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From:	Presidency
To:	Delegations
No. prev. doc.:	12773/25 + COR 1
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 - *Presidency's second compromise proposal*

Delegations will find, in the Annex of this note, a second Presidency compromise text on the above-mentioned proposal.

Changes compared to the Commission proposal are indicated in ~~strikethrough~~ for deletions and **bold/underline** for new text. In addition, changes compared to the first Presidency compromise text (ST 12773/25 + COR 1) are highlighted in grey.

ANNEX

HAVE ADOPTED THIS REGULATION:

Chapter I
General provisions

Article 1

Objectives and subject matter

1. The objective of this Regulation is to **improve the functioning of the internal market by establishing a framework to** strengthen the security of supply **and** the availability of critical medicinal products within the **internal market** ~~Union~~ **Union**, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of ~~other~~ medicinal products **of common interest** ~~**of common interest within the internal market to address market failure, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients.** ~~where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients~~, whilst giving due consideration to ~~the appropriateness to ensure~~ the affordability of **those** medicinal products.

2. To achieve the objectives referred to in paragraph 1, the Regulation sets out a framework to:

   (a) facilitate investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union;

   (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;

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

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

Article 2

Scope

1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products **with the exception of Articles ~~18(3) and~~ 21, which only ~~apply~~ applies to medicinal products of common interest** ~~referred to in Article 131 of Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023) 193 final*].~~

2. ~~Chapter IV~~ **Articles 1, ~~18(3a),~~ 22, 24,** ~~and Article~~ 26(2) point**s** (c) **and (db) and 26(3)** also apply to medicinal products of common interest. ~~Chapter III does not apply to medicinal products of common interest.~~

3. This Regulation complements the Union law on pharmaceuticals, state aid, permitting and public procurement by adding specific rules concerning critical medicinal products and medicinal products of common interest.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(1) ‘medicinal product’ means a medicinal product as defined in Article 4 point (1) of Directive (EU) …/… of the European Parliament and of the Council [*reference to be added to corresponding Article after adoption of cf. COM(2023)192 final*];

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

(3) ‘active substance’ means an active substance as defined in Article 4 point (3) of Directive (EU) …/… [*reference to be added to corresponding Article after adoption of cf. COM(2023)192 final*];

(3a) ‘starting material‘ means material as defined in Article 4 point (4) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];

(3b) 'excipient' means an excipient as defined in Article 4 point (5) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 finall;

(3c) "collecting" means collection of substances of human or animal origin for the purpose of being processed into active substances of critical medicinal products;

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

(5) 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States;

(6) 'vulnerability in the supply chains' means risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level, taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation, that **~~could~~** 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[1] *[reference to be added after adoption cf. COM(2023) 193 final];*

[1] 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]*.

(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*];

(8a) “marketing authorisation holder” means a holder of a marketing authorisation granted in accordance with Directive (EU) …/… of the European Parliament and of the Council or Regulation (EU) …/… of the European Parliament and of the Council [reference to be added after adoption cf. COM(2023) 192 final and COM(2023) 193 final];

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

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

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

(12) ‘permit granting process’ means a process covering all relevant permits to build and operate a strategic project, including~~, but not limited to,~~ 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, Artificial Intelligence, platform techniques, 3D manufacturing;

(15) ‘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;

(16) ‘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;

(17) ~~‘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;~~

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

~~(18a) ‘economic operator‘ means an economic operator as defined in Article 2(1) point (10) of Directive 2014/24/EU;~~

(18b) ‘contingency stock requirement‘ means an obligation imposed by a Member State on marketing authorisation holders and~~/or~~ other ~~economic~~ operators in ~~of~~ the supply chain to ~~establish buffer~~ hold stocks of certain medicinal products to safeguard the security ~~mitigate the risk~~ of supply ~~disruption~~ and which obligation is imposed by law, regulations or administrative provisions, including through the imposition of requirements on stockholding obligations in public procurement procedures. ~~, and/or results from mandatory contractual agreements (e.g. public procurement contracts).~~

