ensuring predictability for economic operators. Those common standards may include:

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

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

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

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

3. During health emergencies and crises, Member States authorities and Union preparedness authorities shall closely coordinate the distribution of critical medicinal products, in particular with systemic wholesalers, in order to ensure equitable and

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

Corresponding recitals

(24) Given that public authorities or entities are the principal buyers of medicinal products for the inpatient sector and that the public procurement of medicinal products is a powerful tool to improve security of supply and the availability and accessibility of other medicinal products of common interest, it is necessary to establish rules that require the use of the procurement requirements referring to Most Economically Advantageous Tender (MEAT) that take into account the supply security and availability considerations ***as well as support the commercial viability of the procurement procedures in a way that actively encourages the participation of pharmaceutical manufacturers in procurement processes***. Procurement requirements based on such considerations should include ***value-based criteria, such as product quality measured by patient impact and clinical value,*** stockholding obligations, a number of diversified suppliers, state of the art monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery and measures in case of non-timely delivery.

(24 a) In order to strengthen the resilience of supply chains for medicinal products and to mitigate the risk of supply disruptions, procurement procedures carried out under this Regulation should, where appropriate, allow for the award of contracts to multiple suppliers for the same product. Such multi-winner procurement approaches can promote diversification of supply, enhance security of supply, and ensure that production capacity is distributed across different manufacturers and geographical locations within the Union. In addition, to provide market predictability and support investment in the production of medicinal products, procurement procedures under this Regulation should, where justified, include predictable mix and weighting of qualitative criteria. Those commitments can serve as an incentive for manufacturers to maintain or scale up production capacity, particularly for medicinal products that are essential for public health but may not be commercially attractive under standard market conditions

(25) Inconsistent use of procurement requirements in public procurement procedures may have negative impact on the internal market as it creates obstacles to cross-border participation and a lack of predictability for bidders. In order to avoid such negative outcomes, the use of MEAT criteria should be mandatory. ***To minimise market fragmentation and create certainty and predictability for both public health system payers as well as for pharmaceutical manufacturers, the Commission should coordinate and maintain a catalogue of such MEAT criteria, as well as relevant best practices to using them in public procurement, for use by the Member States.***

(26) To ensure a high level of health protection and security of supply, it is necessary to procure in a way that promotes diversification of suppliers where dependency on a single or a limited number of third countries, threatening the security of supply, has been established through a vulnerability evaluation. In such situations, contracting authorities in the Member States should introduce procurement requirements that favour suppliers of critical medicinal products that manufacture a significant portion of these products in

the EU. Moreover, the contracting authorities in the Member States, when justified by market analysis and public health considerations, ***should*** apply procurement requirements that favour suppliers of medicinal products of common interest that manufacture a significant portion of these medicinal products in the EU. These measures should be designed and applied in line with the Union's international obligations including the principles of non-discrimination and proportionality. ***In order to ensure legal certainty and consistency in its application, it is important to determine what constitutes a significant proportion of production within the meaning of this Regulation. In that sense, a significant proportion of the production should take place within the Union or, where appropriate, the EFTA countries, in line with the objective of reinforcing the Union's open strategic autonomy.***

(27) The application of procurement requirements should take into account the specific market conditions and public health needs of each procurement procedure, whilst bearing in mind the considerations related to affordability of medicinal products. Certain procurement requirements may not be justified if they result in disproportionate cost for procurers or discourage participation, leading to no bids.

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

(29) The Commission ***should, after consultation with relevant stakeholders such as patients and consumer organisations, healthcare professionals, public healthcare payers and marketing authorisation holders,*** issue guidelines designed to support Member States in implementing their obligations to use procurement requirements including award criteria beyond price considerations with a view to strengthening the security of supply, building on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate.

(30) The procurement of medicinal products is organised differently across Member States, involving various actors. To strengthen the security of supply chains for critical medicinal products, Member States should establish national programmes that promote the consistent use of procurement criteria by contracting authorities within their territory, including the application of multi-winner approaches where beneficial, based on thorough market analysis. To ensure a comprehensive approach, and considering that critical medicinal products are also relevant for outpatient sector where they are often not purchased through public procurement, these programmes may also encompass measures to strengthen supply chain resilience and sustainability through measures related to pricing and reimbursement, where appropriate. ***Such programmes should take into account the economic viability of critical medicines, and recommend relevant measures, including exemptions of specific categories of critical medicines, such as products derived of substances of human origin (SoHO), from national cost containment measures.*** The programmes should be shared with the Commission and the Critical Medicines Coordination Group, established by this Regulation, to facilitate the exchange of best practices and coordination between the Member States. This cooperation should enhance the overall effectiveness of the various measures put

forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality***, as well as the exchange of best practices in stock management, real-time monitoring, expiry alerts, stock rotation, shelf-life optimisation and waste reduction to further strengthen the Union's preparedness and operational effectiveness. These practices will contribute to greater efficiency, minimise losses, and ensure the availability of critical medicinal products during periods of high demand.***

