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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795

Delegations will find attached document COM(2025) 102 final.

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The EU has a strong and competitive pharmaceutical sector, which is a global leader in the production of medicines and a major contributor to the EU economy and directly employs around 800 000 people[1]. It is particularly strong in the research and development of innovative medicines. However, the landscape for pharmaceutical manufacturing has evolved in recent decades. Pharmaceutical production in the EU has focused on more complex products, which require high-tech infrastructure, a skilled workforce and sophisticated processes. Production of inputs for generic medicines has increasingly moved outside Europe. At the same time, almost 70% of the medicines dispensed in Europe are generics[2].

The EU faces increasing challenges to secure a stable and resilient supply of medicines that are critical to ensure the health of the EU patients. Recent global events, including the COVID-19 pandemic and Russia's war against Ukraine, have exposed vulnerabilities in the EU's pharmaceutical supply chains. Shortages of critical medicines present substantial risks to patients and public health and undermine the functioning of healthcare systems.

The root causes of shortages have shown themselves to be complex and multifactorial, with challenges identified along the entire pharmaceutical value chain, from quality and manufacturing problems, commercial decisions, and complex supply chains to industry's competitiveness. Specifically, shortages of medicines result from supply chain disruptions due to lack of diversification of key suppliers and vulnerabilities affecting the supply of key ingredients and components.

When looking at the causes of shortages of critical medicines, which are medicines for which no appropriate alternative is available and for which insufficient supply would result in serious harm or risk of harm to patients, it is important to distinguish between off-patent or generic medicines[3] and innovative or on-patent[4] medicines. Some of the market dynamics, which are observable for generic medicines do not necessarily apply to innovative medicines. EU health systems have made increasing use of generic medicines and tend to procure these, based on *lowest* cost, to reduce the burden on national healthcare budgets.

Industrial challenges have been pointed out as impacting the availability of critical medicines in the EU including the lack of investments in EU manufacturing capacity which has contributed to the increased supply dependency from outside the EU. Fragmented procurement practices across the Member States constitute a challenge and do not contribute to creating the most favourable conditions for investments. Additionally, workforce shortages and the need for specialised skills in pharmaceutical manufacturing further strain the industry's capacity to ensure a stable supply of critical medicines.

The COVID-19 pandemic clearly exposed significant vulnerabilities in the EU's pharmaceutical supply chain, in particular the heavy dependence on foreign sources for active substances. Export restrictions imposed by some countries during the pandemic revealed limitations in Europe's ability to independently produce certain medicines, putting public health across the EU at risk. This situation underscored the critical importance of economic security,

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1 Impact assessment report and executive summary accompanying the revision of the general pharmaceutical legislation, annex 5, 2023.

2 IQVIA White paper. Beneath the Surface: Unravelling the True Value of Generic Medicines April 2024

3 Generic and hybrid medicines | European Medicines Agency (EMA)

4 Patent protection in the EU - European Commission

as disruptions in global supply chains—whether due to pandemics, geopolitical tensions, or other factors—can have severe implications for national and regional security, economic resilience, and public health.

The pandemic highlighted how vital certain sectors, especially medicines, are for maintaining the EU's economic security. As Europe is facing rising geopolitical tensions and global disruptions which may become more frequent, ensuring the stability and reliability of critical supply chains, including those for medicines, is essential. By addressing these vulnerabilities, the EU can enhance its preparedness and resilience, safeguarding the well-being and public health of its citizens and strengthening its overall security.

A survey conducted by the EU4Health programme-funded Joint Action of Member States on shortages (CHESSMEN)[5] identified that over 50% of reported shortages are caused by manufacturing issues, a category which includes shortages related to the availability of active substances.

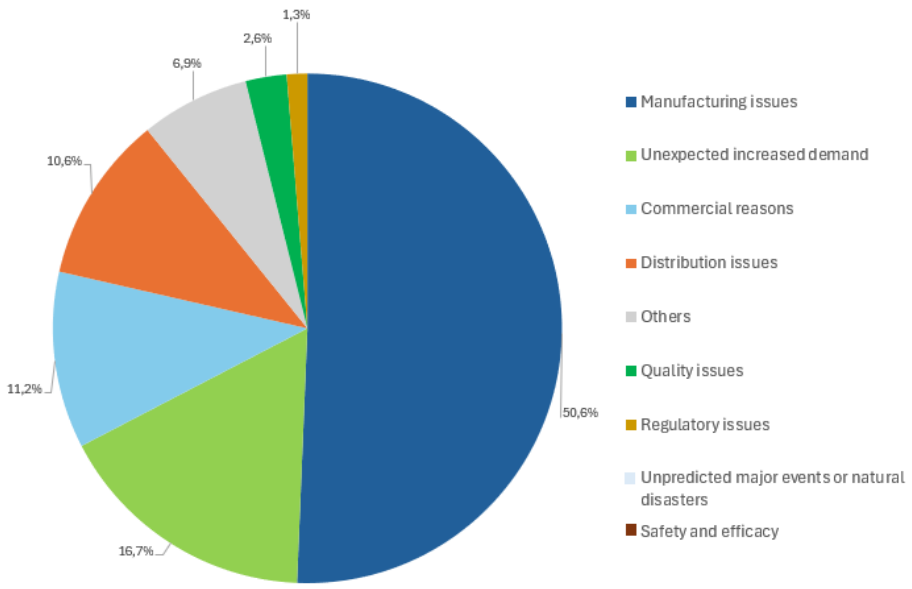

Figure 1: Root causes of medicines shortages in 2022 and 2023 in EU/EEA countries, grouped according to SPOC working party classification (CHESSMEN joint action*)*

Furthermore, for some medicines such as those for rare diseases, access can vary considerably from Member State to Member State. Due to various factors, including the size of the markets, companies market medicines differently across the EU. As a result, patients across the EU may not have equal access to the medicines they need and market failures remain, including within the development of priority antimicrobials that can help address antimicrobial resistance.

Shortages of medicines have been on the EU's political agenda for almost a decade[6]. The **pharmaceutical strategy for Europe** in 2020[7] acknowledged the need to create a future-proof regulatory pharmaceutical framework and give additional support to the pharmaceutical

5 CHESSMEN (2024) Analysis Report on root-causes.

6 See for instance the European Parliament resolution of 2 March 2017 on EU options for improving access to medicine and the EPSCO Council Conclusions (2021/C 269 I/02)

7 A pharmaceutical strategy for Europe - European Commission (europa.eu)

industry in promoting research, innovation and technologies that meet the therapeutic needs of patients while ensuring affordable access to medicines for patients.

The pharmaceutical strategy also included the launch of a **structured dialogue**[8] on the industrial dimension of security of supply. Starting in 2021, this initiative brought together stakeholders from the pharmaceutical industry (including manufacturers of active substances), wholesalers, healthcare professionals and patients, and Member State authorities.

Subsequently, the Commission published a **staff working document on vulnerabilities of the global supply chains of medicines** in 2022[9] which presented the main findings of the structured dialogue with the aim of informing further actions to improve the security of supply and the availability of critical medicines, active substances and raw and starting materials for pharmaceuticals.

Additional steps have been taken since to address the above-mentioned challenges, including the challenge of ensuring supply-chain security of critical medicines. These steps relate in particular to the proposed **revision of the EU pharmaceutical general legislation**[10], which is being negotiated by the co-legislators and the extended mandate of the European Medicines Agency (EMA)[11].

In 2023, the Commission published a Communication on addressing medicine shortages in the EU[12], setting out a number of actions to better prevent and mitigate critical medicine shortages in the EU. While pharmaceutical companies are responsible for ensuring sufficient supply of medicines to cover the needs of patients, Member States ensure the supervision of medicines supply in their territory. Most shortages are managed and resolved at the national level. However, to prevent and mitigate critical shortages where no alternative medicines are available and that cannot be solved at the national level, coordinated action is needed to address supply challenges and to make Europe's medicine supply chains more resilient in the long run.

The 2023 Communication therefore put a particular focus on the most **critical medicines**, for which security of supply in the EU must be ensured at all times. It highlighted the need to publish a **Union list of critical medicines prior to the adoption of the revised EU pharmaceutical legislation.** The first Union list of critical medicines, identified by combining the criteria of seriousness of the disease and the availability of alternative medicines, was published by the European Commission, the EMA and the Heads of Medicines Agencies of the Member States in December 2023 and reviewed in December 2024[13]. It provides a first list from which to analyse the vulnerabilities in the supply chain of these medicines and where further actions are needed to reinforce these supply chains. The list includes over 270 active substances, covering treatments for various illnesses such as infections, cardiovascular diseases, mental health conditions and cancer.

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8 Structured dialogue on security of medicines supply - European Commission (europa.eu)

9 mp_vulnerabilities_global-supply_swd_en.pdf (europa.eu)

10 Reform of the EU general pharmaceutical legislation (europa.eu): the proposals include actions to address systemic shortages and improve security of supply of critical medicines at all times by introducing stronger obligations on supply, earlier notification and a stronger role for EMA in coordinating this with the Member States. Actions are also proposed to strengthen the supply chains of critical medicines by introducing a European alert system for shortages and shortage prevention plans for all medicines.