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

~~**Chapter II**~~
~~**Strengthening the Union's security of supply**~~

~~*Article 4*~~
~~*Strategic objective of the Union*~~

~~1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.~~

~~2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market.~~

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

Chapter III
Enabling coditions for investment

SECTION I

CRITERIA AND PROCEDURE FOR THE RECOGNITION OF STRATEGIC PROJECTS

Article 5

Strategic Projects

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

(a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances;

(b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency;

(c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances **where it is demonstrated that there are supply constraints or limited manufacturing capacity in the Union**;

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

Article 6

Recognition of Strategic Projects

1. Each Member State shall designate an authority ('the designated authority') that shall assess ~~and verify~~ whether ~~or not~~ a project meets at least one of the criteria set out in Article 5 and therefore ~~constitutes~~ **may shall be recognised** ~~constitutes~~ **as** a strategic project.

A Member State may designate more than one designated authority at national or regional level.

2. **In order for a project to be recognised as a strategic project** ~~A~~**a project** promoter ~~may~~ **shall** request the designated authority to assess whether ~~a~~ **the** project is a strategic project. **The designated authority shall provide its assessment to the project promoter without undue delay.**

~~Any Member State authority may request the designated authority to verify its determination of whether a project is a strategic project.~~

The submission of a request for a project to be recognised as a strategic project as provided for in this paragraph does not preclude the project promoter from simultaneously ~~submitting~~ initiating applications ~~procedures~~ to other authorities for the permits needed for the project.

2.**3.** Member States shall communicate to the Commission ~~what is~~ the designated authorit**iesy** for the purposes of paragraph 1~~.~~ **and Article 16(2).**

~~3.~~**4.** The Commission shall provide a simple, accessible webpage on which the contact details and other relevant information on the **tasks of** Member States' designated authorities shall be clearly listed.

~~4.~~**5.** Any other ~~Member State~~ authority **in the Member State** that receives a request from a **project** promoter concerning Articles ~~8 to 14~~**157, 8, 11, 12, 13 and 15** shall **rely on the decision of the designated authority pursuant to paragraph 1 as to**~~assess~~ whether that given project ~~may be~~ **is recognised as**~~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 is a strategic project has been performed by an authority in accordance with this Article, any other authority shall rely on that verification.~~

~~**6. Where a project promoter submits a request to the designated authority pursuant to paragraph 2 as to whether a project is a strategic project, the project promoter shall notify the relevant competent authority for medicinal products in the Member State of the project promoter's intention to submit a request pursuant to Article 11(1).**~~

SECTION II

FACILITATING ADMINISTRATIVE AND PERMIT-GRANTING PROCESSES **FOR RECOGNISED STRATEGIC PROJECTS**

Article 7

Priority status of strategic projects

1. Strategic projects shall be considered as contributing to the security of supply of critical medicinal products in the Union and, therefore, to be in the public interest.

2. The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects are carried out **without undue delay** ~~in the fastest way possible~~, making available, in particular, any form of accelerated procedures that exists in applicable Union and national law.

Article 8

Administrative support

1. Upon request of a project promoter, **~~following the submission of an application to the national competent authority for a permit needed for a strategic project~~** a Member State shall **with regard to the relevant permit-granting processes related to strategic projects** provide to a strategic project located on its territory ~~all~~ the administrative support ~~necessary~~ to facilitate its ~~timely and effective~~ implementation, including assistance **in accordance with national ~~administrative procedure~~ law**:

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

   (b) ~~with regard to informing the public, with the aim of increasing public acceptance of the strategic project;~~

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

2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs) and, where **necessary** ~~appropriate~~**, may** establish a dedicated channel for communication with SMEs to provide guidance and respond to queries related to the implementation of this Regulation.