(30 a) In view of the increasing vulnerabilities in the supply chains of critical medicinal products and the resulting risks of supply disruptions and shortages that can seriously endanger public health and disrupt the functioning of the internal market, it is necessary to establish a Union coordination mechanism operated by the Commission. That mechanism should serve as a structured, solidarity-based instrument to monitor availability, coordinate responses, and, where necessary, enable medicinal products to be redistributed equitably across the Union. While safeguarding the principle of subsidiarity, the mechanism should only be activated as a measure of last resort when all other national and voluntary Union-level means have been exhausted and where shortages or disruptions in one or more Member States are likely to result in serious harm to patients or affect other Member States. Binding redistribution decisions should be based on objective risk assessments and real-time data and should ensure that the Member States providing assistance retain adequate minimum stock levels. To support timely and informed decisions, Member States should report regularly on their national stockpiles and contingency stocks through a harmonised, digital reporting system. Additionally, fair reimbursement and cost-sharing provisions should ensure that solidarity is matched by equity. In order to ensure uniform conditions for the implementation of reporting obligations in relation to national stockpiles and contingency stocks, as well as of procedures for reimbursement or replacement, and for cost-sharing mechanisms between Member States, in the event of a binding redistribution decision, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.

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

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

(30 d) To improve the functioning of the pharmaceutical market in the Union, Member States and the Commission should, when implementing pricing and public procurement practices, take action to achieve the objectives of the 2019 World Health

Assembly Resolution on Improving the transparency of markets for medicines, vaccines, and other health products.

(31) Obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold contingency stocks can have a serious negative impact on the internal market and other Member States. To avoid such an impact, these obligations should be designed taking into consideration the principles of proportionality, transparency and solidarity ***and non-discrimination***. The Member States should give due consideration to forthcoming Commission guidelines designed to facilitate the fulfilment of Member States' obligations as regards the absence of any negative impact on the internal market when proposing and defining the scope and timing of any form of requirements for companies to hold such stocks. ***Effective coordination mechanisms at Union level are therefore necessary to address possible conflicts and to ensure that national measures do not delay patient access, distort supply chains, or fragment the internal market.***

7. COMPROMISE AMENDMENT 7 (ART 20 A (NEW) TO ART 20 H (NEW))

If adopted AMs 114-122 and 1016-1026 fall

SECTION Ia (NEW)

UNION COORDINATION MECHANISM FOR CRITICAL MEDICINAL PRODUCTS

Article 20a

Establishment of a Union coordination mechanism for critical medicinal products

A Union coordination mechanism for national stockpiles and contingency stocks of critical medicinal products is hereby established. It shall be operated by the Commission in collaboration with the Agency and the Critical Medicines Coordination Group.

Through that coordination mechanism, the Commission shall:

(a) monitor the availability and distribution of critical medicinal products across the Union;

(b) enable effective and equitable redistribution in cases of a shortage or a supply disruption in one or more Member States that has a negative impact on the internal market or on other Member States.

Article 20b

Redistribution decisions

1. Where a shortage or a supply disruption of a critical medicinal product is identified in one or more Member States, the Commission shall, as a last resort and only after all other measures have been exhausted, including the voluntary mechanisms provided for in Union legislation, and upon a justified and substantiated request of one or more Member States concerned and subject to the prior approval of the Critical Medicines Group, adopt a binding decision requiring redistribution from a national stockpile or a contingency stock.

2. Any distribution decision as referred to in the first paragraph shall:

(a) be based on an objective risk assessment and regularly updated data establishing both the shortage or supply disruption resulting in serious harm or risk of serious harm to patients and the negative impact in the internal market;

(b) specify the quantities to be transferred, the timeframe for delivery, and any other necessary logistical arrangements;

(c) ensure that transferring Member States retain adequate minimum levels of the relevant medicinal product.