11 Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

12 Communication_medicines_shortages_EN_0.pdf

13 Union list of critical medicines | European Medicines Agency (EMA)

As a key measure towards boosting the security of supply of critical medicines, the Commission also announced in its Communication the launch of a '**Critical Medicines Alliance**'[14]. This Alliance was formally launched in April 2024[15] and follows an approach successfully used by the Commission in other areas (batteries, semiconductors, critical raw materials). The main objective of the Alliance was to 'identify challenges resulting from vulnerabilities and the most appropriate actions and instruments to address the vulnerabilities in the supply chains of critical medicines, with the primary public health goal of reducing the risk of shortages of those critical medicines'. It brought together over 300 organisations (from patient and scientific communities to healthcare providers, industry and public authorities). Following intensive consultations with its members during 2024, the Alliance published its Strategic Report including a set of recommendations on 28 February 2025[16].

This proposed Regulation delivers on the political commitment of President von der Leyen to propose a **Critical Medicines Act** to address severe shortages of medicines and reduce dependencies linked to critical medicines and ingredients, as well as to ensure the supply of affordable medicines[17]. The proposed Regulation will be an important stage in completing the **European Health Union**; it builds on (1) the measures proposed as part of the ongoing revision of the pharmaceutical legislation of the EU; (2) the extended mandate of the EMA in the realm of crisis preparedness and management of medicines; (3) key actions towards completing a European Health Union in which all EU Member States prepare and respond together to health crises and in which medical supplies are available, affordable and innovative[18]; and (4) new industrial policy measures that recently came into force in other 'critical' domains[19].

Scope and objectives

In light of the current geopolitical situation and the importance of a viable European based pharmaceutical industry for the EU's economic security, the proposed Regulation aims to complement the measures proposed in the revision of the EU pharmaceutical legislation in order to address the supply chain vulnerabilities of critical medicines and support the security of supply and availability of these medicines.

The scope of the proposed Regulation is primarily focused on critical medicines on the Union List of Critical Medicinal Products which is formally established in the proposed pharmaceutical Regulation. Following the 2023 Communication, a first Union List of Critical Medicines was compiled with the expertise of the Heads of Medicines Agencies of the Member States, the European Commission, and the EMA in consultation with key stakeholders, including patient organisations and industry associations. This list was published for the first time in December 2023 and updated one year later.

The proposed Regulation also introduces actions to improve access to and availability of other medicines of common interest, to ensure patients across the EU can benefit from these medicines when and where they need them. These medicines can include medicines for rare diseases (orphan medicinal products)[20] or novel antimicrobials.

General and specific objectives

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14 Critical Medicines Alliance - European Commission
15 https://ec.europa.eu/commission/presscorner/detail/en/ip_24_2229
16 3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c_en
17 https://commission.europa.eu/document/download/b1817a1b-e62e-4949-bbb8-ebf29b54c8bd_en?filename=Mission%20letter%20-%20VARHELYI.pdf
18 European Health Union - European Commission
19 European Critical Raw Materials Act and The Net-Zero Industry Act, for instance.
20 Orphan medicinal products - European Commission

The general objective of this Regulation is to strengthen the security of supply and the availability of critical medicines within the EU, thereby ensuring a high level of public health protection and supporting the security of the Union, and to improve the availability and accessibility of other specific medicines, where the functioning of the market does not otherwise sufficiently ensure their availability and accessibility to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.

The specific objectives of the initiative are:

– to facilitate investments in manufacturing capacities for critical medicines, their active substances and other key inputs in the EU;

– to lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures for critical medicines and other medicinal products of common interest;

– to leverage the aggregated demand of participating Member States through collaborative procurement procedures;

– to support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.

- **Consistency with existing policy provisions in the policy area**

The proposal aims to ensure consistency with several existing EU policy provisions and initiatives in the health and pharmaceutical areas, therefore ensuring a high level of human health protection in the definition and implementation of EU policy.[21]

The proposed Regulation complements the ongoing **revision of the EU pharmaceutical legislation**[22] and the main actions of the **pharmaceutical strategy for Europe**[23]. It aligns with its objectives of increasing access to medicines, improving security of supply, and addressing shortages, whilst giving due consideration to the affordability of medicinal products. It complements the main provisions on the availability and security of supply of medicinal products as proposed in the new pharmaceutical legislation[24]. While the revised EU pharmaceutical framework strengthens obligations for marketing authorisation holders to prevent shortages and introduces EU coordinated actions to mitigate critical shortages, this proposed Regulation creates the necessary conditions – investments, procurement coordination – to proactively reduce dependencies and strengthen EU production capacity.

The proposed Regulation upholds the "once-only" principle by preventing duplication of provisions and requirements related to data collection for identifying critical medicines and assessing supply chain vulnerabilities. The proposed Regulation builds on the Union List of Critical Medicinal Products established in Article 131 of the proposed pharmaceutical Regulation. In addition, the proposed Regulation builds on the data collection framework and the methodology for identifying vulnerabilities in the supply chains of critical medicines proposed to be drawn up under the EU pharmaceutical legislation. This guarantees that the assessment of supply chain vulnerabilities is based on a harmonised and scientifically robust methodology developed at the EU level.

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21 Consolidated version of the Treaty on European Union (Consolidated Version)

22 Reform of the EU pharmaceutical legislation - European Commission

23 A pharmaceutical strategy for Europe - European Commission (europa.eu)

24 Regulation COM(2023) 193 final, Chapter X.

Furthermore, the proposed Regulation builds upon the outcomes of the **structured dialogue on pharmaceuticals**[25], and the staff working document on vulnerabilities of the global supply chains of medicines[26], with actions to address vulnerabilities in the pharmaceutical supply chain.

The proposed Regulation also builds on the **EMA's extended mandate**[27]. In this respect, the launch of the **European Shortages Monitoring Platform**[28] was a key requirement of this extended mandate to enhance the monitoring of shortages across the EU. This platform will enable both marketing authorisation holders and national competent authorities to submit data on the supply, demand and availability of centrally and nationally authorised medicines during crises and preparedness situations. The platform will be further expanded in the context of the revision of the EU's pharmaceutical legislation.

The measures in the proposed Regulation regarding collaborative procurement are complementary to the **existing collaborative procurement tools** under Regulation (EU) 2022/2371 on serious cross-border threats to health[29], Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level[30]. The measures for collaborative procurement of medicinal products of common interest also build on the joint clinical assessments and voluntary cooperation among Member States under Regulation (EU) 2021/2282 on **health technology assessment**[31].

The proposed Regulation takes into consideration the work of the **Critical Medicines Alliance**[32], focusing on addressing vulnerabilities in the supply chains of critical medicines.

Finally, this proposal takes into account all funding opportunities available under the current MFF that can support the objectives of this proposed Regulation.

- **Consistency with other EU policies**

This proposal is consistent with the **EU's innovation and competitiveness policy, in particular with the Competitiveness Compass**[33]. This Communication lists the proposed Regulation as one of the flagship actions under Pillar 3 (reducing excessive dependencies and increasing security). It also mentions critical medicines as one of the possible selected areas for pilot cases where the Commission will propose to coordinate EU and Member States' policies. The proposed Regulation will have an indirect positive impact on the EU's competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector, which has traditionally played a fundamental role in the EU's competitiveness[34]. The provisions under the proposed Regulation

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25 Structured dialogue on security of medicines supply - European Commission

26 mp_vulnerabilities_global-supply_swd_en.pdf (europa.eu)

27 Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

28 European Shortages Monitoring Platform (ESMP) | European Medicines Agency (EMA) – Platform fully operational as of January 2025.

29 Regulation - 2022/2371 - EN - EUR-Lex

30 Regulation - 2022/2372 - EN - EUR-Lex

31 Regulation - 2021/2282 - EN - EUR-Lex

32 Critical Medicines Alliance - European Commission

33 A Competitive Compass which includes new plans for Europe's sustainable prosperity and competitiveness. See also: Competitiveness - European Commission

34 See also Chapter 1. Medicines - a strong ecosystem at an important crossroads (Pharmaceutical Strategy for Europe).

may be supported by **Horizon Europe Partnerships**[35], which provide funding for areas such as research and innovation in technologies with the potential to become essential enablers in the production process.

Furthermore, the **European Industrial Strategy**[36] aims to strengthen the single market's resilience and addresses the EU's strategic dependencies. The proposed Regulation supports these objectives by strengthening the pharmaceutical supply chain's resilience and reducing dependence on non-EU sources for critical medicines and active pharmaceutical ingredients. The proposed Regulation is also consistent with the Commission communication on a **Clean Industrial Deal**[37], which outlines concrete actions to turn decarbonisation into a driver of growth, in particular for energy-intensive industries. This includes demand side measures to create the right conditions for companies to thrive, similar to those proposed in this Regulation.

The **EU's Financial Regulation** is the main point of reference for the principles and procedures governing the EU budget, including on joint procurement and procurement on behalf of, or in the name of Member States. Last year, the recast of the Financial Regulation entered into force[38]. The proposed Regulation provides a sector-by-sector basis for these types of procurement to be conducted for critical medicines and other medicines of common interest, being consistent with the procedural framework set out in the Financial Regulation, but setting specific conditions under which the joint procurement and procurement on behalf or in the name of Member states can be launched. These specific conditions related to certain threshold of Member states participating in the procedure and eligibility criteria as regards the medicinal products, reflect the assessment of where the Commission intervention would be the most appropriate in the light of the objectives of the act.

An evaluation of the **EU's public procurement directives** is currently ongoing[39] and the Commission will make a proposal to revise the framework in 2026. It will allow for sustainability, resilience and European preference criteria in EU public procurement for strategic sectors. The proposed Regulation would introduce measures related to national public procurement of certain pharmaceuticals in line with the objectives of this upcoming revision, to help ensure security of supply and enable preference for European products in public procurement for critical medicines and other medicines of common interest, to the extent this is necessary and in line with the Union's international commitments.

