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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Critical Medicines Act)
Subject:	Critical Medicines Act - Comments from delegations

Delegations will find enclosed the comments from the delegations on the first Presidency's compromise text on the Critical Medicines Act (ST 12773/25) following the Working Party on Pharmaceuticals and Medical devices on 8 October 2025.

Written contributions from delegations

PUBLIC

AUSTRIA 2

BELGIUM 18

BULGARIA 23

CZECH REPUBLIC 29

ESTONIA 41

FINLAND and SWEDEN 42

GERMANY 44

IRELAND 49

ITALY 104

LUXEMBOURG 140

ROMANIA 195

SLOVAKIA 202

PUBLIC

AUSTRIA

Presidency's First Compromise Proposal (Dok. 12773/25)	**Drafting suggestions**	**AT Comments**
Article 3		
Definitions		
For the purpose of this Regulation, the following definitions shall apply:		
~~(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		**AT**: Ok.

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 of the supply chain to establish buffer stocks of certain medicinal products to mitigate the risk of supply disruption and which obligation is imposed by law, regulations or administrative provisions and/or results from mandatory contractual agreements (e.g. public procurement contracts).		
~~Chapter II~~ **~~Strengthening the Union's security of supply~~**		

PUBLIC

~~*Article 4*~~		**AT**: We would like this article to remain within the text.
~~*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.~~		

PUBLIC

Chapter III **Enabling conditions for investment**		
SECTION I		
CRITERIA AND PROCEDURE FOR THE RECOGNITION OF STRATEGIC PROJECTS		
Article 5		
Strategic Projects		
A project located in the Union and related to creating**, modernising** or increasing manufacturing capacity **of critical medicinal products** shall be considered as a strategic project if it meets at least one of the following criteria:		

PUBLIC

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

PUBLIC

	AT: New **(e) It contributes to improving the stockpiling of critical medicines, their active substances or key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances, by creating or optimizing storage capacity, logistics processes or digital systems for demand analysis and control.**	**AT**: The proposed Regulation introduces the concept of 'strategic projects', which would benefit from streamlined legal processes and favourable financial conditions to ensure the supply of critical medicines. However, improving the stockpiling of critical medicines within the Union is not yet included as a criterion for recognizing a 'strategic project'. Projects aimed at creating new storage capacities, optimizing existing ones, or improving logistics processes and digital systems for demand analysis and control should be explicitly recognized as 'strategic projects' improving the security of supply of critical medicines.
SECTION II		
FACILITATING ADMINISTRATIVE AND PERMIT-GRANTING PROCESSES FOR RECOGNISED STRATEGIC PROJECTS		

PUBLIC

Article 12		
Environmental assessments and authorisation		
1. A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[1], Directive 2000/60/EC of the European Parliament and of the Council[2], Directive 2001/42/EC of the European Parliament and of the Council[3], Directive 2008/98/EC of the European Parliament and of the Council[4], Directive 2009/147/EC of		**AT**: We agree that environmental protection and chemical regulations are of fundamental importance. A good balance of interests must be found and if in doubt, the supply of **critical** medicinal products should be prioritized.

PUBLIC

[1] 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).

[2] 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).

[3] 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).

[4] 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).

the European Parliament and of the Council[5], Directive 2010/75/EU of the European Parliament and of the Council[6], Directive 2011/92/EU of the European Parliament and of the Council[7] or Directive 2012/18/EU of the European Parliament and of the Council[8], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied.		
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		**AT**: We support an extension to 90 days.

PUBLIC

[5] 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).

[6] 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).

[7] 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).

[8] 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).

environmental impact assessment within 45 days of receiving all necessary information.		
	AT: ***new Article 12a: Coordination with Environmental and Chemical Legislation***	
	AT: ***Environmental and chemical regulations should take into consideration the continuity of supply of critical or jointly prioritized medicinal products. To ensure uninterrupted availability, a cumulative impact assessment of relevant environmental and chemical legislation on manufacturing and supply capacities should be conducted.***	**AT**: Measures under environmental and chemical legislation should take into consideration the supply of critical medicinal products to Union citizens. Therefore, the European Commission and the Member States must ensure that environmental and chemical regulations do not conflict with the objectives of the CMA.

PUBLIC

Chapter V Critical Medicines Coordination Group		
Article 25		
Establishment of Critical Medicines Coordination Group		**AT**: still has strong reservations against the establishment of a separate Critical Medicines Coordination Group as we see a risk of duplication due to a relatively large number of already established structures (e.g. extended EMA mandate, MSSG), which should be used instead) As discussed in the working party, we hold the opinion, that working structures that deal with similar duties and issues already exist and could be expanded to incorporate the mandate of this new group without the necessity of creating an additional group. This would pay into the aspect of legislative harmonisation as well as the reduction of bureaucracy. It is possible to envision an expansion of MSSG or a subgroup of the pharmaceutical committee, for example.

PUBLIC

Article 26		
Tasks of the Critical Medicines Coordination Group		
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		

PUBLIC

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).		

PUBLIC

(c) facilitate discussion of the need for a collaborative procurement initiative for a given medicinal product;		
(d) advise the MSSG to provide the order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of existing evaluations where necessary.		
(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		

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to the application of this Regulation.		
	AT: **New (e) Evaluation of the effectiveness, appropriateness and efficiency of the financial resources allocated by the Union and the Member States, as well as the measures taken to achieve the objectives of this Regulation.**	**AT**: The evaluation of measures taken by the Member States and at Union level to ensure the supply of critical medicines, as well as of the financial resources allocated for this purpose, should form part of the tasks of the Critical Medicines Group. In this way, the Group helps to ensure the effective and efficient use of resources with regard to security of supply.
Chapter VIII Final provisions		
Article 30		
Evaluation		
1. By [OP please insert the date of:] five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the		

PUBLIC

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.		
3. The national authorities and the economic operators shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1.		
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	**AT**: 3a. No later than [~~three~~ **one** years~~s~~] after the ***entry into force*** of a revision of Directive 2014/24/EU, or no later than [five years] after the date of application of this Regulation, whichever	**AT**: proposes to replace the term *"date of application"* with *"entry into force"* since the former is unclear. In addition, AT suggests shortening the review period in the first part from *"three years"* to *"one year"*, in order to ensure an earlier assessment of the scope, functioning and

PUBLIC

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.	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.	efficiency of Article 18 and its coherence with the revised procurement framework.

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BELGIUM

Written comments BE – WPPMD 8 October 2025 – Critical Medicines Act.

Find below Belgium's proposed amendments on articles 4, 19, 25, 26 and 27 of the Presidency's proposal for a compromise on Critical Medicines Act (proposal for a Regulation 2025/102).

Article 4

~~*Strategic objective of the Union*~~***Common action to strengthen the security of supply and continuous availability of critical medicinal products***

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 **and to foster strategic autonomy** through measures that take full advantage of the potential of the internal market. **They shall exchange information on their respective programmes to achieve these objectives within the CMCG.**

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

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 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~~ 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 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 representative~~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 **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 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 **and by establishing [and updating] the secure repository referred to in Article 26(2), ba)**. **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).** ~~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~~ **CMCG** 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. 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.

PUBLIC

(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) facilitate exchange of information on national contingency stocks requirements referred to in Article 20(3), namely via the creation and regular update of a secure repository;

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

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

(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, onmatters 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.~~

3~~5~~. 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~~.

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~~. 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.**

PUBLIC

BULGARIA

On the Proposal for a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795

Legal basis

Further to our previous comments and following the exchange at the WP Pharmaceuticals and Medical Devices, which took place on 8th October, Bulgaria reiterates the request to **add Art. 168 TFEU as a legal basis**. On the one hand, the CMA aims to approximate the legislation of the Member States to create mechanisms for sustainable supply of critical medicinal products and incentivize the production of medicinal products in the Union. On the other hand, the CMA affects the powers of the Member States in shaping their national health policies and spending public healthcare funds, including via the mandatory implementation of the MEAT criteria, which is within Member States competences (Art. 168 (7) TFEU; s. also below our comments to Art. 18, with a change in recital (28)).

According to the settled case-law of the ECJ "the choice of legal basis for a given Community act must be based on objective factors amenable to judicial review, including in particular the aim and content of the act..." (e.g. Case C-300/89 Commission/Council, paragraph 10, Case C-400/05 Commission/Council, paragraph 61, Case C-155/91 Commission/Council, paragraph 7, etc.). The objective of some of the provisions does not justify their inclusion in an act relying on an "internal market" legal basis. **We consider that there are two groups of objective elements which must be covered by the relevant legal bases laid down in the Treaties**.

Medicinal products, including critical ones, are different from other critical products, given the specific rules concerning the organisation and financing of the healthcare systems in Art. 168 TFEU. If any parallel should be sought, it is not with other critical products files, but with sectoral legislation, where similar issues were resolved (such as Regulation (EU) 2021/2282 on health technology assessment, which has Art. 114 and Art. 168 as legal basis). To this end we also remind that there are already relevant opinions of the CLS (such as 9431/09).

Article 2

The scope of the Regulation remains unclear, in particular concerning the vague category **"medicinal products of common interest".** Given the lack of impact assessment, in order to ensure clarity and legal certainty essential for implementation, we support a scope focused on critical products only. If needed, a further extension of the scope can follow upon an evaluation of the Regulation.

In any case, Art. 18 should remain limited to critical medicines: there is no justification to implement the MEAT criteria for "medicines of common interest" in a Member State, which is not among those countries, which have identified "common interest".

Article 18

The obligation on Member States to implement the MEAT criteria goes beyond the measures that the Union legislator may adopt under Art. 114 TFEU, as it does not respect the Member States' responsibility for the definition of their health policy and for the organisation and delivery of health services and medical care (Article 168(7) TFEU). The Union legislator cannot impose such an obligation given the lack of Union competence when it comes to management of health services and medical care and the allocation of the resources assigned to them.

The legally sound solution is a voluntary ("may") approach in paragraph (1). Should that not be accepted by the Presidency, sufficient flexibility for Member States is required by further changes, as outlined below. This should be accompanied by a dual legal basis (Art. 114 and Art. 168), as well as a change in recital (28).

Suggested changes in Art. 18:

1. For ~~award~~**public procurement** procedures ~~of~~ **for 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 subject matter~~, contracting authorities ~~in the Member States~~ shall, **if appropriate,** apply ~~procurement requirements other than price-only award criteria such as procurement~~ requirements that promote the resilience of supply in the Union.

These requirements shall take the form of 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;
(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.

~~With regard to~~**For public procurement procedures for, ~~where contracts as part of their 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, the contracting authorities shall, **where justified,** apply ~~procurement~~ requirements that favour **manufacturers** ~~economic operators~~**s**~~suppliers~~ that **supply these critical medicinal products originating** ~~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.**

We note that the scope of the "made in Europe" requirement is unclear and thus may be non-implementable.