3. A distribution decision adopted pursuant to this Article shall specify the date at which it takes effect and shall be notified by the Commission to the Member States concerned without delay/within ... [and at least 20 days before its date of application].

Article 20c

Appeal mechanism

1. A Member State concerned by a redistribution decision adopted and notified pursuant to Article 20b may submit a reasoned request for a review of the decision referred to in that Article. Such a request shall be submitted to the Commission within 10 days of the notification referred to in that Article and shall state in detail the reasons for which that Member State considers that the decision does not comply with the conditions laid down in that Article or that its application would pose a disproportionate risk to public health.

2. Following consultation of the Critical Medicines Coordination Group, the Commission shall adopt a review decision within 10 days of receipt of the reasoned request referred to in paragraph 1. That decision shall confirm, amend or revoke the distribution decision adopted and notified pursuant to Article 20b and shall state the reasons on which it is based.

3. The submission of a request for review shall not suspend the application of the distribution decision adopted and notified pursuant to Article 20b, unless the Commission, on duly justified grounds, decides to grant a suspension pending the outcome of the review.

Article 20d

Stockpile information and reporting obligations

1. The Commission shall establish and maintain a digital reporting system that enables real-time updates on the status of national stockpiles and contingency stocks where such national stockpiles or contingency stocks are established under national law.

Each Member State shall report to the European Commission at least quarterly on the status of their national stockpiles and contingency stocks, and immediately upon any significant change in stock levels.

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

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

(b) the quantities of such stocks;

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

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

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

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

Article 20e

Committee procedure

1. The Commission shall be assisted by the Standing Committee on medicinal products for human use established by Article 214 of Directive (EU) …/… of the European Parliament and of the Council [reference to be added after adoption cf. COM(2023) 192 final]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

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

Article 20f

Obligations of Member States

Where the Commission adopts a redistribution decision pursuant to Article 20b, Member States shall:

(a) comply with that redistribution decision;

(b) notify, without undue delay, the Commission and the Agency if they impose contingency stocks requirements on economic operators;

(c) cooperate fully and without delay and, where necessary, provide mutual support to any other Member State that has requested assistance pursuant to Article 20b(1), with a view to preventing or mitigating shortages of critical medicinal products.

Article 20g Reimbursement and replacement

1. Where a Member State or economic operator transfers critical medicinal products in accordance with a binding decision adopted pursuant to Article 20b, it shall be entitled to full reimbursement from the receiving Member State for the value of the critical medicinal products transferred and the costs of transport and a reasonable mark-up.

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

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

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

Article 20h

Union Stockpile

1. In order to ensure the timely and effective availability of critical medicinal products with identified vulnerabilities in their supply chains, a Union Stockpile may be established as a last-resort mechanism to be activated in situations where the Union coordination mechanism for critical medicinal products indicates the existence of a recurrent or persistent shortage in national stockpiles and contingency stocks.

2. The Commission is empowered to adopt delegated acts in accordance with Article 30a to supplement this Regulation by establishing:

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

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

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

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

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

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

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

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

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

8. COMPROMISE AMENDMENT 8 (ART 21-24 AND RECITALS 32-36)

If adopted AMs 26-27, 123-142, 375-390, 1027-1121, IMCO 11, 29-49 fall

SECTION II
COLLABORATIVE PROCUREMENTS

Article 21

Commission facilitated Member States' cross-border procurement

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

2. Having received the request, the Commission shall inform all other Member States of the initiative and set an appropriate deadline for them to declare interest. Such a deadline shall not exceed three weeks.

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

4. If the Commission declines the request, it shall provide reasons for the refusal.

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

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

6a. The Commission shall act as a facilitator under this Article subject to the acceptance of the following conditions by the requesting Member States:

(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patients needs in their territory;

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

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

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

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

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 not bear any liability associated with the conduct of the procurement procedure by interested Member States and implementation of the contract resulting from the procedure.

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

Article 22

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

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

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

(b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [13], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.

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

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

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

5. The Commission shall ***communicate to*** the ***requesting*** Member States ***its decision*** within one month of the request, and state its reasons in case of a refusal. ***It shall inform the European Parliament thereof.***

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

5b. The Commission shall conduct a procurement on behalf or in the name of Member States under this Article subject to the acceptance of the following conditions by the requesting Member States:

(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patient needs in their territory;

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

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

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

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

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

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

~~6. deleted~~

7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509[14].