The proposed Regulation is consistent with broader efforts to modernise and adapt EU legislation to current challenges since it aims at reducing administrative burdens and facilitating permit-granting processes for strategic projects. The proposed Regulation is in line with the **Omnibus Proposal**[40] and aims to address vulnerabilities of medicine supply chains without increasing the overall burden on industry.

Digital

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35 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

36 A New Industrial Strategy for Europe

37 Clean Industrial Deal - European Commission

38 EU Financial Regulation - European Commission

39 Commission launches call for evidence and public consultation on the evaluation of the Public Procurement Directives - European Commission

40 Commission simplifies rules on sustainability and EU investments, delivering over €6 billion in administrative relief - European Commission

The proposed Regulation is aligned with recent key European digital initiatives (**Artificial Intelligence (AI)** and **NIS 2 Directive**) that aim to promote secure and interoperable data exchange, the use of advanced technologies and a high common level of cybersecurity across the Union. The AI Act[41] and the NIS 2 Directive[42] provide frameworks for responsible AI use and a high common level of cybersecurity.

Furthermore, the **Interoperable Europe Act**[43], along with dedicated tools like the **European Interoperability Framework (EIF) Toolbox** and reusable components, supports standardised data exchange across Member States. The recently redesigned Tenders Electronic Daily portal[44] ('TED') serves as an efficient tool for sharing and monitoring procurement procedures.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU). This is consistent with the legal basis of existing EU pharmaceutical legislation. Article 114(1) has as its object the establishment and functioning of the internal market. In accordance with Article 114(3) TFEU, the proposal takes as a base a high level of health protection.

• Subsidiarity (for non-exclusive competence)

The objectives of this proposal cannot be sufficiently achieved by Member States acting individually, as the challenges of medicine shortages and supply chain vulnerabilities extend beyond national borders. EU-level action is needed to ensure a coordinated and effective response to these cross-border issues. The proposal takes into account this principle in the design of the individual actions, particularly when procuring critical medicines and other medicinal products of common interest.

• Proportionality

The proposal targets critical medicines for which there is a demonstrated need to intervene, and the selected intervention can lead to an effective reduction in the risk of shortages. Specific measures also apply to other medicines of common interest affected by market access issues in Member States.

• Choice of the instrument

The proposal takes the form of a Regulation of the European Parliament and of the Council. The selection of a Regulation over a Directive is driven by the need for immediate and uniform application across the EU. This choice ensures legal certainty by minimising the risk of divergent interpretations and implementations by Member States. In addition, the cross-border implications of the legislation require a cohesive and consistent approach, achievable through a Regulation.

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41 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence

42 Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive)

43 Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act)

44 TED – EU Tenders, the Supplement to the Official Journal - TED

3. RESULTS OF *EX-POST* EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

The growing issue of medicines shortages poses an immediate and alarming threat to public health. Without swift action to address vulnerabilities in the supply of critical medicines, disruptions could have severe consequences for patient care, including delayed treatments for life-threatening conditions. Our heavy reliance on non-EU suppliers, fragile global supply chains, and geopolitical tensions exacerbate the risk of shortages, making this a pressing challenge.

A rich evidence base and extensive stakeholder input concerning medicine shortages and critical medicines have been gathered and analysed in preparation for the revision of the pharmaceutical reform[45]. In addition, the proposed Regulation was preceded by comprehensive consultations with stakeholders through the structured dialogue on the security of medicines supply[46] and the Critical Medicines Alliance[47].

Given that security of supply and addressing medicine shortages were a central focus during the evidence-gathering activities for the above initiatives, along with the pressing need for urgent action, no dedicated impact assessment or online public consultation could be conducted *ex-ante* for this proposed Regulation.

The *evaluation* of the EU pharmaceutical legislation[48] highlighted that medicine shortages are an increasing problem in the EU and that they have grown worse since the COVID-19 pandemic. Overall, there has been a marked increase in the number of reported shortages across the EU. These shortages are placing a significant burden on health systems and health professionals, putting patients at risk of sub-optimal care and health systems at risk of higher healthcare costs[49].

Supporting evidence

The analysis and supporting evidence including studies commissioned by the Commission will be summarised in a staff working document and published within three months of the proposal's publication.

- ***Ex-post* evaluations/fitness checks of existing legislation**

Not applicable

- **Stakeholder consultations**

In February 2021, the Commission brought stakeholders together in a structured dialogue on security of medicines supply[50]. Participants in this dialogue included: (i) actors in the supply chains of critical medicines; (ii) public authorities; (iii) patient and health non-governmental organisations; and (iv) the research community. This dialogue further deepened the understanding of global pharmaceutical supply chains.

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45 Reform of the EU pharmaceutical legislation - European Commission

46 Structured dialogue on security of medicines supply - European Commission

47 Critical Medicines Alliance - European Commission

48 Reform of the EU pharmaceutical legislation - European Commission

49 Future-proofing pharmaceutical legislation - Publications Office of the EU.

50 The list of organisations can be consulted here: https://health.ec.europa.eu/document/download/bd92f46c-4c55-4fed-8642-81b0aa30ff22_en?filename=structured-dialogue_lp_en.pdf

Consultations for the **EU pharmaceutical reform** in the domain of shortages also explored the stakeholders' view on this topic[51]. These consultations confirmed that stakeholders (in particular, civil society organisations and healthcare professionals) see medicine shortages as a crucial issue. In the targeted surveys, civil society, public authorities and health service stakeholders considered that the area that legislation was the least effective in addressing was issues related to security of supply and medicine shortages. They also gave their view on policy measures, such as shortage prevention plans, a shortage monitoring system at EU level or the shortage notification. Furthermore, a dedicated validation workshop was held on supply chains in April 2022. During this workshop, various stakeholders explained that diversification of the supply chain is challenging and not always feasible due to the difficulty of finding alternative suppliers upstream in the supply chain[52].

More than 300 stakeholders of critical medicine supply chains, as members of the **Critical Medicines Alliance** that includes industry representatives, trade associations, patient organisations, medical profession organisations and Member States, have been consulted on key topics of interest for critical medicines' supply chain strengthening. After the launch of the Alliance in 2024, technical discussions took place at working group level throughout the rest of the year, aiming to prepare recommendations of actions to strengthen manufacturing capacity and diversify supply chain through partnerships with like-minded non-EU countries. The results of these recommendations, compiled by the Steering Board in its Strategic Report[53], provide for actions on vulnerability assessment, incentives for investments in manufacturing capacity, contingency stocks and procurement approaches, as well as leveraging partnerships with non-EU countries. In particular, the Alliance recommends: (i) establishing a European list of Critical Vulnerable Medicines; (ii) implementing a European Investment plan to strengthen production capacities for critical medicines in Europe by combining EU funding programmes and State aid; (iii) implementing a comprehensive harmonised and balanced framework on contingency stocks; (iv) promoting virtuous public procurement practices by means of applying specific 'MEAT' criteria[54] and making further use of joint procurement; and (v) promoting a level playing field for environmental and social standards, as well as fair competition between critical medicines manufactured in the EU and in the rest of the world. On partnerships with non-EU countries, the Alliance specifically recommends making use of the developed methodology to assess the prospects of countries for different types of partnerships. Finally, the Alliance recommends that the MSSG (Executive Steering Group on Shortages and Safety of Medicinal Products) formalises the possibility for outreach to non-EU country jurisdictions, as part of the Voluntary Solidarity Mechanism.

A general consultation on the proposed Regulation was launched in a **Call for Evidence** that was published on 30 January 2025[55].

The Commission received 121 valid contributions, submitted by business associations (26%), company/businesses (25%), non-governmental organisations (22%), EU citizen (5%), public authorities (5%), trade unions (4%), consumer organisations (2%), academic/research institutions (1%), and other (9%).

The responses came from 22 countries (including 5 non-EU countries). Among these, Belgium is the most represented (32%) as most European business associations and civil society

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51 Reform of the EU pharmaceutical legislation - European Commission

52 See Annex 2 synopsis report (stakeholder consultation) for the reform of the EU pharmaceutical legislation: GP_Annexes 1 to 4 - 6 to 9 - 14 to 16_v28102022

53 Critical Medicines Alliance - European Commission

54 Most economically advantageous tender which allows for more prominence to be given to quality beyond price considerations alone.

55 Critical Medicines Act

organisations are headquartered in the country, followed by Germany (15%), France (7%), Italy (6%) and Spain (5%).

A broad majority of the responses supported the Commission in tabling a Critical Medicines Act, seeing it as a crucial tool to address shortages of critical medicines. To highlight some key considerations, the various stakeholders' groups, companies and business associations noted the persistent dependencies on non-EU suppliers, particularly for active pharmaceutical ingredients (APIs), and the resulting increased risk of medicine shortages. They welcomed the European Commission's commitment to securing supply chains, and called for a comprehensive legal framework, promoting EU-based production of APIs, coupled with an improved access to funding mechanisms. To ensure transparency, accountability and efficiency, many NGOs proposed regular risk assessments and vulnerability analyses of the pharmaceutical supply chains and a coordinated monitoring system taking into account existing national systems, to avoid duplications. Public authorities in particular supported the voluntary joint procurement of critical medicines. Responses from various stakeholder groups noted the need to address fragmentation stemming from national stockpiling requirements. The importance of global partnerships aimed at maintaining robust supply chains was widely emphasised. A more detailed analysis of the responses will be included in the staff working document to be produced that will be published by the second quarter of 2025. The Commission has also commissioned a study by an external contractor regarding the proposed regulation, which includes targeted consultations with various stakeholders.