2. (b) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU, that entail that critical medicinal products supplied or provided in the execution and duration of the contract 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 procurement 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 (b) 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~~ during the execution of the contract.

~~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.~~

Rationale: *There is no justification to implement the MEAT criteria for "medicines of common interest" in a Member State, which is not among those countries, where conditions for "common interest" are fulfilled.*

5. Contracting authorities may ~~exceptionally~~ decide not to apply paragraphs 1 **and** ~~,~~ 2 ~~and 3~~ where **this will decrease the efficiency of public spending and limit procurers in making use of public procurement as part of healthcare policies. This may in particular be the case 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 on the national market in the respective Member State and no reasonable alternative or substitute exists and the absence of competition is not the result of an artificial narrowing down of the parameters of the public procurement procedure;

(b) no suitable tenders or no suitable requests to participate have been submitted in response to a similar 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 beyond the planned financial resources ~~having disproportionate costs~~.

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, while respecting the responsibilities of the Member States for the management of health services and medical care and the allocation of the resources assigned to them.

Suggested changes in Recital (28)

This Regulation is without prejudice to national competences in the area of healthcare. 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 **for efficient public spending and use of public procurement in support of their healthcare policies,** ~~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.

Article 19

1. By **12**~~6~~ months after entry into force of this Regulation each Member State shall**, if appropriate and 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~~ **situation and the needs of the healthcare system in the respective Member State,** Such programmes may also include measures ~~for pricing and reimbursement~~ supporting security of supply of ~~those~~ critical medicinal products that are not purchased through public procurement procedures.

Article 21

We suggest to merge Art. 21 and Art. 22.

Alternatively, we can propose the following changes to the text:

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

Rationale: Since the notion of "medicines of common interest" remains unclear, we can support only critical medicines in the scope.

2. Having received the request, the Commission shall inform all other Member States of the initiative and set a~~n appropriate~~ deadline **of at least 15 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. **When assessing the request, the Commission shall give due consideration to the impact on availability and accessibility of the respective medicinal product in non-participating Member States, as well as on distortion of competition.** 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~~**. the deadline in paragraph (2).**

Article 22

1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 **and in exceptional circumstances,** where ~~six~~ **nine** or more Member States jointly request **(`the joint request`),** the Commission to procure on their behalf, or in their name 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, 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.~~

Rationale: Given the lack of positive practical experience, we can only support a scope limited to critical medicines.

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 at least 15 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**. **When assessing the request, the Commission shall give due consideration to the impact on availability and accessibility of the respective medicinal product in non-participating Member States.**

5. **Within 20 working days of** ~~**receiving the joint request**~~ **the deadline in paragraph (3),** **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.

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 procurement processes. Such a procurement procedure may only be initiated once these conditions have been accepted by the interested Member States.~~**

The Commission shall be responsible for conducting the negotiations in good faith, while ensuring transparency and respecting the participating Member States' indications for quantities and price, and any other considerations concerning the content of the contract. Any involved Member State may withdraw from the procedure at any stage before the signature of the procurement contract.

Rationale: Based on the experiences during COVID-19, we cannot agree with the addition of minimum binding quantities and suggest more safeguards in the text.

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.

Article 24

…

2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. **The Commission shall be responsible for conducting the negotiations in good faith, while ensuring transparency and respecting the participating Member States' indications for quantities and price, and any other considerations concerning the content of the contract. Any involved Member State may withdraw from the procedure at any stage before the signature of the procurement contract.**

CZECH REPUBLIC

PUBLIC

CZ comments on the first compromise text CMA

CZ proposed changes are marked in yellow.

Public procurement:

Article 18

- In general, CZ considers some changes in Article 18 to be the most problematic from the whole compromise text. We would like to point out that the main purpose of the Regulation Proposal should be to ensure the secure supply of medicines. However, in order to achieve this objective, it is necessary for these medicines to be manufactured in Member States, and it is not possible to import them into the EU market from the third countries.

Article 18 para 1

- CZ supports including of resilience of supply requirements into this provision as CZ considers them to be a key element in achieving the objectives of the Regulation Proposal. In general, we are in favour of requiring resilience of supply requirements to the greatest extent possible.

Article 18 para 2

- CZ strongly disagrees with extending the list of countries from which medicines may originate which are to be supplied by economic operators who are to be favoured by the contracting authorities on this basis. While being fully aware of international commitments, CZ is of the opinion that including of third countries which are contracting party to WTO Agreement on Government Procurement or third countries which concluded FTA with EU on government procurement could jeopardise the purpose of the Regulation Proposal. Moreover, from the legal perspective, CZ does not share the concerns of Legal Council Service, also with regard to the Article 18 para 2 subpara 2 letter (b) subpara 3 in its original wording. This CZ comment is also relevant for other parts of the Regulation Proposal, where addition "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" was proposed. Therefore, these parts are proposed to be deleted. Please see the changes in wording proposed.

- ~~With regard to~~**For public procurement procedures, where contracts as part of their 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, the contracting authorities shall~~, where justified,~~ apply ~~procurement~~ requirements that favour **economic operators**~~suppliers~~ that **supply these critical medicinal products originating** ~~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~~.

Article 18 para 2 new subpara

- Moreover, CZ is concerned about the practical implementation of this part, as it is unclear how the contracting authorities will learn that there is a vulnerability in the supply chains confirmed through a vulnerability evaluation in the case of the specific medicines that are part of the subject matter of the contract. Furthermore, it is unclear from which moment the obligation laid down in this provision will apply to the contracting authorities (e.g. publication of a vulnerability evaluation by MSSG?). In order to avoid burdensome obligations for the contracting authorities, it would be more appropriate to have a list of 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, ideally in the form of implementing act adopted by the Commission which would activate the obligation for the contracting authorities with a clear date of entry into force (similar to the NZIA). Therefore, CZ proposes to add this provision into Article 18 para 2 as a new subpara. Please see the changes in wording proposed.
    - **The Commission shall adopt implementing act providing for a list of 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.**

Article 18 para 2 subpara 2

- For CZ is unclear, why subpara 2 of this Article only includes options for contract award criteria and contract performance clauses while subpara 1 lists other options (selection criteria or technical criteria) that may be used. CZ considers it beneficial to use these other options in the case of critical medicines 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 as well. This part should be more clarified and these options should be developed in the text of this provision afterwards.

Article 18 para 2 letter b)

- CZ is of the opinion that it would be more appropriate to calculate the share of medicinal products originating in the EU on the basis of the value of those products rather than on the basis of the total value of the contract. Please see the changes in wording proposed:
    - **contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU, that entail that critical medicinal products supplied or provided in the execution and duration of the contract 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 procurement ~~represent at least [25] % or more of the total value of the contract~~ represent at least [x] % of the value of those products, irrespective of whether such products are supplied or provided directly by the successful tenderer or by a subcontractor.**

Article 18 para 2 letter b) subpara 2

- CZ would like to point out that the current provision is indeed similar to NZIA. However, CZ is of the opinion that this template is not suitable for use in a directly applicable Regulation Proposal. Therefore, CZ proposes to move the provision to the recitals or, alternatively, to change the provision so that medicines demonstrably represent at least [x] % of the value. Moreover, CZ believes that subpara 3 would also be more appropriate in the recitals than in the legislative text of the Regulation Proposal. Please see the changes in wording proposed.
    - Where contracting authorities apply contract performance clauses as provided for in subpara 2, letter (b) the contracting authorities must oblige the successful tenderer through a contract performance clause to provide to the contracting authority upon their request **evidence that medicinal products demonstrably represent at least [x] % of the value of the contract ~~adequate evidence of the supply chain~~** at the latest upon completion of the execution of the contract.

Article 18 para 3

- CZ would like to point out that from the legal perspective, this provision should be amended and ideally moved to the recitals. CZ is of the opinion that according to the CJEU case law, not only such an explicit empowerment is unnecessary, but it is even confusing in the legislative text of the Regulation Proposal (please see the point 62, C-652/22, Kolin Inşaat). Moreover, the contracting authorities may discriminate against supplies from third countries without the need for further justification (e.g. by market analysis) and without procedural limitations (such as the reference to para 2).

Article 18 para 3a

- CZ is concerned about the proposed change to this provision which stipulates that the procedure for determining the origin of critical medicines and medicines of common interest shall be governed by the Regulation of the European Parliament and the Council of the EU 952/2013 (Union Customs Code). We do not consider the method of determining the origin in Union Customs Codex appropriate in the case of medicinal products because the Article 60 para 1 states that *Goods of the production of which involves more than one country or territory shall be deemed to originate in the country or territory where they* ***underwent their last, substantial, economically-justified processing or working, in an undertaking equipped for that purpose, resulting in the manufacture of a new product or representing an important stage of manufacture.*** Therefore, any medicine registered in the EU would be considered to have been manufactured in the EU under the current rules on batch release. In this regard, we would be more inclined to support a solution based on the French amendment as follows.
    - ~~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.~~

Article 18 para 3b

- CZ is of the opinion that it is unclear, whether this provision constitutes an empowerment of the Union within the meaning of point 62, C-652/22, Kolin judgment, alternatively point 60, C-266/22, Qingdao. This part should be more clarified.

Article 18 para 5

- In general, CZ welcomes the clarification of the cases in which the contracting authorities may decide not to apply the rules laid down in the Article 18. However, these cases could be described in even greater detail to ensure legal clarity for practice, given that this is a directly applicable Regulation Proposal.

Article 18 para 6

- CZ welcomes the obligation to the Commission to issue guidelines to support Member States in implementing the Regulation, including their incorporation in the legislative text of the Regulation Proposal. However, we consider it important to set a deadline for the Commission to publish these guidelines. Therefore, we propose stipulate a deadline of one year after entry into force of this Regulation. Please see the changes in wording proposed.
    - **By 12 months after entry into force of this Regulation,** 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.

Article 19 para 1

CZ is of the opinion that the period for establishing national programmes should be linked to the date when guidelines issued by the Commission will be published in accordance with Article 18 para 6. Please see the changes in wording proposed.

- By **12** ~~6~~ months after the issue of guidelines according to Article 18 paragraph 6 ~~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 include measures ~~for pricing and reimbursement~~ supporting security of supply of ~~those~~ critical medicinal products that are not purchased through public procurement procedures.

Article 19 para 2

- CZ would like to ask for clarification why the option to issue opinions at the level of the Coordination Group has been excluded from this provision as well as the following obligation for Member States to give consideration to this opinion and option to take it into account when revising the national programmes. CZ is of the opinion that such obligation should be mentioned in the Article 26 which lists tasks of the Coordination Group. Please see the changes in wording proposed in the Article 26.