Article *23*

Joint Procurement

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

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

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

   (b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [15], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.

3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply***,*** availability ***and affordability*** of critical medicinal products in the Union or ***to*** ensure the availability

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14 Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast) (OJ L, 26.9.2024, p. 1, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).

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

accessibility ***and affordability*** of medicinal products of common interest, as applicable.

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

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

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

5b. The Commission shall conduct a joint procurement under this Article subject to the acceptance of the following conditions by requesting Member States:

(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patient needs in their territory;

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

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

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

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

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

~~6. deleted~~

7. The Commission shall ***communicate*** to the ***requesting*** Member States ***its decision*** within one month of the request, and state its reasons in case of a refusal.

8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.

Article 24

Agreement concerning procedures under Article 22 and 23

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

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

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

Corresponding recitals

(32) Availability and access disparities exist for critical medicinal products and medicinal products of common interest throughout the Union, disproportionately affecting some Member States. The collaborative procurement of critical medicinal products and of medicinal products of common interest can be a powerful tool to improve their security of supply and accessibility ***including medicines for rare diseases, antimicrobials, and other innovative, high-cost, or specialised treatments across various therapeutic areas, such as oncology***. ***Economic operators participate in collaborative procurement procedures conducted pursuant to this Regulation on a voluntary basis.***

(33) Directive 2014/24/EU of the European Parliament and of the Council[16] provides for the possibility of procurement involving contracting authorities from different Member States. Whereas it has been found helpful to make small markets attractive for suppliers,

[16] 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).

thereby achieving better availability of medicinal products, its implementation is time- and resource-intensive, especially in the starting phase, and considered a limiting factor. To facilitate the deployment of procurement initiatives involving contracting authorities from different Member States, the Commission, when requested, should provide its assistance during the preliminary phase of setting up such a procurement initiative.

(34) Taking into account experiences resulting from the implementation of joint procurement of medical countermeasures pursuant to Regulation (EU) 2022/2371 of the European Parliament and of the Council[17] and of COVID-19 vaccines, pursuant to Council Regulation (EU) 2016/369[18] in the context of the EU Vaccines Strategy and acknowledging potential benefits that leveraging of several Member States demand in one procurement procedure may have, Member States should be able to consider the use of joint procurement or to consider requesting the Commission to procure on their behalf, or in their name, where such procurement could contribute to the achievement of the objectives of this Regulation.

(35) To ensure that the collaborative procurement initiatives contribute to the achievement of the objectives of this Regulation, while fully respecting the principle of subsidiarity, the Commission's involvement in joint procurement and procurement on behalf, or in the name of the Member States, should be limited to defined cases. For this reason derogations from Article 168 (2) and (3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[19] should be provided.

(36) To ensure transparency, legal clarity, and effective coordination, structured agreement between the Member States and the Commission should govern procurement procedures under this Regulation that rely on an active Commission involvement. Such agreement should set out the division of responsibilities, decision-making processes, the information to be shared as relevant to the procurement procedure, including information on Member States' participation in parallel negotiations through different channels in relation to the same medicinal products or the same active substances as appropriate, and liability provisions, ensuring a fair and efficient framework for participating Member States while preventing market distortions and supply disruptions. This Regulation is without prejudice to and does not prevent the use of joint procurement procedures established under Regulation (EU) 2022/2371 of the European Parliament and of the Council for those critical medicinal products and other medicinal products that also fall within the definition of medical countermeasures as set out in that Regulation. For such medicinal products, the objective of the joint procurement initiative should determine the applicable framework. Where a joint procurement procedure is initiated with the aim of advance purchasing of these medicinal products as medical countermeasures to prepare for and respond to serious cross-border threats to health, such a procurement procedure should be carried out in accordance with Regulation (EU) 2022/2371. This Regulation is without prejudice to Council Regulation

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17 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).

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

19 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).

(EU) 2022/2372[20] setting the framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

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

9. COMPROMISE AMENDMENT 9 (ART 25-31 AND RECITALS 37-41)

If adopted AMs 28-32, 391-418, 143-169, 1122-1313, ENVI 7-9, 23-26, ITRE 19-24, 65-86, IMCO 12-14, 50-55 fall

Chapter V
Critical Medicines Coordination Group

Article 25

Establishment of Critical Medicines Coordination Group

1. A Critical Medicines Coordination Group ('Critical Medicines Group') is hereby established.

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

2a. The representatives appointed to the Critical Medicines Group and its working group or working groups shall make a declaration of their financial and other interests and update it annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve, or give rise to, a conflict of interest.