- **Collection and use of expertise**

The Union List of Critical Medicines[56] was compiled with the expertise of the Heads of Medicines Agencies of the Member States, the European Commission, and the EMA in consultation with key stakeholders, including patient organisations and industry associations. Published for the first time in December 2023 and updated one year later, the list contains 276 active substances used in medicines for human use that are deemed critical using an agreed methodology, based on two key criteria:

- The medicine's therapeutic indication targeting a serious condition;
- The limited availability of appropriate alternatives.

Medicines are included on the Union list if they meet the above-mentioned criteria on their critical status and if they meet additional criteria, such as the number of Member States considering the medicine critical or the marketing status of the medicine. It is important to note that inclusion on the list does not necessarily indicate an imminent shortage, rather it prioritises prevention efforts for these critical medicines.

The Commission conducted a technical assessment of supply chain vulnerabilities for critical medicines[57]. The analysis focused on a selection of 11 critical medicines from the Union list. The issues identified by the pilot included the significant dependences on non-EU active substances suppliers for 4 of the 11 molecules and risks stemming from market concentration. The pilot pointed to the need to strengthen resilience, such as diversifying supply sources, increasing production capacity flexibility and developing robust risk management frameworks to handle economic and market variability effectively. The outcomes of this pilot exercise also showed some limitations, such as the lack of legal basis for data collection and information sharing, the absence of harmonised data format and standards leading to interoperability issues, and the hesitancy of pharmaceutical companies to share highly sensitive commercial data.

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56 Union list of critical medicines | European Medicines Agency (EMA)

57 Commission assessment shows the need to reinforce resilience of critical medicines supply chains - European Commission

Studies: a study by an external contractor is being conducted that focuses on the assessment of policy options in the realm of three main policy strands: horizontal (scope, governance, data); enabling conditions for investments in critical medicines; demand-side measures. The interim report of the study has been taken into account in the preparation of this proposed Regulation, and further results of the study will feed into the staff working document that will be published by the second quarter of 2025 to provide the analysis and all supporting evidence underpinning this proposal.

The Study on best practices in the public procurement of medicines[58], published in 2022, mapped and analysed practices in the public procurement of medicines across 32 European countries. The report presents findings on organisational forms of procurement and the use of different forms of procedures and techniques (including the use of different procurement requirements, such as the Most Economically Advantageous Tender). The possible impacts of public procurement of medicines on access to medicines, affordability and availability of medicines and security of supply were assessed.

Through the work of the Alliance, several studies have also been used as evidence for the preparation of the recommendations, including the Advancy study on 'Strengthening API production industry in France and Europe'[59]. This study highlights the significant competitiveness deficit faced by the European pharmaceutical sector, particularly in the production of essential medicines and active substances. Furthermore, the OECD Report on 'Shortages of medicines in OECD countries'[60] also served as evidence to the Alliance; this study examined the nature and extent of medicine shortages pre-COVID and explored the reasons for this global problem. It concludes that a global multistakeholder approach is necessary, involving all relevant actors, also beyond healthcare.

- **Impact assessment**

Given the urgent need to address the policy challenges identified, the proposed Regulation will be proposed without an impact assessment. However, its provisions are based on existing analyses, stakeholder consultations, and lessons learned from past initiatives to ensure a proportionate and evidence– based approach. To further assess its expected impacts, a staff working document will be published within three months of the proposal's adoption, providing a summary of available evidence on the expected impacts of the proposed Regulation and the analysis underpinning the proposal.

- **Regulatory fitness and simplification**

The proposal does not envisage significant additional regulatory burden. For undertakings developing a strategic project, it will facilitate the creation or expansion of manufacturing capacities of critical medicines, their active substances and key inputs in the EU by fast-tracking permit-granting procedures, streamlining environmental assessments and providing targeted support when needed. For national public administrations, certain reporting obligations are foreseen in relation to financial support provided to strategic projects, national programmes to ensure sustainability and resilience in public procurement and collaborative procurement initiatives. Nevertheless, the proposed Regulation will also generate further synergies and ensure efficient coordination and collaboration between Member States to reach the Union's strategic objective to strengthen the security of supply and availability of critical medicines.

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58 https://op.europa.eu/s/z1Rz

59 https://efcg.cefic.org/wp-content/uploads/2025/01/Advancy-Sicos-report-extract-protected.pdf

60 https://www.oecd.org/en/publications/shortages-of-medicines-in-oecd-countries_b5d9e15d-en.html

- **Fundamental rights**

The proposal helps achieve a high level of human health protection and is therefore consistent with Article 35 of the Charter of Fundamental Rights of the European Union ('the Charter'). Article 16 of the Charter provides for the freedom to conduct a business. The measures under this proposal support creation or expansion of manufacturing capacity and foster demand for critical medicines and other medicines of common interest with resilient supply chains, which can reinforce the freedom to conduct a business in accordance with Union law and national laws and practices.

4. BUDGETARY IMPLICATIONS

The legislative financial statement attached to this proposal sets out the budgetary, human and administrative resource implications. Appropriations will be reallocated within the financial envelope. The costs of this proposal will be fully covered through redeployments within existing financial envelopes of the current multiannual financial framework. For the duration of the 2021-2027 MFF[61], the Strategic Projects may be supported by EU funding, including but not limited to EU4Health Programme[62], Horizon Europe[63], and the Digital Europe programme[64], provided that they comply with the requirements provided for in these instruments.

The indicative overall budgetary impact of the proposal is EUR 83.02 million for the period 2026-2027 under Heading 2b. This amount will finance manufacturing investments and manufacturing capacity and will also cover expenses for meetings. These appropriations will be redeployed within the existing financial envelope of the EU4Health programme. This amount will also cover the increase to the EU contribution to EMA (EUR 1.4 million), due to increased EMA costs for staff, IT investments, and meeting costs. The increased EU contribution to EMA will be covered by the EU4Health programme's budgetary envelope in 2026 and 2027.

The budgetary impact under Heading 7 amounts to EUR 5,5. This amount will cover staff costs and missions' costs and will be covered through internal redeployment.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will evaluate the impact of this proposed Regulation and whether its objectives have been achieved by five years after the date of application and every five years thereafter. The main findings of the evaluation will be presented in a report to the European Parliament and the Council, which will be made public.

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61 Council Regulation (EU, Euratom) 2024/2093 laying down the multiannual financial framework for years 2021 to 2027, as amended (OJ LI 433, 22.12.2020)

62 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)

63 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.

64 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.

This proposal introduces a requirement for Member States to inform the Critical Medicines Coordination Group about their intention to provide national financial support to strategic projects, as well as for the Commission to inform periodically the Critical Medicines Group of the Strategic Projects that benefited from financial support from the Union and of setting up any new funding possibilities. The data gathered is necessary to monitor and evaluate the success of this Regulation over time.

- **Detailed explanation of the specific provisions of the proposal**

This proposal consists of a proposal for a new regulation. The proposed Regulation includes the following main areas:

General provisions

Chapter I presents the objectives and subject matter of the proposed Regulation. The proposal establishes a framework for strengthening the security of supply and the availability of critical medicines as well as the availability of and accessibility to certain other medicines. It also clarifies the scope of the proposed Regulation. While the proposal applies mainly to critical medicines on the Union List of Critical Medicinal Products which is established in the proposed Pharmaceutical Regulation, some provisions of the proposed Regulation also apply to medicines of common interest facing market access issues in a number of Member States, especially demand-side measures. Finally, key definitions used throughout the proposed Regulation are introduced.

Strengthening the EU's security of supply

Chapter II clarifies that the security of supply and availability of critical medicines for all patients is one of the EU's strategic objectives. This objective requires a coordinated approach from the Member States and the Commission.

Enabling conditions for investment

Criteria and procedure for the recognition of strategic projects

Section I of Chapter III defines criteria for recognising some projects as Strategic Projects and describes the steps to recognise such projects at Member State level. A Member State's authority is designated to assess and confirm, upon request, whether the specific project meets the criteria laid down.

Facilitating administrative and permit-granting processes

Section II of Chapter III provides for a priority status for Strategic Projects that are considered to be in the public interest, in the context of permit-granting processes. To ensure the fast-tracking of permit-granting processes, Strategic Projects may also request to be granted the status of highest national significance in Member States where such status exists and request a coordinated or joint procedure when an environmental assessment is required under different EU legislation. Finally, the proposal also provides for the possibility for Strategic Projects promotors to request administrative, regulatory and scientific support from the relevant authorities.

Financial incentives

Section III of Chapter III provides for the possibility for Member States to prioritise financial support for strategic projects that address a supply chain vulnerability and requires due consideration to the outcome of vulnerability evaluations and the strategic orientations of the Critical Medicines Group. Strategic projects may be supported by EU funding under the current MFF, if strategic projects fulfil the conditions and requirements of the calls under the available

programmes. Finally, exchange of information on strategic projects that have or will receive financial support at Member State or EU level is ensured via the Critical Medicines Group.

Demand side measures

Award criteria and other procurement requirements and related measures

Section I of Chapter IV imposes the use of procurement requirements other than price in the context of public procurement procedures by contracting authorities in the Member States, unless justified by market analysis and considerations related to the financing of health services. The proposal also requires, in specific cases, when justified by a vulnerability analysis, that the contracting authorities apply procurement requirements that favour suppliers that manufacture a significant portion of these critical medicines in the EU. The compliance with Union's international commitments should be ensured. Finally, Member States will be required to develop national programmes to ensure security of supply of critical medicines via procurement, and, possibly, pricing and reimbursement practices. When imposing contingency stocks on supply chain actors, Member States shall ensure these requirements are proportionate and respect the principles of transparency and solidarity.