~~*Article 9*~~

~~*Request for granting the status of highest national significance*~~

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

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

~~*Article 10*~~

~~*Procedures relating to dispute resolution*~~

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

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

Article 11

*Regulatory ~~and scientific~~ support from **competent authorities for medicinal products** ~~medicines agencies and pharmaceutical inspectorates~~*

1. Upon request of a project promoter, a Member State shall provide regulatory support to a strategic project located on its territory, including **administrative support for obtaining the necessary authorisations from the competent authority, and** by prioritising Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project.

2. Upon request of a project promoter, the European Medicines Agency ('the Agency') shall provide**, within the scope of its mandate and expertise,** dedicated advice to assist project promoters developing projects relying on innovative manufacturing processes. **Where the Agency provides such advice and the advice includes aspects related to Good Manufacturing Practices, which would be subject to review during inspections for manufacturing sites in a Member State, the Agency shall duly involve the relevant national competent authority for medicinal products ~~when providing~~ in the provision of such ~~the~~ advice.**

~~The Agency may upon request from a project promoter provide other dedicated advice than referred to in subparagraph 1, within the scope of its mandate and expertise, to assist project promoters.~~

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[2], Directive 2000/60/EC of the European Parliament and of the Council[3], Directive 2001/42/EC of the European Parliament and of the Council[4], Directive 2008/98/EC of the European Parliament and of the Council[5], Directive 2009/147/EC of the European Parliament and of the Council[6], Directive 2010/75/EU of the European Parliament and of the Council[7], Directive 2011/92/EU of the European Parliament and of the Council[8] or Directive 2012/18/EU of the European Parliament and of the Council[9], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied.

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2 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).

3 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).

4 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).

5 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).

6 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).

7 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).

8 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).

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

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

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

2. Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information.

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

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

5. With regard to the environmental impacts or obligations referred to in Article 4(7) of Directive 2000/60/EC, Article 9(1), point (a), of Directive 2009/147/EC, 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.

Article 13

Planning

1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant spatial planning data is available.

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[10], the combined assessment shall also cover those impacts.

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.~~

[10] 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).

SECTION III

FINANCIAL INCENTIVES

Article 15

Financial support by Member States

1. Without prejudice to **Union state aid rules as set out in Articles 107 and 108 TFEU and the Commission Regulation (EU) No 651/2014**~~Articles 107 and 108 TFEU~~, Member States may prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines **Coordination** Group **('CMCG')** referred to in Article 26(2) point (a).

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

   ~~**This obligation shall apply for the duration of the strategic project, unless otherwise provided by the Member State under the conditions attached to the financial support.**~~

   Where appropriate, the terms of the financial support shall stipulate for how long the obligation shall continue to apply in case the critical medicinal product is removed from the Union List of Critical Medicinal Products.

3. The Member State that provided financial support to a strategic project may **require** ~~request~~ such undertaking to **prioritise supply and** provide the necessary supplies of a critical medicinal product, active substance or key inputs, as applicable, to the Union market to avoid shortages in one or several Member States.

   Any Member State that encounters a threat of shortages of the critical medicinal product in question may **request** ~~demand~~ the Member State that provided financial support to submit a request on its behalf.

Article 16

Financial support from the Union

1. ~~For the duration of the Multiannual Financial Framework 2021-2027[11]~~ **Financial support for** strategic projects **[under the Multiannual Financial Framework 2021-2027[12]]** may be **provided** ~~supported~~ by **the** Union ~~funding~~ **from Union programmes**~~,~~ including but not limited to**,** ~~such Union programmes as~~ the EU4Health Programme **established by Regulation (EU) 2021/522**[13], Horizon Europe **established by Regulation (EU) 2021/695**[14], and the Digital Europe Programme **established by Regulation (EU) 2021/694**[15] provided that such support is in line with the objectives set out in the regulations establishing those programmes.

The amount of Union financial contribution under this Article shall be established in accordance with the rules of those programmes as part of the annual budgetary procedure, subject to the availability of funding. The budgetary authority shall determine the appropriation available each year.