Article 31

- CZ is of the opinion that obligations for the contracting authorities shall apply only: a) after the entry into force of the implementing act establishing the Union list of critical medicines (according to Article 131 of Regulation Proposal in the Pharmaceutical Package) and b) to procurement procedures launched after that date. Please see the corresponding Article 49 para 3 of NZIA.

Contigency stocks

Article 20 para 1

- CZ prefers the original Commission Proposal which stipulated that contingency stocks requirements shall not result in any negative impact on security of supply of medicines. On the contrary, DK PRES compromise text only stipulates that contingency stock requirements shall aim at ensuring that they do not compromise the security of supply. CZ considers this provision to be significantly weakened. Alternatively, CZ proposes that contingency stocks requirements shall not adversely affect the availability of medicines in other Member States or compromise the functioning of the internal market. Please see the changes in wording proposed.

- ~~Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when~~ **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 shall not adversely affect the availability of such products in other Member States or compromise the functioning of the internal market. ~~shall aim at ensuring 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~~

- In general, CZ is of the opinion that at least to medicines for which vulnerability in the supply chains was identified by a vulnerability evaluation stricter rules on contingency stocks requirements should applied.
- Apart from that, CZ would like to ask for clarification why in this provision the term "other operators" is used while in the other parts of DK PRES compromise text the term "economic operators" is used.

Article 20 para 2

- CZ supports the explicit inclusion of scope and timing into this provision.

Article 20 para 3

- CZ supports inclusion of this new para which establishes the obligation for Member States to inform the other Member States about their intention to impose contingency stocks requirements. However, CZ is of the opinion that the DK PRES compromise text requires a more detailed definition of the scope of information that should be shared. Therefore, we propose to specify this issue in Article 26 para 2 letter ba). Please see the changes in Article 26 para 2 letter ba) proposed.

Article 22 para 6

- CZ would like to ask for clarification of DK PRES changes proposed in this provision.

Strategic projects

Article 5 para 2

- CZ is of the opinion that the obligation stipulated in Article 15 para 2 that an undertaking that has benefitted from financial support for a strategic project shall prioritise supply to the EU 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, should apply to all strategic projects to which support (e.g. administrative) was provided, not only to those that have received financial support. Therefore, the obligation from the Article 15 para 2 should be stipulated in the Article 5 para 2 to apply to all strategic projects in general. Please see the changes in wording proposed.
    - **For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from the 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.**

Article 5 para 3

- Moreover, CZ is of the opinion that the obligation for the Commission to issue guidelines to support Member States on uniform assessment of projects as strategic projects should be included in the Regulation Proposal. Please see the changes in wording proposed.
    - **By 12 months after entry into force of this Regulation, the Commission shall issue guidelines designed to support Member States in assessing whether, or not a project meets the criteria set out in the Article 5 and in recognising projects as strategic projects.**

Article 6

- CZ supports changes proposed by DK PRES on assessment of strategic projects by one designed authority.

Article 6 para 1

- CZ is of the opinion that if a project fulfils the criteria set out in the Article 5, the designed authority must recognise such project as strategic project. Therefore, we propose to use "shall" instead of "may". Please see the changes in wording proposed.
    - 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.

Article 6 para 4

- CZ is of the opinion that the purpose of this provision should be to provide with contracting authorities a list of designed authorities within Member States and not to list their tasks. We would like to ask for clarification of these changes proposed by DK PRES.

Article 6 para 5

- Similarly to para 1 of this Article, CZ is of the opinion that it should be stated also in this case that designed authority has already recognised project as strategic project. Therefore, we propose to change "may be" recognised to "was" recognised. Please see the changes in wording proposed.
    - Any other ~~Member State~~ authority **in the Member State** that receives a request from a **project** promoter concerning Articles 8 to ~~14~~**15** shall **rely on the decision of the designated authority pursuant to paragraph 1 as to** ~~assess~~ whether that given project **may was be 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~~.

Article 16 para 2

- CZ is of the opinion that assessment of whether a strategic project addresses a vulnerability in the supply chains identified by vulnerability evaluation for the purpose of EU funding should be carried out at the level of the Commission rather than at the level of the designed authority. Please see the changes in wording proposed.

- 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 Commission ~~designated authority~~** shall assess whether a strategic project addresses a vulnerability in the supply chains identified following the vulnerability evaluation. **The Commission ~~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.**~~

Article 17 para 1

- CZ prefers the original Commission Proposal regarding the part "sufficiently in advance" included in this provision in order to fully achieve the purpose of the Coordination Group. Please see the changes in wording proposed.

  - Member States shall inform the **CMCG** ~~Critical Medicines Coordination Group ('the Critical Medicines Group')~~ referred to in Article ~~24~~**25** of the intention toprovide financial support to strategic projects **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**.

Article 17 para 1 subpara 2

- Moreover, CZ is of the opinion that Member States should inform each other via the Coordination Group not only about the intention to provide financial support, but also afterwards about the fact whether such financial support has been provided. Furthermore, we are of the opinion that the DK PRES compromise text requires a more detailed definition of the scope of information that should be shared. Therefore, we propose to specify this issue in Article 26 para 2 letter aa). Please see the wording proposed for a new subpara 2.
- Member State shall inform the CMCG that the financial support was provided in accordance with Article 15.

Article 17 para 2 subpara 2

- CZ insists that the Commission should be obliged, rather than merely have the option, to inform the Coordination Group of the intention to propose the establishment of funding possibilities. Please see the changes in wording proposed.

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

Coordination Group on critical medicines

Article 25 para 5

- CZ supports changes proposed by DK PRES on co-chairing the Coordination Group of the Commission and Member States, instead of only the Commission.

Article 26 para 2 letter a)

- CZ would like to ask DK PRES for clarification why the part "the EU market designated production" was added within exchange of information on strategic projects. Moreover, we are of the opinion that in this case all strategic projects should be included in exchange of information, not only those that are financially supported.
- Furthermore, CZ is of the opinion that coordination of strategic orientation at the EU level should be ensured in order to avoid duplication of production capacities for the same medicinal product, API or key inputs. Strategic projects with the same objective should not be supported, unless such duplication is justified by clearly demonstrated needs related to security of supply, geographical distribution or production sites, or the overall resilient of the EU pharmaceutical supply chain. The aim should be to ensure diversification of the EU market. Please see the changes in wording proposed.
    - **(X) A project shall not be considered strategic 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 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 26 para 2 letter aa)

- CZ would like to ask for clarification what information is to be exchanged based on the Article 17. CZ is of the opinion that at least information on the expected creation or increase of manufacturing capacity, including the quantity of manufactured critical medicinal product, and the expected date of creation or increase of manufacturing capacity of the strategic project should be shared. Please see the changes in wording proposed.
    - 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. **When Member State provide information according to Article 17, it shall provide information on the expected creation or increase of manufacturing capacity, including the quantity of manufactured critical medicinal product, and the expected date of creation or increase of manufacturing capacity of the strategic project.**

Article 26 para 2 letter ba)

- CZ supports the inclusion of exchange of information on national contingency stocks requirements among the tasks of the Coordination Group. Moreover, we would like to ask for clarification on what information on contingency stocks should be exchanged. The objective is to create an effective system for information sharing in order to ensure availability of medicines for patients in all Member States. Therefore, we propose to create EU database containing information on contingency stocks which should include at least on API, size of the package, ATC group, the quantity of contingency stocks and possibility of sharing such medicines with other Member States if needed. Alternatively, this information should be part of exchange of information referred in this provision. Please see the changes in wording proposed.

- (ba) exchange information on national contingency stocks requirements referred to in Article 20(3). **When Member State provide information according to Article 20, it shall provide information on API, size of the package, ATC group, the quantity of stocks and the possibility of sharing such medicinal products with other Member States in case of need**.

- Please see the CZ comment on Article 19. A corresponding change (addition of letter b)) should also be made in the Article 26 para 3.

  - (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, **the CMCG may issue opinions and where the CMCG issues an opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes.**

International cooperation

Article 27

- CZ prefers the original Commission Proposal which includes the wording „to increase the security of supply of critical medicinal products in the Union“in the text of the Regulation provision. Please see the changes in wording proposed – below.

- Moreover, CZ welcomes the establishment of the obligation of Commission to inform the CMCG on the ongoing considerations and assessments concerning strategic partnerships.

- In general, CZ is of the opinion that the third countries should be able to participate in the collaborative procurements carried out in accordance with Articles 21 and 22 of the Regulation Proposal while not interfering with the set conditions by Member States or the Commission.

  - Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs **to increase the security of supply of critical medicinal products in the Union**. The Commission shall also explore the possibility of building on existing forms of cooperation, **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 inform the CMCG about their ongoing considerations and assessments.**

The final provisions

Article 29

- Given that the use of the term „economic operator“ has been uniformed in other parts of the Regulation Proposal, CZ is of the opinion that the term „economic operator“ should also be used in the title of the Article 29 instead of „market actors“. Please see the changes in wording proposed.

- *Obligation of the **economic operators** ~~**market actors**~~ to provide information*

Article 29a

- Moreover, CZ is of the opinion that the Regulation Proposal (in its final provisions) should also include the provision on penalties, at least as regards the obligation referred to in the Article 29. Please see the changes in wording proposed.

  - *Penalties* – Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

Article 31

- In general, CZ is of the opinion that in order to ensure legal certainty, the Regulation Proposal should include transitional provisions, for example in the area of public procurement (e.g. transitional provisions for the purposes of ongoing procurement procedures, in particular for concluded framework agreements and dynamic purchasing systems).

- Moreover, in general, we would like to emphasize that the Regulation Proposal should state the applicability of the Regulation taking into account the interconnection with the Pharmaceutical Package.

General provisions:

Article 1

- CZ does not support replacing the phrase „where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients“ with the term „market failure“ as this term is unclear and is not defined in the Regulation Proposal. CZ believes that a definition of market failure is necessary to ensure functioning of the entire system. Please see the changes in the wording proposed in the Article 3 below.

Article 2 para 2

- CZ welcomes clarifying changes made by DK PRES to Article 2. However, CZ would prefer Article 21 not to be included in para 1 of this Article as we see no reason why cross-border procurement should only be used for medicinal products of common interest and not also for critical medicines. Please see the changes in wording proposed.

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 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), 21, 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.~~

Article 3 para 10 and 18

- CZ welcomes the changes made by the DK PRES concerning the recognition of strategic projects by a designated authority in accordance with Article 6 of the Regulation Proposal and also welcomes the addition of the definition of contingency stock requirements.

- Apart from that, please see the CZ comment on Article 1 and the proposal of definition on market failure:
    - **(X) „Market failure“ means a situation where the functioning of the market does not sufficiently ensure the availability and accessibility of the medicinal product for patients in the quantities and presentations necessary to cover the needs of patients in the Member State.**
- Moreover, CZ considers it important to clarify the process of determining a medicinal product of common interest and where their list will be published at the EU level. Please see the changes in wording proposed.
    - **Article 3a – Determining medicinal products of common interest**

1. When a Member State decides that the functioning of the market does not sufficiently ensure the availability and accessibility of a medicinal products to patients in the quantities and presentations necessary to cover the needs of patients they shall inform the Commission.