Collaborative procurements

Section II of Chapter IV provides a framework for Member States to request Commission support in the use of different collaborative procurement tools for critical medicines and other medicines of common interest, depending on the context and respecting the principles of subsidiarity and proportionality. This includes Commission facilitation of cross-border procurement between Member States, Commission procurement on behalf of or in the name of Member States, as well as the Commission and Member States engagement in Joint Procurement.

Critical Medicines Coordination Group

Chapter V established the Critical Medicines Coordination Group, which is composed of the Commission and Member States' representatives. The Critical Medicines Group's main task is to facilitate the application of the Regulation including by facilitating: a) discussion on strategic orientation for financial support of Strategic Projects; b) exchanges and, where appropriate, cooperation on national procurement policies; c) discussion on a need for collaborative procurement initiatives; d) advice on the order of priority for the vulnerability evaluation of critical medicines;. The Critical Medicines Group will also enable a discussion on strategic partnerships.

International cooperation

Chapter VI requires the Commission to investigate the possibility of establishing strategic partnerships.

Final provisions

Chapter VII contains provisions amending Regulation (EU) 2024/795. Chapter VIII imposes an obligation on the market actors to provide the information necessary for the application of the proposed regulation. It also defines the timeline for the evaluation of the proposed Regulation and sets the dates of entry into force and application of the different provisions.

2025/102 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and activities. The availability of safe, efficacious and high-quality medicinal products is vital to achieving this objective and to safeguarding public health across the Union.

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

(3) Shortages of medicinal products can have very different and complex root causes, with challenges identified along the entire pharmaceutical value chain. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. These include existing dependencies on a limited number of suppliers globally and lack of Union capacities to produce certain medicinal products, their active substances or key raw pharmaceutical materials. Through diversification of supply sources and investment in local production, the Union can reduce its risk of exposure to shortages of medicinal products.

(4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in particular, for key raw pharmaceutical materials and active substances. Setting up new, or modernising existing manufacturing capacities in the Union for critical medicinal products, their key

[1] OJ C , , p. .

inputs and active substances, which have often been on the market for a long time and are considered to be relatively inexpensive, is currently not seen as a sufficiently attractive option for private investment, also in view of lower energy costs, lesser environmental and other legal requirements elsewhere in the world. Workforce shortages and the need for specialised skills in pharmaceutical manufacturing further add to the industrial challenges to manufacturing in the Union. Targeted financial incentives, simplified administrative processes, and better Union-level coordination can contribute to supporting efforts to increase manufacturing capacities in the Union and strengthen the supply chains for critical medicines.

(5) To enhance the security of supply for medicinal products and thereby contribute to a high level of public health protection, the Union has implemented a range of measures that contribute to building a European Health Union. In particular, Regulation (EU) 2022/123 of the European Parliament and of the Council[2] has reinforced the European Medicines Agency's ('the Agency') mandate by enhancing monitoring, coordination, and reporting mechanisms to prevent and mitigate supply disruptions of critical medicinal products across Member States. That Regulation also established the Agency's Executive Steering Group on Shortages and Safety of Medicinal Products ('the MSSG'), which brings together representatives from the Agency and Member States, to coordinate urgent actions within the Union to manage existing shortages and issues related to the quality, safety, and efficacy of medicinal products.

(6) In addition, Regulation (EU) …/… of the European Parliament and of the Council[3] No *[reference to be added after adoption cf. COM(2023) 193 final*] further strengthens the continuity of supply and availability of medicinal products through developing the core tasks already granted to the Agency by Regulation (EU) 2022/123 and setting out a framework for the activities to be deployed by the Member States and the Agency to improve the Union capacity to react efficiently and in coordinated manner to support the shortages management and security of supply of medicinal products, including by strengthening the obligations of marketing authorisation holders as it regards the shortages prevention and reporting.

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

(8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to

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

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

strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. Uncoordinated national measures risk disrupting the internal market, fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for further harmonisation.

(9) Some medicinal products of common interest which are key for the provision of adapted care to patients, while not affected by supply security issues, may still not be available to patients in some Member States. This may be caused by a variety of factors, including product or geographical demand market size, which can impact the timely availability of medicinal products in certain Member States.

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

(11) The measures introduced by this Regulation are without prejudice to marketing authorisation holders' obligations, in particular under Directive (EU) …/… of the European Parliament and of the Council [*reference to be added to corresponding Article after adoption of cf. COM(2023)192 final*], Regulation (EU) …/… [*reference to be added after adoption cf. COM(2023) 193 final*] and Regulation (EU) 2022/123, including the obligation to ensure sufficient supplies of medicinal products, within the limits of their responsibility. These measures are aligned with the principles of the internal market. This Regulation is without prejudice to Union competition law, including antitrust, merger and State aid rules.

(12) While the primary objective of this Regulation should be to strengthen the security of supply and ensure the availability of critical medicinal products and of medicinal products of common interest, given a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation should also support the Union's competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector. Ensuring the security of supply and availability of critical medicinal products and the availability and accessibility of other medicinal products of common interest should moreover contribute to the Union's preparedness, resilience, and economic and overall security, including when cross-border supply chains risk being disrupted.

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

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

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

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

(17) Certain projects can have a positive impact on security of supply as they increase the Union's manufacturing capacity for critical medicinal products and strengthen the resilience of the Union's supply chains. In order to encourage private investments in these projects, the concept of strategic projects should be introduced. Given their role in ensuring the Union's security of supply for critical medicinal products, the relevant permitting authority should consider strategic projects to be in the public interest. To ensure their expedient implementation, national authorities should ensure that the relevant permit granting processes are carried out in the fastest way possible making available, in particular any form of accelerated procedures that exists in applicable Union and national law. National authorities should consider, when possible, their streamlining as well as enable digital submission of required information.

(18) To avoid unnecessary delays and the creation of additional administrative layers, the verification of whether a project fulfils the strategic project criteria should be performed by any Member State authority requested to provide advantages offered in this Regulation. A designated authority should, when solicited, verify whether a given project is a strategic project. In order to accelerate and facilitate their deployment, strategic projects should benefit from streamlined administrative processes, priority status in the context of permit granting procedures and related dispute resolution procedures, as well as, be offered targeted regulatory support. In this context, the Member States should give particular attention to small and medium sized enterprises (SMEs) which should have a fair chance to initiate strategic projects.

(19) The production of medicinal products has environmental implications and may negatively impact not only the environment itself but also human health. The environmental assessments and authorisations required under Union law are an integral

part of the permit-granting process for strategic projects and an essential safeguard to ensure negative environmental impacts are prevented or minimised. However, to ensure that permit-granting processes for strategic projects are predictable and timely, it should be possible to streamline the required assessments and authorisations by the relevant authority, while not lowering the level of environmental protection.

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

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

(22) Union-level funding may be leveraged to facilitate investments in strategic projects. Strategic projects may benefit from access to existing EU funding instruments, such as the EU4Health Programme[4], Digital Europe Programme[5] and Horizon Europe[6] (relevant, for example, for active substances referred to in Article 5(d) of Regulation (EU)2021/695), as well as the Strategic Technologies for Europe Platform (STEP), when they fulfil the criteria established in these instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 of the European Parliament and of the Council[7] (STEP) should in particular consider supporting strategic projects addressing a vulnerability in the supply chains of critical medicinal products and therefore Regulation (EU) 2024/795 should be amended.

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4 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)

5 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)

6 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)

7 Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, (OJL 2024/794, 29.2.2024, ELI: http://data.europa.eu/eli/reg/2024/795/oj)

(23) To allow for a more coordinated approach to financial support, it is appropriate that Member States and the Commission exchange the information on financial support to strategic projects. As regards the strategic projects that have benefitted from EU funding, the beneficiaries should follow the relevant communication and visibility rules[8].

(24) Given that public authorities or entities are the principal buyers of medicinal products for the inpatient sector and that the public procurement of medicinal products is a powerful tool to improve security of supply and the availability and accessibility of other medicinal products of common interest, it is necessary to establish rules that require the use of the procurement requirements referring to Most Economically Advantageous Tender (MEAT) that take into account the supply security and availability considerations. Procurement requirements based on such considerations should include stockholding obligations, a number of diversified suppliers, state of the art monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery and measures in case of non-timely delivery.

(25) Inconsistent use of procurement requirements in public procurement procedures may have negative impact on the internal market as it creates obstacles to cross-border participation and a lack of predictability for bidders. In order to avoid such negative outcomes, the use of MEAT criteria should be mandatory.

(26) To ensure a high level of health protection and security of supply, it is necessary to procure in a way that promotes diversification of suppliers where dependency on a single or a limited number of third countries, threatening the security of supply, has been established through a vulnerability evaluation. In such situations, contracting authorities in the Member States should introduce procurement requirements that favour suppliers of critical medicinal products that manufacture a significant portion of these products in the EU. Moreover, the contracting authorities in the Member States, when justified by market analysis and public health considerations, may apply procurement requirements that favour suppliers of medicinal products of common interest that manufacture a significant portion of these medicinal products in the EU. These measures should be designed and applied in line with the Union's international obligations including the principles of non-discrimination and proportionality.

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

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

(29) The Commission intends to issue guidelines designed to support Member States in implementing their obligations to use procurement requirements including award criteria beyond price considerations with a view to strengthening the security of supply,

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

building on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate.