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

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

~~[13] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of Health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, (OJ L 107, 26.3.2021, p.1, ELI: http://data.europa.eu/eli/reg/2021/522/oj)~~

~~[14] Regulation (EU) 2021/695 of the European Parliament and of the council of 28 April 2021 establishing Horizon //Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L170, 12.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/695/oj)~~

~~[15] Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240(OJ L166, 11.5.2021, p.1, ELI: http://data.europa.eu/eli/reg/2021/694/2023-09-21)~~

2. At the request of a project promoter, justified by **the** 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 receiving the request** ~~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.

Where the designated authority considers that the submitted particulars accompanying the request referred to in the first subparagraph is incomplete, it shall inform the project promoter accordingly and shall set a time line for submitting the missing information and documentation. In case the designated authority sets such a time linme, the time line referred to in the first subparagraph shall be suspended until such time as the supplementary information and documentation required has b een provided for.

Article 17

Exchange of information on funded projects

1. Member States shall**, without prejudice to their right to decide whether to provide financial support to strategic projects,** inform the **CMCG** ~~Critical Medicines Coordination Group ('the Critical Medicines Group')~~ referred to in Article ~~24~~**25** of the intention to provide **such** financial support ~~to strategic projects sufficiently in advance to allow the group to carry out its~~ **sufficiently in advance to allow the group to carry out its ~~for the purposes of the group's~~** coordination task as set out in Article ~~25~~**26**.

2. The Commission shall inform periodically the ~~Critical Medicines Group~~ **CMCG** of the strategic projects that benefited from financial support from the Union **to allow the group to carry out its coordination task**.

The Commission ~~may~~ **shall** inform the ~~Critical Medicines Group~~ **CMCG** of **planned proposals for** ~~the intention to propose~~ the establishment of funding possibilities specifically designed to address vulnerabilities in the supply chains as well as inform of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes.

Chapter IV Demand side measures

SECTION I

~~AWARD CRITERIA AND OTHE PROCUREMENT~~ REQUIREMENTS **FOR PUBLIC PROCUREMENT PROCEDURES** AND RELATED MEASURES

Article 18

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

1. For ~~award~~ **public procurement** procedures ~~of critical medicinal products~~ falling within the scope of Directive 2014/24/EU ~~of the European Parliament and of the Council~~, **where contracts have critical medicinal products as ~~part of~~ their main subject matter,** contracting authorities ~~in the Member States~~ shall apply ~~procurement requirements other than price-only award criteria such as procurement~~ requirements that promote the resilience of supply in the Union.

These resilience requirements shall take the form of at least one of the following:

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

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

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

(c) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU~~; or~~.

~~(d) award criteria within the meaning of Article 67 of Directive 2014/24/EU.~~

Those ~~procurement~~ **resilience of supply** requirements ~~shall be defined in accordance with Directive 2014/24/EU and~~ may**, inter alia,** relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, ~~their~~ transparency **of the supply chains** ~~to the contracting authority~~ and contract performance clauses on timely delivery. ~~**Member States may specify such requirements in national laws, regulations, administrative provisions or in the national programmes referred to in Article 19 of this Regulation.**~~

The resilience requirements do not preclude contracting authorities from using multiple-winner approaches.

2. ~~With regard to~~ **For public procurement procedures, where contracts as ~~part of~~ their main subject matter have** 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 **outside the Union**, the contracting authorities shall~~, where justified, apply procurement requirements that~~ favour **~~economic operators~~** ~~suppliers that~~ **supply these critical medicinal products or their active substances ~~originating~~ manufactured** ~~manufacture a significant proportion of these critical medicinal products~~ in the Union.~~**, in a third country which is a Party to the WTO Agreement on Government Procurement or in a third country with which the Union has concluded a free trade agreement covering government procurement.**~~

Contracting authorities shall favour these critical medicinal products or their active substances by applying ~~The~~ requirements that ~~referred to in subparagraph 1 shall~~ take the form of at least one of the following:

~~(-a)~~ technical specifications or requirements within the meaning of Article 42 of Directive 2014/24/EU regarding critical medicinal products or their active substances; or