2. When the Commission is informed according to paragraph 1 of this Article by three or more Member States in case of a certain medicinal product they shall communicate such information to the Member States.

3. The Commission shall publish and update a list of medicinal products of common interest on its website.

- CZ also believes that the Regulation Proposal should establish the rules for updating the vulnerability evaluation in connection with strategic projects, including their publication as we consider it necessary to indicate where the results of evaluation can be found at the EU level. Please see the changes in wording proposed.
    - **Article 3b – Vulnerability evaluation**

1. When Member State informs the Critical Medicines Group of the intention to provide financial support to a strategic project according to the Article 17 paragraph 1, the MSSG shall update the vulnerability evaluation based on the expected creation or increase of manufacturing capacity, including the quantity of manufactured critical medicinal product, and the expected date of creation or increase of manufacturing capacity of the strategic project financially supported by the Member State.

2. When the Commission informs the Critical Medicines Group of the strategic projects that benefited from financial support from the Union according to the Article 17 paragraph 2, the MSSG shall update the vulnerability evaluation based on the expected creation or increase of manufacturing capacity, including the quantity of manufactured critical medicinal product, and the expected date of creation or increase of manufacturing capacity of the strategic project financially supported by the Union.

3. The Agency shall publish the vulnerability evaluation and its updates on her website.

ESTONIA

Article 3

(5) 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which ~~in~~ three or more Member States **have requested to initiate a collaborative procurement in accordance with Article 21 for the reason that** 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;

Explanation: We propose to link this definition to common procurements as this is the main scope for such medicines. Accordingly, the definition is better aligned with the needs as determined by those Member States.

Article 26 p.2

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

Explanation: We should avoid potential duplication of efforts between different bodies involved in collaborative and joint procurement processes. CMCG should not take over practical coordination of specific collaborative procurement initiatives but could facilitate discussions on a more general strategic level. When it comes to initiatives related to specific medicinal products and practical arrangements, these could be agreed in the Agreement as foreseen in Article 24.

While our current comments focus on certain key parts of the text, we are continuing our internal analysis and we may come back with additional written input on the remaining articles at a later stage.

PUBLIC

FINLAND and SWEDEN

PUBLIC

FI and SE joint proposal for Article 3

Our addition to Article 3 (18b) based on the information by the Commission on a Pharmaceutical Committee Meeting on 19 November 2024

Article 3. (18b)

Definitions

(18b) 'contingency stock requirement' means an obligation imposed by a Member State on marketing authorisation holders and/or other economic operators of the supply chain to establish buffer stocks of certain medicinal products to mitigate the risk of supply disruption and which obligation is imposed by law, regulations or administrative provisions, and/or results from mandatory contractual agreements (e.g. public procurement contracts). to be distinguished from stockpiling by a public health institution or other public entity in order to anticipate and manage a specific crisis.

And a common FI and SE proposal for an Article 20 of the CMA

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 When **imposing requirements on marketing authorisation holders and other economic 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. Member States shall aim at ensuring that adequate planning and transition periods with a view to adapt to the balance between internal market requirements and national needs and circumstances. any form of such requirements do not compromise the security of supply in other Member States,**

2. **As part of the preparation of the requirements referred to in paragraph 1**, Member States shall **aim to carry out an assessment to make sure** 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,** are proportionate **with regard to the Member State's own national needs, security of supply and local circumstances.** and respect the principles of transparency and solidarity.

3. Member States shall, if contingency stocks requirements or changes thereof are deemed necessary, inform other Member States of their intention to impose these requirements, in the CMCG as specified in Article 26. When sharing information on the national requirements with other Member States, the Member States shall respect the principles of transparency in so far as the information and can be provided without conflict with national security interests. Member States shall also respect the principle of solidarity.

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.

Justification:

- *The negative impact of Member States' stockpiles on the internal market and other Member States is not self-evident. Potential negative impacts are mainly limited to the establishment phase of the stockpiles, when the demand of pharmaceuticals may rapidly increase. The extent of the impact is largely determined by adequate planning and the length of the transition period and thus, the long lead times of the pharmaceutical industry should be taken into account when transition period will be set. This enables the adjustment of production capacities to meet increased demand in order to minimize negative impacts.*

- *It is very difficult for Member States to assess which and what types of measures or requirements could compromise the security of supply in other Member States. We propose to delete the requirement, because there are no criteria or standards to evaluate the effects. Instead, it would be very important that Member States' any contingency stocks requirements are proportionate with regard to the Member State's own national needs, security of supply and local circumstances.*

- *The addition of the need to inform other Member States is in line with the TFEU, Article 347 and will be a bridge between Chapter X in the Pharma package to the CMA being in line with the proposed article 134 of the Regulation on Pharma package, which states that the Commission may draw up recommendations for national measures to improve security of supply of medicinal products included in the Union list of critical medicinal products. When informing, Member States need to respect the principles of transparency in so far as the information and can be provided without conflict with national security interests. In particular, under Article 346 TFEU, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security.*

PUBLIC

GERMANY

Art. 17 CMA-E – Exchange of information on funded projects

- Amendment for Art. 17 (2): ***" The Commission shall inform the CMCG of the intention to provide financial support from the Union to strategic projects and shall inform periodically of the strategic projects that benefited from this financial support."***

Rationale: We understand that, due to certain financing mechanisms, the COM cannot always provide advance notice of its intention to provide financial support for strategic projects. However, once the programmes for the financial support for strategic projects are established (Art. 16), the COM should inform the CMCG in advance of its intention to promote certain strategic projects. This is in line with the requirements for the obligation of the Member States set out in paragraph 1.

Art. 18 – Incentivising resilience in public procurement procedures

DEU has based its proposal in form, wording and rationale on the French proposal

Text proposed by the Presidency	*Amendment*
18(2)	
For public procurement procedures, where contracts as part of their 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, the contracting authorities shall, where justified apply requirements that favour **economic operators** that **supply these critical 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.**	For public procurement procedures~~, where contracts as part of their subject matter have~~ ***focussing on*** critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation ~~pointing to the high level of dependency on a single or a limited number of third countries,~~ the contracting authorities shall, ~~where justified~~, apply requirements that favour economic operators that supply these critical medicinal products ***with active ingredients manufactured in sites located*** ~~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.
Rationale: The new wording (after the deletion "where contracts as part of their subject matter have") ensures, that it is not sufficient for only a very minor part of the contract to relate to critical	

medicinal products. Otherwise, the reference to contracts, where such products are only "part" of the subject matter would lead to an overly broad application and would catch all contracts containing critical medicinal products. The concept of dependence on one or more third countries might restrict the scope of the products concerned. For example, a critical medicine produced by a single laboratory located in the EU remains vulnerable, but could not be classified as such under the current wording, as there is no dependence on a third country. Broadening the wording of Article 18 (2) in this regard enables a thorough vulnerability evaluation. Explicitly defining the 'resilience' criterion in the regulations increases the legal certainty of its application, by providing contracting authorities with a clear and objective framework, and can guarantee that the application of this criteria will match the objective, which is to stimulate a demand for European-produced critical medicines with vulnerability. The resilience criterion should focus on the location of production for the API, as this is the most critical production step. This also addresses the CMA's goal of minimizing strategic dependencies.

Text proposed by the Presidency	Amendment
The requirements referred to in **subparagraph 1 shall take the form of**: (a) contract 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 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 entail that critical medicinal products supplied or provided in the execution and duration of the contract 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 procurement** represent at least [25] % or more of the total value of the contract, irrespective of whether such products are supplied	The requirements referred to in ~~sub~~paragraph ~~1~~ **2** shall take the form of: (a) contract 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 supplied or provided in the execution and duration of the contract such as delivery process and delivery security; or~~ ***Such criteria shall account for at least X% of the overall weighting applied to the award of the contract;*** or (b) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU, ~~that entail that critical medicinal products supplied or provided in the execution and duration of the contract and~~ ***that require the medicinal***

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 (b) 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.	***products to originateing*** 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 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**.** ***(bi)*** Where contracting authorities apply contract performance clauses as provided for in ~~sub~~paragraph 2, point (b) 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.
Rationale: We support the use of an award criterion for the resilience requirement. To have an impact it should be assorted with a minimum weighting applied to the award contract. In the Council, we should strive, based on empirical data, to define the percentage (X) to apply in order to find the right level of incentives for EU producers while not resulting in an excessive impact on affordability. The wording in letter b) was deleted. The new text contributes to the clarity of the norm.	

Text proposed by the Presidency	*Amendment*
Art. 18(3)	
For the purposes of determining the origin of critical medicinal products as referred to in	***DELETED***

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.	
Rationale: At this stage, it remains uncertain whether the customs code would be an appropriate tool to determine the origin of medicinal products. The rules of non-preferential origin under the Union Customs Code rely primarily on concepts such as "last substantial transformation" (CTH/CTSH), which may not capture the specific vulnerabilities of pharmaceutical supply chains. For example, a product finished in Europe from an active ingredient manufactured entirely in a third country would typically be deemed of European origin, even though the critical dependency lies in the API. This raises doubts as to whether customs-based origin rules provide a sufficiently accurate or operational basis for a resilience criterion aimed at assessing and incentivising European production capacity. Further analysis is ongoing.	

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Art. 20 – Safeguards related to Member States contingency stocks requirements

DEU supports the ITA proposal:

"Member States shall, if contingency stocks requirements are deemed necessary, inform ***the Agency and the MSSG*** ~~**other Member States of their intention to impose these requirements, in the CMCG as specified in Article 26**~~."

Art. 22 CMA-E Commission facilitated Member States' cross-border procurement

- Amendment for Art. 22 (1) 2: ***"The actual costs for the procured medicinal products shall be paid by the mandating Member States"***

Rationale: As we understand art. 22, the Commissions procurement on behalf or in the name of Member States does not include financial support from the COM. We would therefore like to suggest a clarifying addendum. From a German perspective, the use of EU funds would intervene with the obligation of Member States to finance their health system.

Art. 23 – Joint Procurement

DEU is in favour of the deletion of Article 23. It is not needed and a deletion streamlines the procedures for collaborative procurement. A legal basis for the COM with the aim of donating medicines to third countries fits neither in terms of content nor in terms of the legal basis (Art. 114 TFEU) into the Critical Medicines Act.

Furthermore, joint procurement should be limited to crisis situations. Joint procurement in the context of cross-border health threats by the EU for crisis times is already regulated in the Regulation on cross-border health threats (Regulation EU 2022/2371). It is important to avoid a duplication of structures.