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

4. The Commission***, acting as the Secretariat of the Critical Medicines Group,*** shall organise ***regular meetings*** and coordinate the work of the Critical Medicines Group.

5. A representative of the Commission shall chair the meetings of the Critical Medicines Group.

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

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

7. The Critical Medicines Group shall use its best endeavours to reach consensus, where possible. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the Critical Medicines Group's position.

Article 26

Tasks of the Critical Medicines Coordination Group

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

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

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

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

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

(c) facilitate discussion of the need for a collaborative procurement initiative for a given medicinal product;

(ca) issue guidelines on measures to support availability and affordability in the Union market of critical medicinal products in the context of strategic projects that have received financial support;

(d) ***provide recommendations to*** the MSSG ***on*** order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of existing evaluations where necessary***;***

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

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

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

(dd) assess Union needs to determine whether specific projects concerning medicinal products of common interest should qualify as strategic projects;

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

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

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

(dh) based on relevant financial expertise, examine the bottlenecks and Union wide financial needs of strategic projects, advise on ways of coordinating Union and national financing with regard to those financial needs, and share best practices;

(di) establish the process for the strategic foresight report and prepare the annual strategic foresight report on strategic projects in accordance with Article 26a;

(dj) issue a recommendation concerning the applicability of any of the provisions referred to in Article 2 (2a) to medicinal products of common interest.

2a. In carrying out the task referred to in paragraph 2(dc) of this Article, only the representatives of the Member States within the Critical Medicines Group shall have

the right to vote. The decision shall be adopted by a two-thirds majority of the Member States present and voting.

3. The Critical Medicines Group shall enable the exchanges of information between the Member States and the Commission as referred to in Article 17 and shall enable, where necessary, a coordination of respective actions aiming to attain the objectives of this Regulation.

4. The Critical Medicines Group shall periodically discuss the potential contribution of strategic partnerships to the objectives of this Regulation, prioritisation of third countries for this purpose, and the consistency and potential synergies between Member States' cooperation with relevant third countries and the actions carried out by the Union.

5. The Critical Medicines Group, at the Commission's request, may provide an opinion on matters related to the application of this Regulation in the context of performing tasks as referred to in this Article.

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

Article 26a

Strategic Foresight on Critical Medicinal Products

1. In order to strengthen the Union's preparedness and ensure a coordinated approach to future challenges in the supply of critical medicinal products, the Critical Medicines Group shall establish a strategic foresight process.

2. The strategic foresight process shall be established after consultation with the Commission, the Agency, and the Critical Medicines Alliance.

3. The strategic foresight process shall identify medicinal products of common interest that would advance the objectives of this Regulation if included in Chapter III.

4. The strategic foresight process shall identify and assess potential strategic projects, taking into account long-term trends, vulnerabilities, opportunities for enhancing the resilience and sustainability of supply chains within the Union, and patients' unmet medical needs.

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

6. Following the preparation of the foresight report, the Critical Medicines Group shall make recommendations to the Commission and Member States on actions to be taken, including the identification and support of projects. Where there is a need to strategically reserve manufacturing capacity, recommendations shall specifically include proposals for strategic projects pursuant to Article 5(2), for the production of

specific pharmaceutical forms, active substances, key inputs, or technologies within a defined timeframe.

Chapter VI
International cooperation

Article 27

International cooperation and s*trategic partnerships*

Without prejudice to the prerogatives of the Council, the Commission, shall ***seek to conclude*** strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also ***aim to build*** on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union.

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

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

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

The Commission shall inform the Critical Medicines Group about possible strategic partnerships on an annual basis.

The Commission shall, within the framework of strategic partnerships, promote the harmonisation of Union quality, safety and environmental standards for pharmaceutical production between the Union and third countries.