(a) ~~contract~~ best price-quality ratio as award criteria within the meaning of Article 67 of Directive 2014/24/EU ~~, that include the best price-quality ratio,~~ which may be assessed on the basis of criteria also relating to delivery condition for the critical medicinal products or their active substances ~~supplied or provided in the execution and duration of the contract such as delivery process and delivery security~~; or

(b) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU, ~~that~~ entailing that at least [25] % of the total contract value of the critical medicinal products or their active substances supplied or provided in the execution and duration of the contract are manufactured ~~and originating~~ in the Union~~, in a third country which is a Party to the WTO Agreement on Government Procurement or in a third country with which the Union has concluded a free trade agreement covering government are manufactured in the Union and represent at least [25] % or more of the total value of the contract~~. ~~irrespective of whether such products are supplied or provided directly by the successful tenderer or by a subcontractor.~~

~~Where contracting authorities apply contract performance clauses as provided for in subparagraph 2, point (bc) the contracting authorities must oblige the successful tenderer through a contract performance clause to provide to the contracting authority upon their request adequate evidence of the supply chain at the latest upon completion of the execution of the contract.~~

The requirements set out in this paragraph shall apply irrespective of whether products are supplied or provided directly by the successful tenderer or by a subcontractor.

The requirements do not preclude contracting authorities from using multiple-winner approaches.

The~~se~~ requirements **set out in this paragraph** shall be applied in compliance with the Union's international commitments ~~including the Government Procurement~~

Agreement in WTO and other international agreements of which the Union is bound.

3. With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities may apply procurement requirements **in accordance with the requirements set out in paragraph 2** that favour **economic operators** suppliers that manufacture at least a significant proportion of these medicinal products **supply these medicinal products originating** in the Union**, in a third country which is a Party to the WTO Agreement on Government Procurement or in a third country with which the Union has concluded a free trade agreement covering government procurement**. These requirements shall be applied in compliance with the Union's international commitments.

3a. For the purposes of determining the origin of critical medicinal products as referred to in paragraph 2 and the origin of medicinal products of common interest as referred to in paragraph 3 the origin shall be determined in accordance with Regulation 952/2013/EU.

3b. This Article shall not preclude Member States from specifying the requirements referred to in paragraphs 1 and 2 and defining additional requirements in accordance with Directive 2014/24/EU in national laws, regulations, administrative provisions or in the national programmes referred to in Article 19 of this Regulation.

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

5. Contracting authorities may exceptionally decide not to apply paragraphs 1 **and** ~~,~~ 2 ~~and 3~~ where**:** ~~- justified by market analysis or considerations related to the financing of health services.~~

(a) **the required critical medicinal product can only be supplied by a specific economic operator and no reasonable alternative or substitute exists and the absence of competition is not the result of an artificial narrowing down of the parameters of the public procurement procedure; or**

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

(c) **their application would oblige that contracting authority to acquire critical medicinal products having disproportionate costs; or**

(d) it is strictly necessary due to reasons of extreme urgency brought about by events unforeseeable by the contracting authority.

6. The Commission shall issue guidelines designed to support Member States in implementing the obligation to use requirements in public procurement procedures with a view to strengthening the security of supply at the latest 6 months after the entry into force of this Regulation. The guidelines shall respect the responsibilities of the Member States for the management of health services and medical care and the allocation of the resources assigned to them.

Article 19

Programmes supporting sustainability and resilience in public procurement procedures

1. By **12**~~6~~ months after entry into force of this Regulation each Member State shall**, with due respect to the organisation of the procurement of medicinal products within the Member State,** establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of ~~procurement~~ requirements **in public procurement procedures** by contracting authorities within a given Member State~~ as well as multi-winner approaches, where beneficial in light of the market analysis~~. Such programmes may also **promote the consistent use of multi winner approaches, where beneficial in light of the market analysis, and may** include measures~~ for pricing and reimbursement~~ supporting security of supply of~~ those~~ critical medicinal products that are not purchased through public procurement procedures.