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IRELAND

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PRES COMPROMISE	IE Suggested amendment	IE Comments
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 **internal market** ~~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 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,~~ 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 referred to in Article 131 of Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023) 193 final*].		
2. ~~Chapter IV~~ **Articles 18, 21, 22, 24** and Article 26(2) point (c) also apply to medicinal products of common		

PUBLIC

interest. ~~Chapter III does not apply to medicinal products of common interest.~~		
Article 3 *Definitions*		
For the purpose of this Regulation, the following definitions shall apply:) '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*];) '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*];		When read in conjunction with point c) in Art 5, this expanded definition will result in many projects being eligible to be designated as strategic projects even if the key input in question is widely used and widely available. See related comments in Art 5 where IE propose to qualify the associated criterion to maximise impact while mitigating the risk of excessive volume.

PUBLIC

(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 final];** (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 final].** ~~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;		

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(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 Council1 *[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 an industrial project **recognised as a strategic project by a designated**		

PUBLIC

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	(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;	This proposal would potentially extend the scope to other undefined areas and more clarity would be needed on which other permits could be covered. Therefore IE is in favour of the original definition.

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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 of the supply chain to establish buffer stocks of certain medicinal products to mitigate the risk of supply disruption and which obligation is imposed by law, regulations or administrative provisions and/or results from mandatory contractual agreements (e.g. public procurement contracts).**		

PUBLIC

(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 conditions for investment**		

PUBLIC

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 it 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; (d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.	(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 existing supply constraints or limited manufacturing capacity in the Union;**	The criteria described are quite broad (particularly when considered in conjunction with the broad definition of a 'key input') and could potentially be met by any manufacturing site producing any raw material for a critical medicinal product regardless of the number of existing alternative manufacturing sites in the EU. As per the Commission staff working paper, the current Union list of critical medicinal products includes 276 active substances representing 18,700 medicinal products on the EU market. In relation to criterion c), we would suggest that this is further qualified by adding "where it is demonstrated that there are existing

PUBLIC

		supply constraints or limited manufacturing capacity in the Union". Without such a qualifier, given the number of critical medicinal products on the Union list, essentially any project related to the manufacture of any raw material used for such products will be eligible for designation as a strategic project even if significant manufacturing capacity already exists in the Union.
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 be recognised**~~constitutes~~ **as** a strategic project.	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 **~~may~~ shall be recognised** as a strategic project.	The inclusion of 'may' here suggests that MSs could have discretion as to whether a project is recognised as a strategic project. We welcome the Presidency's intention to clarify that there is no discretion once the assessment confirms that the criteria is met. Original COM wording ok for IE.
2. A **project** promoter ~~may~~ **shall** request the designated authority to assess whether a project is a strategic project. **The designated authority shall provide its assessment to the project promoter without undue delay.**		In relation to the additional text added at the end of this paragraph, while we would have no objection in principle to simultaneous submissions, a project promoter should only be able to avail of the benefits attached to designation as a strategic project after a designated authority has confirmed that it is a strategic project.

PUBLIC

~~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 applications to other authorities for the permits needed for the project.**		
2.**3.** Member States shall communicate to the Commission ~~what is~~ the designated authority 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~~**15** shall **rely on the decision of the designated authority pursuant to paragraph 1 as to**~~assess~~ whether that given project **may be recognised as**~~meets the criteria to be considered~~ a strategic project ~~as provided for in Article 5 and where~~		

PUBLIC

~~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.~~		IE supports the deletion of this article.
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).	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~~ **if it intends** to submit a request pursuant to Article 11(1).	IE proposes this change to better reflect that requests under Article 11 are optional for the project promoter.
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.		

PUBLIC

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 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;~~		IE supports the PRES compromise text IE supports the deletion of (b)

PUBLIC

~~(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*~~		

PUBLIC

~~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 by prioritising Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the		

PUBLIC

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 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 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.**	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 expertise 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 **in the provision of** ~~when providing the~~ **such** 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.~~	As this support will relate to manufacturing sites located in the EU, and the inspection of such sites is a national rather than an EMA competency, it is essential that the relevant national competent authority is directly involved in the provision of any advice related to GMP aspects. IE proposes that the intention behind the last subparagraph needs further clarification. IE considers it preferable to simply integrate "within the scope of its mandate and expertise" in the first subparagraph as per this text suggestion.

PUBLIC

Article 12 *Environmental assessments and authorisation*		
1. A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC**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. 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.		

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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.	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~~ **90 working** days of receiving all necessary information.	45-day timeframe is not feasible. Suggest mirroring the CRMA.
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.	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~~ **20 working** 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.	15-day timeframe is not feasible.
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		

PUBLIC

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.		

PUBLIC

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~~		

PUBLIC

~~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.~~		
SECTION III **FINANCIAL INCENTIVES**		
Article 15 *Financial support by Member States*		
1. Without prejudice to Articles 107 and 108 TFEU, Member States may prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines **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		We welcome the intention to clarify that 'duration' refers to the operational lifetime of the strategic project'. We could also accept the deletion of the added sentence in the interest of avoiding confusion due to referencing two different timeframes. IE notes that the wording of the first paragraph will be limited in effect as it only requires the

PUBLIC

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.**		project promoter to "prioritise supply" to the Union and use "its very best efforts" to ensure that critical medicines remain available. **It will be important that appropriate conditions are attached to any financial support depending on the nature of the project.**
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.		It would be best to safeguard against perverse incentives, such as manufacturers intentionally reducing activity to qualify for a SP. We would propose to address this via an amendment to the linked recital 21 which should refer to ensure that best efforts are made to avoid supply chain vulnerabilities prior to seeking financial support: (Recital 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 **despite best efforts to avoid supply chain vulnerabilities** 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

PUBLIC

		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.
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 2021-202712]** 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**		

PUBLIC

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.		
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 lime, the time**		IE considers the MSSG best placed to assess whether a strategic project addresses a previously identified vulnerability which has been identified at EU-level. Further consideration is required regarding the link with MSSG/CMCG and Union funding decisions. IE is supportive of the addition of the subparagraph on incomplete applications.

PUBLIC

line referred to in the first subparagraph shall be suspended until such time as the supplementary information and documentation required has been provided for.		
Article 17 *Exchange of information on funded projects*		
1. Member States shall inform the **CMCG** ~~Critical Medicines Coordination Group ('the Critical Medicines Group')~~ referred to in Article ~~24~~**25** of the intention to provide financial support to strategic projects ~~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. The Commission may inform the ~~Critical Medicines Group~~ **CMCG** of the intention to propose the establishment of funding possibilities specifically designed to address vulnerabilities in the supply chains as well as inform of any other programmes that may benefit the availability of critical medicinal products,		

PUBLIC

under specific rules and conditions of these Union funding programmes.		
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~~**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 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 requirements shall take the form of: **(a) selection criteria within the meaning of Article 58 of Directive 2014/24/EU;**		

PUBLIC

(b) technical specifications or requirements within the meaning of Article 42 of Directive 2014/24/EU; **(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.**		
2. ~~With regard to~~**For public procurement procedures, where contracts as part of their 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		

PUBLIC

countries, the contracting authorities shall, ~~where justified~~, apply ~~procurement~~ requirements that favour **economic operators**~~suppliers~~ that **supply these critical medicinal products originating** ~~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.** **The requirements referred to in subparagraph 1 shall take the form of:** **(a) contract 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 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 entail that critical medicinal products supplied or provided in the execution and duration of the contract and**		

PUBLIC

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 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 (b) 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~~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**.		

PUBLIC

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 defining additional requirements in accordance with Directive 2014/24/EU in national laws,**		

PUBLIC

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;** **(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**		

PUBLIC

(c) their application would oblige that contracting authority to acquire critical medicinal products having disproportionate costs.		
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.		
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 include measures		IE supports the longer implementation timeline

PUBLIC

~~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~~ 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*~~		IE considers the principles outlined in paragraphs 1 and 2 of this article relevant to contingency stocks for all medicines. Noting the Presidency's proposed narrowing of the scope to critical medicinal products, as a compromise, we could accept the principles

PUBLIC

		outlined in paras 1 and 2 being reflected in a recital.
~~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~~ when **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 shall aim at ensuring 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,** are proportionate and respect the principles of transparency and solidarity.		
3. Member States shall, if contingency stocks requirements are deemed necessary, inform other		As the MSSG has an established role related to the security of supply and management of shortages of critical medicinal products (which will be further elaborated as part of the

PUBLIC

Member States of their intention to impose these requirements, in the CMCG as specified in Article 26.		ongoing revision of the pharmaceutical legislation), IE would suggest that the MSSG rather than the CMCG may be best placed at least initially to consider the impact, if any, on any proposed contingency stock requirements on the security of supply of critical medicinal products. If the MSSG identified a concern in relation to this matter it could then liaise with the CMCG as required.
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~~		

PUBLIC

2014/24/**EU**~~C~~16 **where the procurement concerns**~~EC17 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 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.**	Having received the request, the Commission shall inform all other Member States of the initiative and set **a** deadline of ~~15~~ **20** working days for them to declare their interest in participating in the procedure. Participation in the procedure shall be voluntary for Member States.	15-day timeframe is not feasbile. IE supports other MS in proposing an increased timeframe.
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		

PUBLIC

provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products.		
6. The facilitation offered by the Commission shall be limited in time and **shall** end at the latest upon signature of the procurement contract by the participating contracting authorities. **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		

PUBLIC

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 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.		

PUBLIC

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 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.~~	The participation in the procurement procedure shall be open to all Member States. Having received the joint request, the Commission shall inform all other Member States of the joint request, through the CMCG, and set a deadline of ~~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 State.	15-day timeframe is not feasible.
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~~		

PUBLIC

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.		
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 procurement processes. Such a procurement procedure may only be initiated once these conditions have been accepted by the 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, **linked to individual Member States' requirements** ~~.or refraining from participating in competing procurement processes. Such a procurement procedure may only be initiated once these conditions have been accepted by the interested Member States.~~	In principle IE supports para 6 but 'minimum binding quantities' need to be linked to MS need/populations. Also, precluding other procurement activities has the potential to impact on MS timing with existing advanced, ongoing procurements.

PUBLIC

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.~~		
~~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;~~		

PUBLIC

~~(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~~		

PUBLIC

~~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.~~		
~~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 Articles 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. **The participating** Member		

PUBLIC

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 **additional expert representatives to**	2. The Member States and the Commission are Members of the CMCG. Each Member State shall appoint one permanent representatives~~,~~ with strategic expertise relevant for implementing the different measures set out in this Regulation. As necessary, Member States may appoint **an alternate permanent representative** and additional expert representatives to accompany the permanent Member State representative in order to support the different tasks of the CMCG**.** The Agency shall have an observer status	IE welcomes the flexibility PRES has introduced here. Our text proposal seeks to clarify that it is also possible to appoint an alternate permanent representative.