By ... [two years from the entry into force of this Regulation], the Commission shall develop a structured methodology when identifying and prioritising such partnerships, distinguishing between:

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

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

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

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

Chapter VII
Amendments to Regulation (EU) 2024/795

Article 28

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

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

'(iii) biotechnologies, ***and directly related enabling technologies necessary for the development or manufacturing of critical medicinal products, including their active substances and key inputs,*** as defined in Critical Medicines Act *;

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* Regulation (EU) … of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of critical medicinal products as well as for improving the availability of, and access to, medicinal products of common interest, and amending Regulation (EU) 2024/795.' [*D.G.: reference to be completed with the definitive title of the 'Critical Medicines Act' and with its publications references once they are available*];'

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

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

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

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

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

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

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

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

Chapter VIII
Final provisions

Article 29

Obligation of the market actors to provide information

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

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

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

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

Article 29 a

Obligation of the Commission to collect information on medicinal products with no adequate Union substitute

1. The Commission shall collect the necessary information from the Agency and national authorities of the Member States and establish, taking as a basis the list of critical shortages of medicinal products referred to in Chapter X of Regulation (EU) No …/… [reference to be added after adoption cf. COM(2023) 193 final], a list of critical medicinal products originating from third countries for which no adequate substitute produced within the Union is available. The Commission shall maintain and keep that list regularly updated.

2. The list referred to in paragraph 1 shall serve to identify and monitor strategic dependencies and to support the adoption of appropriate measures under this Regulation aimed at ensuring the continuous supply and availability of such medicinal products within the Union.

3. In developing and updating the list referred to in paragraph 1, the Commission shall take into account the public health relevance, therapeutic importance, and criticality of the medicinal products.

Article 30

Evaluation

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

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

(a) data on the number of new manufacturing sites opened or modernised within the Union and the number of existing manufacturing lines extended;

(b) the number and nature of projects confirmed, supported, or recommended by the Critical Medicines Group under this Regulation;

(c) progress made in diversifying sources of active substances, starting materials, and other key inputs;

(d) the effectiveness of measures adopted to mitigate structural risks and strengthen supply resilience;

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

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

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

Article 30a

Exercise of the delegation

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

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

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

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

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

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

Article 31

Entry into force and application

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

It shall apply from [….].

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

Done at Strasbourg,

For the European Parliament

For the Council

Corresponding Recitals

(37) Ensuring a structured and coordinated approach to strengthening the security of supply of critical medicinal products requires collaboration between the Member States and the Commission. To facilitate this, the Critical Medicines Coordination Group ('the Critical Medicines Group') should be established to facilitate effective coordination across the relevant policy areas. The Critical Medicines Group should be composed of high-level representatives of Member States with expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health***, the European Medicines Agency ('the Agency) and representatives from patient organisations and healthcare professional organisations.*** The Commission should be a member of the group. To ensure structured discussions, the Commission should chair the Critical Medicines Group and perform the functions of its secretariat.

(38) To ensure coordinated implementation of this Regulation, the Critical Medicines Group should enable exchanges of information related to funding of strategic projects and facilitate the strategic orientation of financial support for strategic projects. The Critical Medicines Group should also facilitate the exchange of information on national programmes, including on the approach to contingency stock requirements in public procurement contracts. When relevant, the Critical Medicines Group should facilitate the coordination of national programmes. The Critical Medicines Group should furthermore facilitate discussions on the need to launch a collaborative procurement initiative and the need to prioritise the vulnerability evaluation for specific critical medicinal products. ***In order to ensure solidarity and an effective Union-level response to shortages or supply disruptions of critical medicinal products, it is necessary to establish a clear decision-making process for the redistribution of such products. To that end, the Member States should be included in the decision-making process through the Critical Medicines Group established under this Regulation.***

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

(39) The Union ***should*** further enhance the availability and security of supply of critical medicinal products by providing access to alternative sources of supply in third

countries through international trade agreements or other forms of international cooperation. The Union ***should***, to that end, rely on its network of existing trade agreements and additionally pursue strategic partnerships with third countries to further deepen bilateral cooperation, especially with candidate countries. In this context, the Commission should assess whether existing partnerships effectively address the intended aims or could be further improved or upgraded, and what types of potential partnerships could be concluded with the most relevant third countries. This should be done without prejudice to the prerogatives of the Council in accordance with the Treaties. ***As part of these partnerships, the Commission should promote a collaborative innovation ecosystem that integrates small and medium-sized enterprises, start-ups and deep-tech innovators alongside established pharmaceutical companies in order to enhance resilience, foster technological advancement and boost the competitiveness of the Union's pharmaceutical sector. The Commission should specifically consider the inclusion of access to active pharmaceutical ingredients (API) and their starting materials in the scope international partnership.***

(40) To ensure the application of this Regulation, it is necessary that economic operators make available information and data to public authorities. The Member States and the Commission must therefore be able to request, when necessary and avoid duplication of information requests, the information necessary for the application of this Regulation, including its evaluation, from any economic operator in the supply and distribution chains of critical medicinal products and medicinal products of common interest.