2. Member States shall **inform** ~~notify their programmes to~~ the Commission in its role of the secretariat of the ~~Critical Medicines Group~~ **CMCG about their programmes.** The Commission shall ensure the distribution to all members of the **CMCG** ~~Critical Medicines Group~~ forthwith. The **CMCG** ~~Critical Medicines Group~~ shall facilitate a discussion **as referred to in Article 26(2), point (b) on the national programmes aiming to ensure coordination of national programmes** ~~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 on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact~~ **W~~w~~**hen **imposing requirements on marketing authorisation holders and other operators in the supply chain to hold contingency stocks for the purpose of safeguarding the security of supply of critical medicinal products within their territory, or making changes to existing requirements, Member States shall aim at ~~ensuring~~ avoiding that any form of such requirements negatively impacts the security of supply in other Member States in compliance with the internal market provisions of the TFEU. ~~that any form of such requirements do not compromise the security of supply in other Member States.~~** ~~proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks.~~

2. Member States shall ensure that any **contingency stocks** ~~-~~requirements **referred to in paragraph 1**~~they impose on companies in the supply chain to hold contingency stocks~~**, including ~~their scope and timing~~ the extent and implementation timeline,** are proportionate and respect the principles of transparency and solidarity.

3. ~~Member States shall, if contingency stocks requirements are deemed necessary, inform other Member States of their intention to impose these requirements or make significant changes to existing requirements, in the CMCG as specified in Article 26.~~

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

SECTION II

COLLABORATIVE PROCUREMENTS

Article 21

Commission facilitated Member States' cross-border procurement

1. Upon a reasoned request **from** ~~of~~ three or more Member States ('the request'), the Commission may act as facilitator for the requesting Member States' cross-border procurement as laid down in Article 39 of Directive ~~of the European Parliament and of the Council~~ 2014/24/**EU**~~C~~[16] **where the procurement concerns** ~~EC~~[17] ~~for~~ medicinal products of common interest.

2. Having received the request, the Commission shall inform all other Member States of the initiative and set a~~n appropriate~~ deadline **of** ~~15~~ **20 working days** for them to declare **their** interest **in participating in the procedure.** ~~. Such a deadline shall not exceed three weeks.~~**Participation in the procedure shall be voluntary for Member States.**

3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall **inform** ~~communicate to~~ the interested Member States **of** its decision on whether it agrees~~, or not,~~ to facilitate the proposed initiative within **15 working days** ~~three weeks~~ of receiving the request.

4. If the Commission declines the request, it shall **state its** ~~provide~~ reasons for the refusal.

5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the **involved** ~~interested~~ Member States. The Commission shall facilitate communication and cooperation between the involved Member States and provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products.

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[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/2014/24/2024-01-01).**

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

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

~~**The involved Member States may at any time decide to continue the procedure without the Commission's facilitation, including by agreement on another facilitator in accordance with Directive 2014/24/EU. Any involved Member State may withdraw from the procedure at any stage before the signature of the procurement contract.**~~

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 **no** ~~any~~ liability associated with the conduct of the procurement procedure by **participating** ~~interested~~ Member States **or for the** ~~and~~ implementation of the contract resulting from 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 **six** ~~nine~~ or more Member States jointly request **(`the joint request`),** the Commission to procure on their behalf, or in their name **and at their costs,** the Commission may initiate a procurement procedure under the conditions **laid down**~~set out~~ in this Article when the procurement **concerns** ~~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**/EU** ~~of the European Parliament and the Council~~ [18], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States **pursuant to** ~~as per~~ Article 23(1) point (e) of that Regulation.

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

3. The participation in the procurement procedure shall be open to all Member States. **Having received the joint request, t**~~T~~he Commission shall inform all **other** Member States of the **joint** request, through the ~~Critical Medicines Group~~ **CMCG**, and **set a deadline of** ~~15~~ **20 working days for them to declare their interest in participating in the procedure. Participation in the procurement procedure shall be voluntary for Member States** ~~invite them to join the procedure~~.