PUBLIC

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 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.**		IE supports this proposal
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**		

PUBLIC

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).** ~~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.~~		IE is in favour of retaining the last line for clarity regarding diverging positions.
Article 26 *Tasks of the Critical Medicines Coordination Group*		
1. The ~~Critical Medicines Group~~ **CMCG** 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. The CMCG may, where appropriate, advise the Commission or**		

PUBLIC

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		IE is unclear what EU-market designated production is. Suggest deleting to avoid potential negative consequences due to a lack of legal clarity.

PUBLIC

~~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 discussion of the need for a collaborative procurement initiative for a given medicinal product; (d) advise the MSSG to provide the order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of existing evaluations where necessary. **(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~~		

PUBLIC

~~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.~~		
3~~5~~. 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		

PUBLIC

key inputs ~~to increase the security of supply of critical medicinal products in the Union.~~ The Commission shall also explore the possibility of building on existing forms of cooperation, **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 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		

PUBLIC

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:		

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‘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.		

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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 or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation.		
2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.		
3. The Commission and national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other economic operators, requested to provide information per paragraph 1, and shall protect any information that is commercially confidential against unjustified disclosure.		
Article 30		

PUBLIC

Evaluation		
1. By [OP please insert the date of:] five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.		
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 the Commission may need for its assessment pursuant to in paragraph 1. **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**		

PUBLIC

<u>findings to the European Parliament and to the Council.</u>		
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* *The President The President*		IE supports early entry into force while emphasising the need for a reasonable implementation timeframe.

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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 **internal market** ~~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 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~~, 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.

PUBLIC

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*].

2. ~~Chapter IV~~ **Articles 18, 21, 22, 24** and Article 26(2) point (c) also apply to medicinal products of common interest. ~~Chapter III does not apply to medicinal products of common interest.~~

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];

PUBLIC

(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 final];

(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 final].** ~~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[9] *[reference to be added after adoption cf. COM(2023) 193 final];*

[9] 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*];

(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;

PUBLIC

~~(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 of the supply chain to establish buffer stocks of certain medicinal products to mitigate the risk of supply disruption and which obligation is imposed by law, regulations or administrative provisions 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.

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~~**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 conditions for investment

SECTION I

CRITERIA AND PROCEDURE FOR THE RECOGNITION OF STRATEGIC PROJECTS

Article 5

Strategic Projects

A project located in the Union and related to creating**, modernising** or increasing manufacturing capacity **of critical 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 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;

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(c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances;

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

Article 6
Recognition of Strategic Projects

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

2. A **project** promoter ~~may~~ **shall** request the designated authority to assess whether a 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 applications to other authorities for the permits needed for the project.

2.**3.** Member States shall communicate to the Commission ~~what is~~ the designated authority 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.

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4.**5.** Any other ~~Member State~~ authority **in the Member State** that receives a request from a **project** promoter concerning Articles 8 to ~~14~~**15** shall **rely on the decision of the designated authority pursuant to paragraph 1 as to**~~assess~~ whether that given project **may be 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.

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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 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.~~

PUBLIC

~~*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 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 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 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[10], Directive 2000/60/EC of the European Parliament and of the Council[11], Directive 2001/42/EC of the European Parliament and of the Council[12], Directive 2008/98/EC of the European Parliament and of the Council[13], Directive 2009/147/EC of the European Parliament and of the Council[14], Directive 2010/75/EU of the European Parliament and of the Council[15], Directive 2011/92/EU of the European Parliament and of the Council[16] or Directive 2012/18/EU of the European Parliament and of the Council[17], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied.

[10] 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).

[11] 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).

[12] 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).

[13] 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).

[14] 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).

[15] 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).

[16] 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).

[17] 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.

PUBLIC

Article 13
Planning

1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant spatial planning data 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[18], 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.~~

[18] 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 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.

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.

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Article 16
Financial support from the Union

1. ~~For the duration of the Multiannual Financial Framework 2021-2027[19]~~ **Financial support for** strategic projects **[under the Multiannual Financial Framework ~~2021-2027~~ in force [20]]** 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**[21], Horizon Europe **established by Regulation (EU) 2021/695**[22], and the Digital Europe Programme **established by Regulation (EU) 2021/694**[23] 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.

~~[19] 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)~~

[20] 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)

~~[21] 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)~~

~~[22] 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)~~

~~[23] 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 lime, the time line referred to in the first subparagraph shall be suspended until such time as the supplementary information and documentation required has been provided for.

Article 17
Exchange of information on funded projects

1. Member States shall inform the **CMCG** ~~Critical Medicines Coordination Group (‘the Critical Medicines Group’)~~ referred to in Article ~~24~~**25** of the intention to provide financial support to strategic projects ~~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.

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

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

3. 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 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 requirements shall take the form of:

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

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

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

(h) 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.

2. ~~With regard to~~**For public procurement procedures, where contracts as part of their 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, the contracting authorities shall~~, where justified,~~ apply ~~procurement~~ requirements that favour **economic operators**~~suppliers~~ that **supply these critical medicinal products originating** ~~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.**

PUBLIC

The requirements referred to in subparagraph 1 shall take the form of:

(a) contract 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 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 entail that critical medicinal products supplied or provided in the execution and duration of the contract 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 procurement 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 (b) 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.

These 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**.

PUBLIC

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 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~~.

PUBLIC

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;

(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.

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.

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 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~~ 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~~ when **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 shall aim at ensuring 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,** are proportionate and respect the principles of transparency and solidarity.

3. Member States shall, if contingency stocks requirements are deemed necessary, inform ***the Agency and the MSSG*** ~~**other Member States of their intention to impose these 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~~[24] **where the procurement concerns**~~EC~~[25] ~~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 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.

[24] **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).**

~~[25] 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).~~

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.

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.

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 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~~ [26], 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 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**.

[26] 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)

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.

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 procurement processes. Such a procurement procedure may only be initiated once these conditions have been accepted by the interested Member States.**

7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509[27].

~~*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.~~

[27] 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 [28], 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.

[28] 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.~~

~~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 Articles 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. **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~~ **and one alternate**~~, 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 **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 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).** ~~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~~ **CMCG** 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. 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;

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

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

(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.~~

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~~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.~~

3~~5~~. 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~~. 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 inform the CMCG about their ongoing considerations and assessments.**

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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.';

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(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.

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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 or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation.

2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.

3. The Commission and national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other economic operators, requested to provide information per paragraph 1, and shall protect any information that is commercially confidential against unjustified disclosure.

Article 30
Evaluation

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

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.

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

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.

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LUXEMBOURG

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Commission proposal	Drafting suggestions	Comments
Recitals		
[…]		
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 **internal market** ~~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 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,~~ whilst giving due consideration to ~~the appropriateness to ensure~~ the affordability of **those** medicinal products.	The objective of this Regulation is to strengthen the security of supply, ~~**and**~~ the availability **and the free movement** of critical medicinal products…	We would like to reiterate that the legal basis, Article 114 TFEU, should be reflected in the objective of the text. This article aims at the harmonisation of the laws of the Member States with a view to improving the functioning of the Internal Market. Therefore, the following terms (in bold) should be included in Article 1.

Commission proposal	Drafting suggestions	Comments
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 referred to in Article		

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Commission proposal	Drafting suggestions	Comments
131 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final].		
2. ~~Chapter IV~~ **Articles 18, 21, 22, 24** and Article 26(2) point (c) also apply to medicinal products of common interest. ~~Chapter III does not apply to medicinal products of common interest.~~		
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;		

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Commission proposal	Drafting suggestions	Comments
(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 final];		
(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 final].** ~~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		

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Commission proposal	Drafting suggestions	Comments
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 Council29 [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)		

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[29] 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]*.

Commission proposal	Drafting suggestions	Comments
…/… 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 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		

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Commission proposal	Drafting suggestions	Comments
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;		

PUBLIC

Commission proposal	Drafting suggestions	Comments
(18b) 'contingency stock requirement' means an obligation imposed by a Member State on marketing authorisation holders and/or other economic operators of the supply chain to establish buffer stocks of certain medicinal products to mitigate the risk of supply disruption and which obligation is imposed by law, regulations or administrative provisions and/or results from mandatory contractual agreements (e.g. public procurement contracts).		The term "Marketing Authorisation Holders" is mentioned in Article 29 of the CMA, but its definition is missing. The term is only used in one other definition, that of the term "contingency stock requirement". For the sake of clarity, we would think it would be necessary to consider a common definition of this term.
(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.		
Article 3 bis	***Article 3 bis*** ***Free movement*** Member States shall not prohibit, restrict or impede, for reasons relating to the aspects covered by this Regulation, the making available on the market of critical medicines and other medicinal products within the scope of this Regulation which comply with this Regulation.	We note the absence of a free movement clause in the proposal, even though it is based on Article 114 of the TFEU and one of its objectives is to "strengthen […] the availability of critical medicinal products within the Union" and to "improve the availability and accessibility of other medicinal products". In order to fulfil the objectives of this regulation, namely to ensure the accessibility of critical medicinal products and other medicinal

PUBLIC

Commission proposal	Drafting suggestions	Comments
		products throughout the Union, we support our proposal to insert a new Article 3a, which would take the following wording:
~~**Chapter II**~~ ~~**Strengthening the Union's security of supply**~~		
~~*Article 4*~~		We wonder about the reasons for the entire deletion of this article.
~~*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 conditions for investment**		
SECTION I		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 it 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;		

PUBLIC

Commission proposal	Drafting suggestions	Comments
d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.		
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 be recognised as** a strategic project.		
2. A **project** promoter ~~may~~ **shall** request the designated authority to assess whether a project is a strategic project. **The designated authority shall provide its assessment to the project promoter without undue delay.**		The terms "without undue delay" in paragraph 2 of Article 6 do not provide a clear and certain time limit for the designated authority to provide its assessment. The risk we anticipate is that of a disparity in time limits in practice. We would recommend to define/clarify the concept of "without undue delay".
~~Any Member State authority may request the designated authority to verify its determination of whether a project is a strategic project.~~		

PUBLIC

Commission proposal	Drafting suggestions	Comments
~~2.~~ 3. Member States shall communicate to the Commission ~~what is~~ the designated authority 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~~**15** shall **rely on the decision of the designated authority pursuant to paragraph 1 as to** ~~assess~~ whether that given project **may be 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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 <u>for recognised strategic projects</u>		
Article 7		We believe this provision is rather wishful thinking, imposing obligations of means rather than of results on Member States.
Priority status of strategic projects		
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.		
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.		Similarly, the terms "without undue delay" in paragraph 2 of Article 7 are quite vague and would benefit from being regulated (compliance with the deadline by the authority).
Article 8		
Administrative support		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 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.		