(30) The procurement of medicinal products is organised differently across Member States, involving various actors. To strengthen the security of supply chains for critical medicinal products, Member States should establish national programmes that promote the consistent use of procurement criteria by contracting authorities within their territory, including the application of multi-winner approaches where beneficial, based on thorough market analysis. To ensure a comprehensive approach, and considering that critical medicinal products are also relevant for outpatient sector where they are often not purchased through public procurement, these programmes may also encompass measures to strengthen supply chain resilience and sustainability through measures related to pricing and reimbursement, where appropriate. The programmes should be shared with the Commission and the Critical Medicines Coordination Group, established by this Regulation, to facilitate the exchange of best practices and coordination between the Member States. This cooperation should enhance the overall effectiveness of the various measures put forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality.

(31) Obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold contingency stocks can have a serious negative impact on the internal market and other Member States. To avoid such an impact, these obligations should be designed taking into consideration the principles of proportionality, transparency and solidarity. The Member States should give due consideration to forthcoming Commission guidelines designed to facilitate the fulfilment of Member States' obligations as regards the absence of any negative impact on the internal market when proposing and defining the scope and timing of any form of requirements for companies to hold such stocks.

(32) Availability and access disparities exist for critical medicinal products and medicinal products of common interest throughout the Union, disproportionately affecting some Member States. The collaborative procurement of critical medicinal products and of medicinal products of common interest can be a powerful tool to improve their security of supply and accessibility.

(33) Directive 2014/24/EU of the European Parliament and of the Council[9] provides for the possibility of procurement involving contracting authorities from different Member States. Whereas it has been found helpful to make small markets attractive for suppliers, thereby achieving better availability of medicinal products, its implementation is time- and resource-intensive, especially in the starting phase, and considered a limiting factor. To facilitate the deployment of procurement initiatives involving contracting authorities from different Member States, the Commission, when requested, should provide its assistance during the preliminary phase of setting up such a procurement initiative.

(34) Taking into account experiences resulting from the implementation of joint procurement of medical countermeasures pursuant to Regulation (EU) 2022/2371 of the European

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

Parliament and of the Council[10] and of COVID-19 vaccines, pursuant to Council Regulation (EU) 2016/369[11] in the context of the EU Vaccines Strategy and acknowledging potential benefits that leveraging of several Member States demand in one procurement procedure may have, Member States should be able to consider the use of joint procurement or to consider requesting the Commission to procure on their behalf, or in their name, where such procurement could contribute to the achievement of the objectives of this Regulation.

(35) To ensure that the collaborative procurement initiatives contribute to the achievement of the objectives of this Regulation, while fully respecting the principle of subsidiarity, the Commission's involvement in joint procurement and procurement on behalf, or in the name of the Member States, should be limited to defined cases. For this reason derogations from Article 168 (2) and (3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[12] should be provided.

(36) To ensure transparency, legal clarity, and effective coordination, structured agreement between the Member States and the Commission should govern procurement procedures under this Regulation that rely on an active Commission involvement. Such agreement should set out the division of responsibilities, decision-making processes, the information to be shared as relevant to the procurement procedure, including information on Member States' participation in parallel negotiations through different channels in relation to the same medicinal products or the same active substances as appropriate, and liability provisions, ensuring a fair and efficient framework for participating Member States while preventing market distortions and supply disruptions. This Regulation is without prejudice to and does not prevent the use of joint procurement procedures established under Regulation (EU) 2022/2371 of the European Parliament and of the Council for those critical medicinal products and other medicinal products that also fall within the definition of medical countermeasures as set out in that Regulation. For such medicinal products, the objective of the joint procurement initiative should determine the applicable framework. Where a joint procurement procedure is initiated with the aim of advance purchasing of these medicinal products as medical countermeasures to prepare for and respond to serious cross-border threats to health, such a procurement procedure should be carried out in accordance with Regulation (EU) 2022/2371. This Regulation is without prejudice to Council Regulation (EU) 2022/2372[13] setting the framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

(37) Ensuring a structured and coordinated approach to strengthening the security of supply of critical medicinal products requires collaboration between the Member States and the Commission. To facilitate this, the Critical Medicines Coordination Group ('the Critical Medicines Group') should be established to facilitate effective coordination across the

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

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

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

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

relevant policy areas. The Critical Medicines Group should be composed of high-level representatives of Member States with expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. The Commission should be a member of the group. To ensure structured discussions, the Commission should chair the Critical Medicines Group and perform the functions of its secretariat.

(38) To ensure coordinated implementation of this Regulation, the Critical Medicines Group should enable exchanges of information related to funding of strategic projects and facilitate the strategic orientation of financial support for strategic projects. The Critical Medicines Group should also facilitate the exchange of information on national programmes, including on the approach to contingency stock requirements in public procurement contracts. When relevant, the Critical Medicines Group should facilitate the coordination of national programmes. The Critical Medicines Group should furthermore facilitate discussions on the need to launch a collaborative procurement initiative and the need to prioritise the vulnerability evaluation for specific critical medicinal products.

(39) The Union could further enhance the availability and security of supply of critical medicinal products by providing access to alternative sources of supply in third countries through international trade agreements or other forms of international cooperation. The Union could, to that end, rely on its network of existing trade agreements and additionally pursue strategic partnerships with third countries to further deepen bilateral cooperation, especially with candidate countries. In this context, the Commission should assess whether existing partnerships effectively address the intended aims or could be further improved or upgraded, and what types of potential partnerships could be concluded with the most relevant third countries. This should be done without prejudice to the prerogatives of the Council in accordance with the Treaties.

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

(41) In order to ensure that this Regulation effectively meets its objectives, it is essential to assess its implementation and impact over time. The Commission should carry out an evaluation of this Regulation five years after its application and every five years thereafter. This evaluation should include an assessment of the extent to which the Regulation's objectives, as set out in Article 1, have been achieved, including its impact on stakeholders, regulatory procedures, and market dynamics. In particular, the Commission's evaluation should take into account the views of Member States, economic operators, and other relevant stakeholders, ensuring that their feedback contributes to the continuous improvement of the regulatory framework. The results of this evaluation should be presented to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. In order to facilitate this evaluation, national authorities and economic operators should provide relevant data and information upon request to support the Commission's assessment.

(42) Since the objectives of this Regulation to establish a framework to strengthen the availability and security of supply of critical medicinal products within the Union and to improve the availability and accessibility of medicinal products of common interest

through coordinated and targeted action of Member States cannot be sufficiently achieved by the Member States acting alone, but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the TFEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve its objectives.

HAVE ADOPTED THIS REGULATION:

Chapter I
General provisions

Article 1

Objectives and subject matter

1. The objective of this Regulation is to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby 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, 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 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 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 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*];

(4) ‘critical medicinal product’ means a medicinal product 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 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[14] *[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 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 building, chemical and grid connection permits

[14] 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]*.

and environmental assessments and authorisations where those are required and encompassing all applications and procedures;

(13) ‘innovative manufacturing process’ means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform techniques, 3D manufacturing;

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

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

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

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

(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

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 or increasing manufacturing capacity 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.

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 a strategic project.

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

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

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

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

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

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

SECTION II

FACILITATING ADMINISTRATIVE AND PERMIT-GRANTING PROCESSES

Article 7

Priority status of strategic projects

Strategic projects shall be considered as contributing to the security of supply of critical medicinal products 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 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, a Member State shall provide to a strategic project located on its territory all the administrative support necessary to facilitate its timely and effective implementation, including assistance:
   (a) with regard to compliance with applicable administrative and reporting obligations;
   (b) with regard to informing the public, with the aim of increasing public acceptance of the strategic project;
   (c) along the permit-granting process.
2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs) and, where appropriate, establish a dedicated channel for communication with SMEs to provide guidance and respond to queries related to the implementation of this Regulation.

Article 9

Request for granting the status of highest national significance

1. A project promoter may request that their application for a permit is granted the status of the highest national significance, when such a status exists in national law, and be treated accordingly.
2. National authorities shall grant the status of the highest national significance to an application for a permit without prejudice to obligations provided for in Union law.

Article 10

Procedures relating to dispute resolution

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

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

Article 11

Regulatory and scientific support from 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.

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[15], Directive 2000/60/EC of the European Parliament and of the Council[16], Directive 2001/42/EC of the European Parliament and of the Council[17], Directive 2008/98/EC of the European Parliament and of the Council[18], Directive 2009/147/EC of the European Parliament and of the Council[19], Directive 2010/75/EU of the European Parliament and of the Council[20], Directive 2011/92/EU of the European

[15] 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).

[16] 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).

[17] 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).

[18] 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).

[19] 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).

[20] 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).

Parliament and of the Council[21] or Directive 2012/18/EU of the European Parliament and of the Council[22], 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.

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

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

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

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

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

Article 13

Planning

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

2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of

[21] 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).

[22] 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).

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[23], 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.

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 Group 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 the Member States where it is being marketed.
3. The Member State that provided financial support to a strategic project may request such undertaking to 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.

[23] 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).

Any Member State that encounters a threat of shortages of the critical medicinal product in question may 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[24] strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme[25], Horizon Europe[26], and the Digital Europe Programme[27] provided that such support is in line with the objectives set out in the regulations establishing those programmes.