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

5. **Within 20 working days of receiving the joint request, t**~~T~~he Commission shall inform the interested Member States ~~within one month of the request~~ of its decision and state its reasons in case of a refusal.

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[18] 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)

6. ~~If in light of the Commission assessment, it is necessary, in order to achieve the objectives of this Regulation, to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, the Commission agreement to pursue the procedure may be conditioned upon acceptance of these conditions by interested Member States.~~ **Where based on its assessment, the Commission may, if necessary to achieve the objectives of this Regulation, make the initiation of the procurement procedure conditional upon the interested Member States accepting binding minimum quantities or refraining from participating in competing subsequent procurement processes. Such a procurement procedure may only be initiated once these conditions have been accepted by the interested Member States.**

6a. By way of derogation to Article 168(2) of Regulation 2024/2509/EU, at least six Member States may exceptionally initiate a joint procurement procedure together with the Commission.
The conditions established in paragraphs 1(a) and 1(b) as well as in paragraphs 2-6 of this Article apply mutatis mutandis to such procedure.

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[19].

~~*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 nine Member States may engage, as contracting parties, in a joint procurement procedure.~~

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

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

(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 [20], 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 and availability of critical medicinal products in the Union or ensure the availability and accessibility 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.

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

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

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[20] 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)

~~7. The Commission shall inform the interested Member States within one month of the request of its decision and state its reasons in case of a refusal.~~

~~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~~s~~ 22 ~~and 23~~

1. Member States participating in the procurement procedures covered by Article~~s~~ 22**,** ~~and 23~~ shall share with the Commission any information relevant for the procurement procedure. **The participating** Member States shall provide **the** resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge.

2. 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.

Chapter V
Critical Medicines Coordination Group

Article 25

Establishment of Critical Medicines Coordination Group

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

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

3. The **CMCG** ~~Critical Medicines Group~~ shall work closely with the MSSG, the Agency, and national **competent** authorities ~~responsible~~ for medicinal products. For discussions where input from the medicines regulatory authorities' perspective is necessary, the **CMCG** ~~Critical Medicines Group~~ may organise joint meetings with the MSSG.

4. The Commission shall organise and coordinate the work of the **CMCG** ~~Critical Medicines Group~~ by means of the Secretariat. **The CMCG shall establish its rules of procedure, including procedures relating to the working group referred to in paragraph 6.**

5. ~~A representative of the Commission shall chair the meetings of the Critical Medicines Group.~~ **The CMCG shall be co-chaired by a representative of the Commission and by a representative of the Member States, who shall be elected by and from among the representatives of the Member States.**

6. The **CMCG** ~~Critical Medicines Group~~, at the proposal of the **co-c**~~C~~hair or any **of** its members, may decide to establish a working group.

7. The **CMCG**~~Critical Medicines Group~~ shall use its best endeavours to reach consensus, where possible**, when providing advice as referred to in Article 26(2) points (d) and (db) and providing an opinion as referred to in Article 26 (3). If such consensus cannot be reached, the CMCG shall issue its position by a majority of its members.** ~~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.~~ **Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the CMCG's position.**

Article 26

Tasks of the Critical Medicines Coordination Group

1. The ~~Critical Medicines Group~~ **CMCG** shall facilitate coordination in the implementation of this Regulation**, including,** ~~and,~~ **where appropriate advise to the Commission** ~~where appropriate, advise the Commission~~ **or Member States at their request**, so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market **or on national healthcare systems.** ~~**The CMCG may, where appropriate, advise the Commission or Member States on matters relating to the application of this Regulation.**~~

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

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

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

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

~~**(ba) exchange information on national contingency stocks requirements referred to in Article 20(3).**~~

(c) facilitate **strategic** discussion ~~of the need for a~~ **on** collaborative procurement initiative**s** ~~for a given medicinal product~~;

(d) advise the MSSG to provide the order of priority of critical medicinal products for vulnerability evaluation **as set out in Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]**, and propose a review or an update of existing evaluations where necessary.