PUBLIC

Commission proposal	Drafting suggestions	Comments
~~*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~~		

PUBLIC

Commission proposal	Drafting suggestions	Comments
~~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 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 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**		

PUBLIC

Commission proposal	Drafting suggestions	Comments
State, the Agency shall duly involve the relevant national competent authority for medicinal products when providing 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/EEC30, Directive 2000/60/EC of the European Parliament and of the Council31, Directive 2001/42/EC of the European Parliament and of the Council32, Directive 2008/98/EC of the European Parliament and of the Council33, Directive 2009/147/EC of the European Parliament		Article 12 allows a promoter to request that a coordinated procedure be applied, but it is not clear to whom. The text could be clarified or at least made more explicit.

[30] 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).

[31] 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).

[32] 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).

[33] 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).

Commission proposal	Drafting suggestions	Comments
and of the Council34, Directive 2010/75/EU of the European Parliament and of the Council[35], Directive 2011/92/EU of the European Parliament and of the Council[36] or Directive 2012/18/EU of the European Parliament and of the Council[37], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied.		
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.		Article 12 also states that "a competent authority coordinates", without further details.
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		

PUBLIC

[34] 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).

[35] 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).

[36] 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).

[37] 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).

Commission proposal	Drafting suggestions	Comments
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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council38, 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.~~		

[38] 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).

Commission proposal	Drafting suggestions	Comments
Section III		
Financial incentives		
Article 15		
Financial support by Member States		
1. Without prejudice to Articles 107 and 108 TFEU, Member States may prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines **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**		Paragraph 2, subparagraph 2 underlines that the obligation to make products available in all Member States must apply for the duration of the strategic project, unless an exception is provided by the Member State in the conditions attached to the financial support. According to the interpretation of this text, it is not clear whether these conditions will be determined by the Member State that financially supports the project, or whether the conditions will have to be determined by the European Commission.

PUBLIC

Commission proposal	Drafting suggestions	Comments
the Member State under the conditions attached to the financial support.		
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 2021-202712]** 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)**		

PUBLIC

Commission proposal	Drafting suggestions	Comments
2021/52213, Horizon Europe **established by Regulation (EU) 2021/69514**, and the Digital Europe Programme **established by Regulation (EU) 2021/69415** 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.**		
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.		Paragraph 2, subparagraph 2 introduces an information and documentation procedure between the project promoter and the designated authority, including a timetable for the promoter to resubmit these documents. For the sake of clarity, it would be relevant to determine the duration of this timetable more precisely, in order to avoid fragmentation of deadlines between Member States.

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 lime, the time line referred to in the first subparagraph shall be suspended until such time as the supplementary information and documentation required has been provided for.		
Article 17		
Exchange of information on funded projects		
1. Member States shall inform the **CMCG** ~~Critical Medicines Coordination Group ('the Critical Medicines Group')~~ referred to in Article 24**25** of the intention to provide financial support to strategic projects ~~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.		

PUBLIC

Commission proposal	Drafting suggestions	Comments
The Commission may inform the ~~Critical Medicines Group~~ **CMCG** of the intention to propose the establishment of funding possibilities specifically designed to address vulnerabilities in the supply chains as well as inform of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes.		
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~~**public procurement** procedures ~~of critical medicinal products~~ falling within the scope		Certain concepts remain vague as they stand, in particular "the obligation to promote the resilience of supply in the Union." How can "monitoring of

PUBLIC

Commission proposal	Drafting suggestions	Comments
of Directive 2014/24/EU ~~of the European Parliament and of the Council,~~ **where contracts have critical medicinal products as part of their 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 requirements shall take the form of: **(a) selection criteria within the meaning of Article 58 of Directive 2014/24/EU;** **(b) technical specifications or requirements within the meaning of Article 42 of Directive 2014/24/EU;** **(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.**		supply chains" be analysed and compared? How will a contracting authority be able to analyse these criteria among the offers submitted by tenderers? It would be essential for the Commission to develop such criteria either in the guidance that will be published or in an implementing act.

PUBLIC

Commission proposal	Drafting suggestions	Comments
2. ~~With regard to~~**For public procurement procedures, where contracts as part of their 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, the contracting authorities shall, ~~where justified~~, apply ~~procurement~~ requirements that favour **economic operators**~~suppliers~~ that **supply these critical medicinal products originating** ~~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.** **The requirements referred to in subparagraph 1 shall take the form of:**		
(a) contract 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 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,		

PUBLIC

Commission proposal	Drafting suggestions	Comments
that entail that critical medicinal products supplied or provided in the execution and duration of the contract 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 procurement 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 (b) 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.		
These 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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 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.		Article 3b allows Member States to define additional criteria, in line with the Public Procurement Directive. However, it should be emphasized that these criteria must not exceed the conditions already imposed by the directive, nor the CMA's obligations. This article seems to open the door to possible "gold-plating" by national authorities. We would recommend that this risk is considered.

PUBLIC

Commission proposal	Drafting suggestions	Comments
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;** **(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.**		
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.		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 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**		We note the changes made following our initial comments. However, we reiterate our proposal that, before the development of national programmes, the Critical Medicines Group should issue an opinion/guidelines to standardise these programmes at the time of their design, and not when these programmes have already been adopted.

PUBLIC

Commission proposal	Drafting suggestions	Comments
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*~~		
~~Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact~~ when **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 shall aim at ensuring 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.~~		This article provides for an obligation of means, a priori the responsibility of the Member State in question, in order not to compromise the security of supply of other Member States. It would be highly relevant for this obligation of means to be strictly regulated because otherwise it could be harmful to the internal market (reference is made to the national territory).

PUBLIC

Commission proposal	Drafting suggestions	Comments
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,** 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, 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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 an ~~appropriate~~ deadline **of 15 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. f 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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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.		
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. **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.		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 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.		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 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**		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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.		
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 procurement processes. Such a procurement procedure may only be initiated once these conditions have been accepted by the interested Member States.**		
7. Except for the derogations provided for in this Regulation, the procurement referred to in this		

PUBLIC

Commission proposal	Drafting suggestions	Comments
Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509[39].		
~~*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.~~		
~~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;~~		

[39] 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).

PUBLIC

Commission proposal	Drafting suggestions	Comments
~~(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 [40], 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~~		

[40] 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)

Commission proposal	Drafting suggestions	Comments
~~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.~~		
~~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 Articles 22 ~~and 23~~		
1. Member States participating in the procurement procedures covered by Articles 22~~, and 23~~ shall share with the Commission any information		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 representative~~s~~, with **strategic**~~the~~ expertise relevant for implementing ~~all~~ the different measures set out in this Regulation. **As**		

PUBLIC

Commission proposal	Drafting suggestions	Comments
necessary ~~Where relevant as regards the function and expertise~~, Member States may appoint **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 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**		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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).** ~~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~~ **CMCG** 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. The CMCG may, where appropriate, advise the Commission or Member**		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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 discussion of the need for a collaborative procurement initiative for a given medicinal product;		
(d) advise the MSSG to provide the order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of existing evaluations where necessary.		
(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~~		

PUBLIC

Commission proposal	Drafting suggestions	Comments
~~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.~~ 3. 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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs ~~to increase the security of supply of critical medicinal products in the Union~~. The Commission shall also explore the possibility of building on existing forms of cooperation, **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 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 *;		
_____		

PUBLIC

Commission proposal	Drafting suggestions	Comments
* 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		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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:		

PUBLIC

Commission proposal	Drafting suggestions	Comments
(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 or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation.		
2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.		
3. The Commission and national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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.		
Article 30		
Evaluation		
1. By *[OP please insert the date of:]* five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.		
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 the Commission may need for its assessment pursuant to in paragraph 1.		

PUBLIC

Commission proposal	Drafting suggestions	Comments
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		
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		
The President		

PUBLIC

Commission proposal	Drafting suggestions	Comments
The President		

PUBLIC

ROMANIA

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

Romania welcomes the proposal for a Critical Medicines Act and considers it to be absolutely necessary to strengthen the supply chains of critical medicines at the level of the European Union. In the current international context, marked by geopolitical tensions, instability in global supply and emerging public health risks, it is essential for Member States to strengthen their strategic autonomy and rapid reaction capacity.

Chapter I- General provisions

Article 1 - Objectives and purpose

We support the inclusion of medicines of common interest in the scope of the regulation, given that they have a key role to play in keeping health systems functioning, especially in situations of health crisis or supply disruption. Medicines of common interest, although not formally classified as 'critical', are widely used for common conditions and can have a significant impact on public health in the event of a shortage.

We propose to amend the article by inserting the phrase **'maintaining patient safety'**: 'The objective of this Regulation is to strengthen the security of supply and availability of critical medicinal products within the Union, thereby ensuring a high level of protection of public health, **maintaining patient safety** and supporting the security of the Union.'

Article 2 – Scope

We support the changes in the text, which extend the legal framework for medicines of common interest.

MS may voluntarily use a set of public policy tools to manage security of supply that may apply exclusively to these medicines, namely:

- the optional possibility to use procurement criteria favoring production in the EU, referred to in Art. 18 para 3,
- the joint cross-border procurement mechanism, facilitated by the Commission, described in Article 21,

The amendment also extends the mandate of the CMCG in relation to medicines of common interest, practically the entire mechanism for the exchange of information and coordination of actions between MS and COM, managed by the CMCG, now becomes explicitly applicable to medicines of common interest as well.

Article 3 - Definitions

Definition 6, "vulnerability in supply chains" we support the addition of the word ***could*** which gives the definition the focus on risk management because it is sufficient to demonstrate the existence of a credible risk.

With regard to definition 7 , **'vulnerability assessment'** we reiterate the need for this assessment to be carried out taking in consideration the shortages of the past 2 years, the complexity of the products, the specific characteristics and the compliance with the EU's international commitments performed by the MSSG in consultation with the respective marketing authorisation holders and in accordance with Regulation (EU) .../... of the European Parliament and of the Council (reference to be added after adoption cf. COM(2023) 193 final)

This addition ensures the vulnerability evaluation is timely, focused and globally compliant. Considering recent shortages and product complexities highlights real-world risks and identifies fragile supply chains. Factoring in specific characteristics ensures critical medicines are prioritized while respecting international commitments safeguards the EU's legal obligations.

Regarding definition 18.b, "contingency stock requirement" – we support the introduction of the definition and call for the addition of a new definition 18c on national reserve stock. In this regard, we propose to add the following definition: "national stock represents the quantity of reserve of a critical medicinal product or a medicinal product regulated according to national legislation at the level of each MS for use in the field of public health, in the form of a national strategic reserve."

We believe that it is necessary to clarify the terminology regarding the differences between contingency stocks, necessary to maintain an average turnover to ensure short-term need, and national reserve stocks, necessary for unforeseen or emergency situations, as separate definitions are needed.