2. At the request of a project promoter, justified by necessity to provide results of vulnerability evaluation for the purpose of an application for Union funding, the designated authority shall assess whether a strategic project addresses a vulnerability in the supply chains identified following the vulnerability evaluation. The designated authority shall provide its assessment to a project promoter within 15 working days of its request. The designated authority shall inform the Commission about the strategic projects identified as addressing an existing vulnerability in the supply chains without delay.

Article 17

Exchange of information on funded projects

1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article 24 of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article 25.

2. The Commission shall inform periodically the Critical Medicines Group of the strategic projects that benefited from financial support from the Union.

   The Commission may inform the Critical Medicines Group 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.

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24 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)

25 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)

26 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)

27 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)

Chapter IV
Demand side measures

SECTION I

AWARD CRITERIA AND OTHER PROCUREMENT REQUIREMENTS AND RELATED MEASURES

Article 18

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

1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery.

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

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 that favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments.

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

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

Article 19

Programmes supporting sustainability and resilience in public procurement procedures

1. By 6 months after entry into force of this Regulation each Member State shall establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given

Member State as well as multi-winner approaches, where beneficial in light of the market analysis. Such programmes may also include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures.

2. Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Group. The Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion 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 proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks.

Member States shall ensure that any requirements they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity.

SECTION II

COLLABORATIVE PROCUREMENTS

Article 21

Commission facilitated Member States' cross-border procurement

1. Upon a reasoned request of three or more Member States ('the request'), the Commission 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/EC[28] for medicinal products of common interest.

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

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

[28] 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 provide reasons for the refusal.

5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the interested Member States. The Commission shall facilitate communication and cooperation between the 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 end at the latest upon signature of the procurement contract by the participating contracting authorities.

7. The Commission shall not be responsible, nor held liable, for any breaches of Union or national procurement laws by the participating contracting authorities. The Commission shall not bear any liability associated with the conduct of the procurement procedure by interested Member States and implementation of the contract resulting from the procedure.

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 nine or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission may initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below;

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

   (b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation (EU) 2021/2282 of the European Parliament and the Council [29], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States as per Article 23(1) point (e) of that Regulation.

2. The joint request referred to in paragraph 1 shall only be made where the medicinal product concerned fulfils one of the criteria set out in that paragraph and if the requested procurement procedure will help to improve the security of supply and availability of critical medicinal products in the Union or 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. The Commission shall inform all Member States of the request, through the Critical Medicines Group, and invite them to join the procedure.

4. The Commission shall assess the utility, necessity and proportionality of the request 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.

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[29] 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. 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.

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. 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[30].

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;

   (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 [31], 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

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[30] 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).

[31] 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)

particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.

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

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. Member States shall provide 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 ('Critical Medicines Group') is hereby established.

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

3. The 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 Critical Medicines Group may organise joint meetings with the MSSG.

4. The Commission shall organise and coordinate the work of the Critical Medicines Group by means of the Secretariat.

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

6. The Critical Medicines Group, at the proposal of the Chair or any its members, may decide to establish a working group.

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

Article 26

Tasks of the Critical Medicines Coordination Group

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

2. In order to attain the objectives referred to in paragraph 1, the 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 on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security and availability of critical medicinal products within the Union;

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

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

   (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.

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

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

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

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, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union.

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 *;

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

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

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

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

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

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

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

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

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

Chapter VIII
Final provisions

Article 29

Obligation of the market actors to provide information

1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission 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.

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.

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*

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1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

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.

1.2. Policy area(s) concerned

Heading 2: Cohesion, Resilience and Values

EU4Health

1.3. Objective(s)

1.3.1. General objective(s)

The general objective of this Regulation is to strengthen of the security of supply and the availability of critical medicines within the EU, thereby ensuring a high level of public health protection and supporting the security of the Union. It is also to improve the availability and accessibility of other specific medicines, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicines to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicines.

1.3.2. Specific objective(s)

The specific objectives of the initiative are:

a) to facilitate investments in manufacturing capacity for critical medicines, their active substances and other key inputs in the EU;

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

c) to leverage the aggregated demand of the interested Member States through collaborative procurement procedures;

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

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposed act is expected to strengthen the resilience of the EU's medicines supply chains, contributing to improved security of supply. It should also reduce shortages of critical medicines and enhance public health and trust. Economically, the proposal is expected to strengthen the manufacturing base of critical medicines and make the pharmaceutical sector more competitive, including through diversification. On a social level, the proposed act should improve access to critical medicines and certain other medicines for EU patients. These outcomes will directly contribute to achieving Sustainable Development Goal (SDG) 3, ‘Good health and well-being’. Besides the public health-related benefits, the proposal is expected to mostly affect the pharmaceutical industry involved in the supply of critical medicines, as the industry

may benefit from administrative and regulatory support and access to funding for certain strategic projects. In addition, the proposed act will likely affect national administrative authorities and procurers active in the public procurement of critical medicines and other medicines of common interest.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Objective	Indicator	Target and baseline	Data source and availibility
/	# of critical medicinal products on the Union List of Critical Medicinal products	276 – this number is expected to increase then plateau	EMA/Union List of Critical Medicines already available
/	# of critical shortages escalated to the SPOC WP for the critical medicinal products on the Union list	The number of reported shortages of critical medicines is dependent on the reporting rate. Shortages of critical medicines may be driven by external forces (such as increased demand due to a new pandemic), therefore any trends in this number should be interpreted with prudence.	EMA/already available
/	Proportion (%) of critical shortages escalated to the SPOC WP that corresponded to a critical medicinal product listed on the Union list.	Of the 63 INN critical shortages received by EMA from EU/EEA countries in 2024, 29 (~45%) corresponded to the critical medicines on the Union list. The proportion s expected to decrease.	EMA/already available
Specific objective a)	# of strategic projects identified as addressing an existing vulnerability in the supply chains of critical medicinal products	0 / target: highly dependent on demand	MS reporting as defined in article 16
Specific objective a)	# of strategic projects for critical medicines that benefit from national financial support	0 / target: highly dependent on demand and	MS reporting as defined in article 17
Specific objective a)	# of strategic projects for critical medicines that benefit from financial support from the Union	0 / target: highly dependent on demand	MS reporting as defined in article 17
Specific objective a)	# of dedicated advice provided by EMA to project promoters of Strategic Projects with innovative manufacturing processes	0 / target: highly dependent on demand	EMA
Specific objective b)	# of national programmes issued	0 / target: 27	MS reporting as defined in article 19
Specific objective c)	# of cross-border procurement, procurement on behalf or joint procurements for critical medicines and other medicines of common interest	0 / target: highly dependent on demand	as procurement would be done by the EC, data will be easily available
Specific objective c)	# countries benefiting from cross-border procurement, procurement on behalf or joint procurements for critical medicines and other medicines of common interest	0 / target: highly dependent on demand	as procurement would be done by the EC, data will be easily available

1.4. The proposal/initiative relates to:

☒ a new action

☐ a new action following a pilot project / preparatory action[96]

[96] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

☐ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The adoption is expected for Q4 2025 and the implementation will start in 2026.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

Medicine shortages have hit every Member State in the EU over the last decade. While an individual Member State can act to improve its supply of certain medicines, these efforts are fragmented and insufficient to address the broader, cross-border supply chain problems, including dependency on certain non-EU countries. To address these challenges and to achieve a secure and reliable supply of critical medicines, a common effort at EU level is needed through this proposed Act. Adding to this issue, access problems can also exist for other medicines of common interest, disproportionately affecting some Member States, such as those with a smaller market size. To improve the availability of and access to these medicines, this Act therefore proposes measures to leverage the aggregated demand of the interested Member States through collaborative procurement procedures.

1.5.3. Lessons learned from similar experiences in the past

The Union List of Critical Medicines, created collaboratively by Member States, the European Medicines Agency and the European Commission, identifies medicines crucial for treating serious conditions with limited alternatives. Initially published in December 2023 and updated a year later, it includes 276 active substances. The Commission's analysis of supply chain vulnerabilities for 11 representative medicines found reliance on non-EU suppliers and market concentration risks, underscoring the need for strategic interventions to bolster resilience through diversified supply sources, flexible production capacity, and robust risk management. Some Member States have been involved in cross-border procurement of medicinal products, pursuant to the public procurement directive. Whereas it has been found helpful to make small markets attractive for suppliers, thereby achieving better availability of medicinal products, its implementation is time and resource-intensive, especially in the starting phase, what is considered a limiting factor. The potential benefits that leveraging of several Member States demand in one procurement procedure may have is also illustrated by the experiences resulting from the implementation of joint procurement of medical countermeasures and COVID-19 vaccines.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

For the duration of the Multiannual Financial Framework 2021-2027, the strategic projects may be supported by EU funding, including but not limited to EU4Health programme, Horizon Europe, and the Digital Europe Programme, in line with the

objectives set out in the Regulation establishing those programmes. Authorities in charge of the Union programmes covered by the STEP Regulation should in particular consider supporting Strategic projects addressing vulnerability in the supply chain of critical medicinal products. These projects should be deemed to contribute to STEP.

1.5.5. Assessment of the different available financing options, including scope for redeployment

N/A

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☒ **unlimited duration**

– Implementation with a start-up period from 2026 to 2027,

– followed by full-scale operation as of 2027.