(41) In order to ensure that this Regulation effectively meets its objectives, it is essential to assess its implementation and impact over time. The Commission should carry out an evaluation of this Regulation five years after its application and every five years thereafter. This evaluation should include an assessment of the extent to which the Regulation's objectives, as set out in Article 1, have been achieved, including its impact on stakeholders, regulatory procedures, and market dynamics. In particular, the Commission's evaluation should take into account the views of Member States, economic operators, and other relevant stakeholders, ensuring that their feedback contributes to the continuous improvement of the regulatory framework. The results of this evaluation should be presented to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. In order to facilitate this evaluation, national authorities and economic operators should provide relevant data and information upon request to support the Commission's assessment. ***When an evaluation reveals a potential risk to the availability or security of supply of a critical medicinal product in the Union, the Commission should conduct a coordinated, evidence-based assessment and, where appropriate, propose proportionate mitigating measures in consultation with Member States and relevant stakeholders to safeguard continuous supply.***

10. COMPROMISE AMENDMENT 10 (CITATIONS AND RECITALS 1-11, 42)

If adopted AMs 1-6, 172-241, 419-425, ENVI 1-2, ITRE 1-9, IMCO 1-2 fall

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

(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[21],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and activities. The availability of safe, efficacious and high-quality medicinal products***, underpinned by a resilient and competitive pharmaceutical industry and secure, reliable supply chains forming the backbone of the supply of medicine,*** is vital to achieving this objective and to safeguarding public health across the Union ***and improving the preparedness and the Union's overall security***.

(2) In recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages of medicinal products for which insufficient supply ***and lack of transparency of supply chains*** results in serious harm or risk of serious harm to patients ***and healthcare systems***.

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

(3) Shortages of medicinal products can have very different and complex root causes, with challenges identified along the entire pharmaceutical value chain. In particular, shortages of medicinal products can result from supply chain disruptions and

[21] OJ C , , p. .

vulnerabilities affecting the supply of key ingredients and components***, including starting materials, intermediates and other raw pharmaceutical materials and feedstock***. These include existing dependencies on a limited number of suppliers globally and lack of Union capacities to produce certain medicinal products, their active substances or key raw pharmaceutical materials. Through diversification of supply sources and investment in local production, the Union can reduce its risk of exposure to shortages of medicinal products.

(4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in particular, for key raw pharmaceutical materials and active substances. Setting up new, ***expanding*** or modernising existing manufacturing capacities in the Union for critical medicinal products, their key inputs and active substances, which have often been on the market for a long time and are considered to be relatively inexpensive, is currently not seen as a sufficiently attractive option for private investment, also in view of lower energy costs, lesser environmental and other legal requirements elsewhere in the world. Workforce shortages and the need for specialised skills in pharmaceutical manufacturing further add to the industrial challenges to manufacturing in the Union. Targeted financial incentives, simplified administrative processes, and better Union-level coordination can contribute to supporting efforts to increase manufacturing capacities in the Union and strengthen the supply chains for critical medicines ***whilst upholding the highest social, health and environmental standards. Moreover, strengthening skills and knowledge transfer will help build a resilient and future-ready workforce capable of smoothly embracing innovation and technological advancement. At the same time, developing manufacturing capacity throughout the supply chain requires substantial long-term investment, adequate industrial infrastructure, strong research capabilities, regulatory predictability and a skilled workforce.***

4a While medicine shortages can occur for any type of product, they disproportionately affect older, off-patent, and generic medicines, primarily due to their low profit margins, which reduce incentives for investment in robust manufacturing capacity. Older, off-patent, and generic medicines make up the majority of the medicinal products placed on the Union List of Critical Medicinal Products, due to low profit margins that limit investment in manufacturing. Many off-patent and generic medicines suppliers have outsourced manufacturing or relocated production of finished products outside the Union, and frequently source their APIs from third countries. Consequently, the Union relies on a limited number of API suppliers and manufacturers, many located outside its borders.

(5) To enhance the security of supply for medicinal products and thereby contribute to a high level of public health protection, the Union has implemented a range of measures that contribute to building a European Health Union. In particular, Regulation (EU) 2022/123 of the European Parliament and of the Council[22] has reinforced the European Medicines Agency's ('the Agency') mandate by enhancing monitoring, coordination, and reporting mechanisms to prevent and mitigate supply disruptions of critical medicinal products across Member States. That Regulation also established the Agency's Executive Steering Group on Shortages and Safety of Medicinal Products ('the MSSG'), which brings together representatives from the Agency and Member

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

States, to coordinate urgent actions within the Union to manage existing shortages and issues related to the quality, safety, and efficacy of medicinal products.