PUBLIC

Chapter II - Strengthening the Union's security of supply

Article 4 – Strategic objective of the Union

We are concerned about the elimination of the Commission's support to achieve the objective of this Regulation, as the coordination of the MS by the COM is an essential element. We propose to retain this article in the text and to add a new paragraph on the Commission's development of a set of recommendations for assessing the availability of medicinal products on the internal market and a Union list of medicinal products without a therapeutic alternative at Union level, originating in third countries.

We consider it essential to support patients' needs in line with the objectives of the proposal. The list of medicinal products without a therapeutic alternative is necessary for the identification and monitoring of strategic dependencies and the adoption of appropriate measures to ensure continuity of supply in the Union.

Chapter III – Favourable conditions for investment

Article 12 – Environmental assessments and authorisation

We indicate review reserve. Romania supports the introduction of a clear coordination mechanism with horizontal environmental and chemical legislation, especially in the context of the undersized impact of the Urban Waste Water Treatment Directive. Applicable environmental legislation should not create barriers to the continued production or availability of critical medicines. The Commission should carry out coordinated impact assessments and, where appropriate, propose mitigating measures, including legislative proposals.

Article 15 – Financial Incentives, Financial Support for Member States

The EU should offer Member States the possibility to apply for more flexible regional aid by increasing the share of aid allocated to the production of critical medicines, particularly in regions with an industrial tradition. This approach would allow companies to strengthen and expand their existing production capacities, leveraging the availability of both skilled and unskilled labor, as well as existing industrial infrastructure.

As a result, in order to achieve the objectives of this proposal, we consider it necessary to establish more relaxed or more targeted state aid rules (e.g., introducing a new article dedicated to critical medicines in Commission Regulation (EU) No. 651/2014 or in the Commission Decision of 20.12.2011 on the application of Article 106(2) of the TFEU to State aid in the form of compensation granted to certain undertakings entrusted with the operation of services of general economic interest), so that the applicable procedure is simpler and/or faster.

PUBLIC

We propose completing the article by including the possibility of reclaiming the financial support granted and sanctioning beneficiary companies in case of failure to meet the obligations related to the status of a strategic project.
Companies that benefit from financial support must take responsibility for ensuring the availability of critical medicines within the Union. Introducing corrective measures is essential to guarantee the efficiency of the support provided.

PUBLIC

Article 16 - Financial support from the Union

We would like to reiterate that the proposal lacks a funding line dedicated to the large-scale production of critical medicines, the main financing instruments being those already approved in the current Multiannual Financial Framework 2021-2027, thus underlining the primary role of national funding, limited funding, as mentioned above in art. 15.
Therefore, in line with the recommendations made in the report of the Alliance for Critical Medicines, which clearly highlights the lack of a specific instrument and the need for such a coordinated EU funding programme, it is clear that there is a need to create a dedicated fund for the objectives set out in the proposed AMC, as well as through the defence and competitiveness funds.

Article 20 – Safeguards related to Member States' contingency stocks requirements

Romania proposes introducing the possibility of adopting a decision to redistribute from a national or reserve stockpile in the event of a supply disruption or shortage, based on quantifiable criteria that allow for the assessment of the impact on Member States. We also support the establishment of a Union-level stockpile of critical medicines as a last-resort mechanism.
The proposed measures contribute to increasing the Union's resilience in the face of major public health crises and enable a coordinated and effective response in emergency situations.

Art. 21 – Facilitation by the Commission of Cross-Border Public Procurement by Member States

Paragraph 6: We support clarifying the timing at which a Member State can be added to or removed from an ongoing procedure, based on how that procedure is affected by such addition or removal, taking into account also the threshold of 3 Member States provided in paragraph 1.

Chapter V - Critical Medicines Coordination Group

Article 25 – Establishment of the Coordination Group for Critical Medicines

Analyzing the compromise act with the amendments proposed by Pres DK, compared to REGULATION (EU) 2022/123 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, we see that there are several areas where the overlap of CMCG/MSSG roles/activities remains intentional, namely at the level of coordination and advice and, respectively, at the level of information exchange and issuance of recommendations on the prevention/mitigation of deficits with which we agree.

Article 25 para 2 - We support the amendment of the text – a single member with relevant expertise from each country, so that the representative has a high-level perspective (political, economic, strategic) and not just a purely administrative or technical one. This representative can bring in technical experts, if needed. The appointment of permanent representatives with Member States' expertise in the Critical Medicines Coordination Group ensures a broad spectrum of expertise, allowing informed decisions to be taken into account different perspectives in the management of critical medicines.

Article 26 – Objectives of the Coordination Group for Critical Medicines

In Article 26 para. 2 lit. a we support the inclusion of "active substances and key inputs", being a more robust approach to security of supply, as it recognizes the vulnerabilities of the entire supply chain, not just the final product; we also support the specification of the exchange of information on the production capacity designated for the EU market, as it is relevant how much of the production of economic operators is actually destined for Europe.

We support the removal of the phrase **"where available".** The lack of information determines an inability of the CMCG in the evaluation, so it will operate with incomplete information. The transparency and binding nature of sharing this data remain essential, as mentioned in point aa.

In Article 26 para. 2 lit. aa – new , placing this task (exchange of information) at the top of the list highlights its importance. in the CMCG, with a focus on streamlining the exchange of information at MS level.

However, in conjunction with the **"where available"** condition (Art. 26, para. 2, lit. a) for the exchange of information on production capacity and key inputs, it is a major weakness. Without a mandatory mechanism for collecting and sharing critical data from manufacturers and Member States, the CMCG will operate with incomplete information, affecting its ability to identify and address vulnerabilities.

PUBLIC

Article 26 para. 2 lit. B

With regard to the involvement of the Critical Medicines Coordination Group in the exchange of information and best practices on the national programmes referred to in Article 19, as well as cooperation in the field of public procurement policies of the Member States, it is important that those programmes are developed within a unitary framework and that the designated members are involved in such policies at national level. In this regard, we consider that it is necessary to eliminate the phrase **"voluntary cooperation"** in the context of public procurement. The dependence on good faith of MS, without a firm obligation, can lead to fragmented and inefficient coordination, undermining efforts to strengthen security of supply.

Article 26 para. 2 lit. da - new

We support the introduction as a separate paragraph, as it reinforces the recognition of the global nature of supply chains and stresses the importance of strategic partnerships with third countries and the need for coherence between MS and Union actions.

Chapter VI - International cooperation

Article 27 - Strategic partnerships

We support the addition of the sentence: 'The Commission will inform the CMCG of its ongoing considerations and assessments.' This creates a formal mechanism of accountability and transparency. The Commission can no longer explore strategic partnerships in isolation, but has a legal obligation to report constantly to the CMCG (made up of MS representatives). This allows the MS to oversee the COM's work, provide early feedback and ensure that the COM's external actions are aligned with their strategic interests. The role of the CMCG as a supervisory body is strengthened.

For the purposes of legal clarity, it is necessary to elaborate on the scope of the phrase **"exploring the possibilities of concluding strategic partnerships"** by addressing the following aspects:

- The defined frequency for conducting feasibility analyses and for communicating their outcomes to the Member States.
- The mechanisms that will ensure transparency in the conclusion of strategic partnerships.
- The potential establishment of a platform to facilitate transparent information-sharing, with mutual access for the Member States and the Commission.

Romania stresses that partnerships with third countries must be structured in such a way as to ensure quality standards equivalent to those in the EU, thus also supporting European producers. To strengthen the resilience of pharmaceutical supply chains, the Critical Medicines Act (ACM) should promote international trade and regulatory cooperation in strategic partnerships with third countries.

Furthermore, the CMA should promote regulatory convergence and harmonisation through mutual recognition agreements and confidence-building in regulators.

PUBLIC

SLOVAKIA

Comments of the Slovak Republic on the Presidency's Compromise Proposal (CMA – doc. 12773/25)

Article 4 – Strategic objective of the Union

The Slovak Republic considers that deleting Article 4 weakens the overall framework of the Regulation, as it removes a clear declaration that the security of supply and availability of critical medicines constitute a strategic objective of the Union. Such a formulation has not only political but also legal significance, as it provides a teleological foundation for the interpretation and implementation of other measures under this Regulation (investments, procurement, coordination, etc.). For smaller markets such as Slovakia, this declaration is essential — it reinforces the principle of solidarity, strengthens the position of smaller Member States in joint procurement initiatives, and supports eligibility for Union financial instruments.

Slovakia proposes that Article 4 be retained in the operative part of the Regulation.

As a possible compromise solution, Slovakia might support the inclusion of this principle in the recitals, provided that the declarative nature and strategic intent of the provision are clearly preserved**.**

Article 11 – Regulatory and scientific support (GMP advice)

The Slovak Republic welcomes the inclusion of the obligation for the European Medicines Agency (EMA) to involve national competent authorities when providing advice on Good Manufacturing Practice (GMP) aspects.

This clarification is crucial for preserving the competences of national authorities such as ŠÚKL (State Institute for Drug Control) and for preventing duplicate or inconsistent recommendations between EMA and national agencies.

Proposed addition / clarification:

The involvement of the national competent authority should take place **with sufficient advance notice** and through a **transparent procedure**, ensuring that the national authority has a real and timely opportunity to contribute its views.

Article 15 – Financial support by Member States

The Slovak Republic welcomes the amendment from "may request" to "may require," as this strengthens the position of Member States and allows them to effectively safeguard the availability of medicines on the EU market when providing financial support.

To ensure this provision has practical effect, Slovakia suggests considering the inclusion of a clear rule that **supplying the EU market should be a standard eligibility criterion for projects receiving public support.**

Such a condition would mitigate the risk that beneficiaries of public funding would still prioritise non-EU markets despite having received Union or national support.

Article 20 – Contingency stock requirements

The Slovak Republic is concerned that the compromise text does not include any upper limit or coordination mechanism regarding the duration or volume of stockpiling obligations.

Without such safeguards, larger Member States could impose disproportionately high stock requirements on manufacturers, which could indirectly divert medicines away from smaller markets such as Slovakia.

Proposed addition / consideration:

Include a **maximum threshold** for contingency stock obligations, or alternatively, establish a **coordination mechanism within the CMCG** to ensure proportionality and fairness for smaller and more vulnerable markets.

Articles 25–26 – Critical Medicines Coordination Group (CMCG)

The Slovak Republic welcomes the strengthened role of the CMCG in the compromise text, recognising it as a key forum for coordination between the Member States and the Commission.

However, Slovakia considers it essential that the Regulation explicitly states that **the CMCG, when preparing its recommendations, shall take into account the needs of small and vulnerable markets.**

Such a reference would operationalise the principle of solidarity and ensure that the CMCG acts not only as a discussion platform but as a practical mechanism for balancing differences between Member States.

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