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

(db) where appropriate, advise the Commission or Member States, at their request, on matters relating to the application of this Regulation.

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.~~

35. The **CMCG** ~~Critical Medicines Group~~, at the Commission's **or Member States`** request, may provide an opinion ~~on matters~~ **where providing** ~~related to the~~ **advice** ~~application of this Regulation in the context of performing tasks~~ as referred to in **paragraph 2, points (d) and (db)** ~~this Article~~.

Chapter VI
International cooperation

Article 27

Strategic partnerships

Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to 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.** ~~to increase the security of supply of critical medicinal products in the Union~~. The Commission shall also explore the possibility of building on existing forms of cooperation, **where appropriate** ~~when possible~~, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. **The Commission shall periodically inform the CMCG about their ongoing considerations and assessments.**

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 any other technologies relevant for manufacturing of critical medicinal products as defined in Critical Medicines Act *;

_____

* Regulation (EU) … of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of 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. **For the purposes of Articles 6, 8, 11(1), 12, 15, 16(2) and 26(2) point (a) the national competent authorities concerned may request information from project promoters,** ~~M~~**m**arketing authorisation holders and other ~~economic operators~~ **actors** in the supply and distribution chains of critical medicinal products**, their active substances or** ~~including their~~ key inputs**, including from importers and manufacturers of medicinal products, active substances or key inputs and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public,** and active substances or ~~medicinal products of common interest shall upon request provide the Commission or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation.~~

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

For the purposes of Article 11(2) the Agency may request information from the market actors referred to in subparagraph 1.

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

2a Where a Member State considers that the disclosure of information submitted pursuant to this Article is likely to compromise its defence or national security interest, it may, by means of a reasoned notice, object to the disclosure of that information. Market actors shall comply with this notice.

3. **Where a market actor submits information pursuant to paragraph 1, the actor shall indicate whether the information provided contains any commercially confidential information, identify the relevant parts of that information having a commercially confidential nature and explain why that information is of such nature.** The **national competent authority or the Agency, as relevant,** ~~Commission and national authorities of the Member States~~ shall assess the merits of **each** ~~duly substantiated~~ confidentiality claim~~s~~ made by **the actors** ~~marketing authorisation holders and other economic operators, requested to provide information per paragraph 1,~~ and shall protect any information that is commercially confidential against unjustified disclosure **in accordance with Article 29a**.

(new) Article 29a.

Handling of confidential information

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

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

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

4. Any obligations on sharing information pursuant to this Regulation shall not apply to data that concerns the essential interests of the Member States' security or defence.

Article 30

Evaluation

1. By [OP please insert the date of:] **at the latest** five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.

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

2. No later than [three years] after the date of transposition of a revision of Directive 2014/24/EU, or no later than [five years] after the date of application of this Regulation, whichever the earlier, the Commission shall review the scope, functioning and efficiency of Article 18 as well as coherence with the revised Directive 2014/24/EU, and shall report its findings to the European Parliament and to the Council.

~~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.~~

~~3.~~ The national authorities ~~and the economic operators~~ shall, upon request, provide the Commission with any relevant information they have and that **is necessary for** the Commission ~~may need~~ for its assessment **and review** pursuant to ~~in~~ paragraph**s** 1 **and 2 ~~3a~~**.

~~3a. No later than [three years] after the date of application of a revision of Directive 2014/24/EU, or no later than [five years] after the date of application of this Regulation, whichever the earlier, the Commission shall review the scope, functioning and efficiency of Article 18 as well as coherence with the revised Directive 2014/24/EU, and shall report its findings to the European Parliament and to the Council.~~

Article 31

Entry into force and application

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

2. It shall apply from [….].

3. **Article 18 (1) and (2) shall apply from [6 months after the date of application in para 2].**

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

Done at Strasbourg,

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