(6) In addition, Regulation (EU) …/… of the European Parliament and of the Council[23] No *[reference to be added after adoption cf. COM(2023) 193 final*] further strengthens the continuity of supply and availability of medicinal products through developing the core tasks already granted to the Agency by Regulation (EU) 2022/123 and setting out a framework for the activities to be deployed by the Member States and the Agency to improve the Union capacity to react efficiently and in coordinated manner to support the shortages management and security of supply of medicinal products, including by strengthening the obligations of marketing authorisation holders as it regards the shortages prevention and reporting.

(7) However, despite regulatory obligations on marketing authorisation holders to ensure the continuous supply of medicinal products to meet patients' ***needs*** and the additional regulatory mechanism introduced by Regulation of the European Parliament and of the Council (EU) 2022/123 and Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023)193 final*] to mitigate and respond to shortages, the functioning of markets alone does not always guarantee the availability of medicinal products. This risk is particularly evident in cases of supply chain disruptions, especially when the supply of a given medicinal product relies on a limited number of global suppliers and production facilities or where there is a high dependency on a single or a limited number of third countries.

(8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care***, and enhance patient's access to medicines they need***. Uncoordinated national measures risk disrupting the internal market, fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for further harmonisation***, while avoiding duplication or overlap of existing structures***. *Furthermore,* ***existing data infrastructures and databases should be fully leveraged in order to reduce reporting burdens, streamline the monitoring of medicinal product supply chains, and improve the efficiency of data exchange between competent authorities and stakeholders. The use of existing structures would also help ensure more stable and predictable data flows.***

(9) Some medicinal products of common interest which are key for the provision of adapted care to patients, while not affected by supply security issues, may still not be ***available and accessible*** to patients in some Member States. This may be caused by a variety of factors, including ***administrative and budgetary barriers***, product or geographical demand market size, which can impact the timely availability of medicinal products in certain Member States ***increasing inequalities between patients in the Union and undermining the Union's commitment to achieving universal access to essential medicine by 2030 in line with the United Nations sustainable development goal 3.8***.

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[23] Regulation (EU) …/… of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ … *[OP: Please complete publication references]*).

This Regulation aims at strengthening the resilience of supply chains, addressing concrete security-of-supply vulnerabilities, and reducing such inequalities among Member States, ensuring more equitable access to medicinal products across the Union, so that patients enjoy the same level of access regardless of their country of residence.

(10) The smooth functioning of the internal market and a high level of protection of human health should be ensured as regards medicinal products and it should be aimed to complementing other Union pharmaceutical legislation by providing for a harmonised framework supporting Member States' coordinated efforts to encourage investments in new and existing manufacturing capacities for critical medicinal products, encouraging the strategic use of public procurement instruments by the Member States as well as the coordination of the Member States' approaches, including through leveraging aggregated demand through Commission facilitated collaborative procurement procedures of critical medicinal products and medicinal products of common interest. Due to the international dimension of the security of supply, in particular taking into account that diversification of supply chains and an overall increase of supply are elements of a solution for ensuring the security of supply, international cooperation should be encouraged.

(11) The measures introduced by this Regulation are without prejudice to marketing authorisation holders' obligations, in particular under Directive (EU) …/… of the European Parliament and of the Council [*reference to be added to corresponding Article after adoption of cf. COM(2023)192 final*], Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023) 193 final*] and Regulation (EU) 2022/123, including the obligation to ensure sufficient supplies of medicinal products, within the limits of their responsibility. These measures are aligned with the principles of the internal market. This Regulation is without prejudice to Union competition law, including antitrust, merger and State aid rules. ***The implementation of this Regulation should be coherent with Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space (EHDS) to enhance the interoperability, secure exchange, and real-time monitoring of health data relevant to the availability and supply of medicinal products. Improved integration between this Regulation and the EHDS will contribute to early detection of shortages, cross-border distribution, and streamlined access to critical medicines.***

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

(42 a) ***In order to supplement this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the specification and harmonisation of the conditions applicable to the determination of the categories, types and quantities of critical medicinal products to be included in the Union Stockpile, the determination***

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