1.7. Method(s) of budget implementation planned[97]

☒ **Direct management** by the Commission

– ☒ by its departments, including by its staff in the Union delegations;

– ☒ by the executive agencies

☐ **Shared management** with the Member States

☒ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☒ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments

[97] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Annual monitoring foreseen on the defined indicators

The proposal relies on existing workstreams in the European Commission and the European Medicinal Agency, which will facilitate monitoring of several indicators. For these, continuous data/information will be available.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The actions for strengthening of the security of supply and the availability of critical medicinal products within the Union and for improving the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of these medicinal products to patients, will be implemented through direct management, using the implementation modes offered by the Financial Regulation, mainly being grants and procurement. Direct management allows to establish grant agreements/contracts with beneficiaries/contractors directly engaged in activities that serve Union policies. The Commission ensures direct monitoring over the outcome of the actions financed. The payment modalities of the actions funded will be adapted to the risks pertaining to the financial transactions.

In order to ensure the effectiveness, efficiency and economy of the Commission controls, the control strategy will be oriented towards a balance of ex-ante and ex-post checks and focus on three key stages of grant/contract implementation, in accordance with the Financial Regulation:

– Selection of proposals/tenders that fit the policy objectives of the Regulation;

– Operational, monitoring and ex-ante controls that cover project implementation, public procurement, pre-financing, interim and final payments, management of guarantees; Ex-post controls at the beneficiaries/contractors' sites will also be carried out on a sample of transactions. The selection of these transactions will combine a risk assessment and a random selection

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The proposal will be implemented through grants and public procurement, taking into account the funding opportunities facilitated by the Strategic Technologies for Europe Platform ('STEP'), and those offered by, inter alia, the InvestEU programme, the Recovery and Resilience Facility, Horizon Europe, EU4Health, Digital Europe Programme and cohesion policy programmes as well as the Technical Support Instrument. The grants and procurements will mainly be awarded and concluded to support Strategic Projects, as well as to support activities to non-governmental organisations, respective competent authorities of the Member States.

The main risks are the following:

• Risk of not fully achieving the objectives of the Regulation due to insufficient uptake or quality/delays in the implementation of the selected projects or contracts;

Risk of inefficient or non-economic use of funds awarded, both for grants (complexity of funding rules) and for procurement (limited number of economic providers with the required specialist knowledge entailing insufficient possibilities to compare price offers in some sectors);

• Reputational risk for the Commission, if fraud or criminal activities are discovered; only partial assurance can be drawn from the third parties' internal control systems due to the rather large number of heterogeneous contractors and beneficiaries, each operating their own control system.

The Commission put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations. Within this framework, the Commission continues to explore possibilities to enhance the management and to realise efficiency gains. Main features of the control framework are the following:

Controls before and during the implementation of the projects:

• An appropriate project management system will be put in place focusing on the contributions of projects and contracts to the policy objectives, ensuring a systematic involvement of all actors, establishing a regular project management reporting complemented by on-site-visits on a case by case basis, including risk reports to senior management, as well as maintaining appropriate budgetary flexibility.

• Model grant agreements and service contracts used are developed within the Commission. They provide for a number of control provisions such as audit certificates, financial guarantees, on-site audits as well as inspections by OLAF. The rules governing the eligibility of costs are being simplified, for example, by using unit costs, lump sums, contributions not linked to costs and other possibilities offered by the Financial Regulation. This will reduce the cost of controls and put the focus on checks and controls in high risk areas.

• All staff sign up to the code of good administrative behaviour. Staff who are involved in the selection procedure or in the management of the grant agreements/contracts (also) sign a declaration of absence of a conflict of interest. Staff is regularly trained and uses networks to exchange best practices.

• Technical implementation of a project is checked at regular intervals at the desk on the basis of technical progress reports of the contractors and beneficiaries; in addition contractors'/beneficiaries' meetings and on-site-visits are foreseen on a case by case basis.

Controls at the end of the project: Ex-post audits are performed on a sample of transactions to verify on-the-spot the eligibility of cost claims. The aim of these controls is to prevent, detect and correct material errors related to the legality and regularity of financial transactions. With a view to achieving a high control impact, the selection of beneficiaries to be audited foresees to combine a risk based selection with a random sampling, and to pay attention to operational aspects whenever possible during the on-site audit.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

The yearly costs of the suggested level of controls under the third Health programme 2014-2020 represented approximately 4 to 7% of the yearly budget of the operational expenditure. This is justified by the diversity of transactions to be controlled. Indeed, in the area of health, direct management involves the attribution of numerous contracts and grants for actions of very small to very large sizes, and the payment of numerous operating grants to non-governmental organisations. The risk related to these activities concerns the capacity of (especially) smaller organisations to effectively control expenditure.

The Commission considers that the average costs of controls is likely to be the same for the actions proposed under this Regulation.

Under the third Health Programme 2014-2020, on a 5 years basis, the error rate for the on-the-spot audits of grants under direct management was 1.8% while for procurement contracts it was below 1%. This level of error is considered acceptable, as it is under the materiality level of 2%.

The proposed actions will not affect the way the appropriations are currently managed. The existing control system proved to be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them. It will be adapted to include the new actions and to ensure that residual error rates (after correction) remain below the threshold of 2%.

2.3 Measures to prevent fraud and irregularities

As for its activities in direct management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties. To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019) 196), covering notably the following preventive, detective and corrective measures:

The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding.

The Commission also implements a series of measures such as:

- decisions, agreements and contracts resulting from the implementation of the Regulation will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections and to recover amounts unduly paid and, where appropriate, impose administrative sanctions;

- during the evaluation phase of a call for proposals/tender, the applicants and tenderers are checked against the published exclusion criteria based on declarations and the Early Detection and Exclusion System (EDES);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation ;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[98]	from EFTA countries [99]	from candidate countries and potential candidates [100]	From other third countries	other assigned revenue
2	06 06 01 - EU4Health Programme	Diff.	YES	YES	YES	NO

98 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
99 EFTA: European Free Trade Association.
100 Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below

The allocations will be redeployed within the existing envelope of the EU4Health programme

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

			Year 2024	Year 2025	Year 2026	Year 2027	**TOTAL MFF 2021-2027**
Operational appropriations							
06 06 01 - EU4Health Programme	Commitments	(1a)			40,405	41,213	**81,618**
	Payments	(2a)			28,284	40,971	**69,254**
06 10 03 Union contribution to the European Medicines Agency	Commitments	(1b)			0,651	0,758	**1,408**
	Payments	(2b)			0,651	0,758	**1,408**
Appropriations of an administrative nature financed from the envelope of specific programmes							
Budget line		(3)					**0,000**
TOTAL appropriations	Commitments	=1a+1b+3	**0,000**	**0,000**	**41,056**	**41,971**	**83,027**
	Payments	=2a+2b+3	**0,000**	**0,000**	**28,934**	**41,729**	**70,663**

EUR million (to three decimal places)

			Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
TOTAL operational appropriations (including contribution to decentralised agency)	Commitments	(4)	0,000	0,000	41,056	41,971	**83,027**
	Payments	(5)	0,000	0,000	28,934	41,729	**70,663**
Ÿ TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0,000	0,000	0,000	0,000	**0,000**
TOTAL appropriations under HEADING 2 of the multiannual financial framework	Commitments	=4+6	**0,000**	**0,000**	**41,056**	**41,971**	**83,027**
	Payments	=5+6	**0,000**	**0,000**	**28,934**	**41,729**	**70,663**

EUR million (to three decimal places)

			Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
• TOTAL operational appropriations (all operational headings)	Commitments	(4)	0,000	0,000	41,056	41,971	**83,027**
	Payments	(5)	0,000	0,000	28,934	41,729	**70,663**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0,000	0,000	0,000	0,000	**0,000**
TOTAL appropriations Under Heading 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+6	**0,000**	**0,000**	**41,056**	**41,971**	**83,027**
	Payments	=5+6	**0,000**	**0,000**	**28,934**	**41,729**	**70,663**

Heading of multiannual financial framework	7	'Administrative expenditure'[101]

EUR million (to three decimal places)

		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
Ÿ Human resources		0,000	0,000	1,793	3,586	**5,379**
Ÿ Other administrative expenditure		0,000	0,000	0,035	0,070	**0,105**
Total	Appropriations	**0,000**	**0,000**	**1,828**	**3,656**	**5,484**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0,000**	**0,000**	**1,828**	**3,656**	**5,484**

EUR million (to three decimal places)

		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
TOTAL appropriations under HEADINGS 1 to 7	Commitments	**0,000**	**0,000**	**42,884**	**45,627**	**88,511**
of the multiannual financial framework	Payments	**0,000**	**0,000**	**30,762**	**45,385**	**76,147**

[101] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

3.2.1.2. Appropriations from external assigned revenues

N/A

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Indicate objectives and outputs			**Year**		**Year**		**TOTAL 2021-2027**	
⇩			**2026**		**2027**			
06 06 01 - EU4Health Programme	**OUTPUTS**							
	Type	Average cost	No	Cost	No	Cost	No	Cost
OBJECTIVE No 1: Security of supply and the availability of critical medicinal products								
A. facilitate investments in manufacturing capacities	Grants			40,000		40,800	**0**	**80,800**
A. facilitate investments in manufacturing capacities	Meetings			0,027		0,028	**0**	**0,055**
B. National public procurement criteria	Meetings			0,027		0,028	**0**	**0,055**
C. collaborative procurement procedures	Meetings			0,027		0,028	**0**	**0,055**
D. International Cooperation	Meetings			0,027		0,028		**0,055**
Subtotal for objective No 1			**0**	**40,108**	**0**	**40,910**	**0**	**81,018**
OBJECTIVE 2: Availability and accessibility of certain other medicinal products								
B. National public procurement criteria	Meetings			0,027		0,028	**0**	**0,055**
C. collaborative procurement procedures	Meetings			0,270		0,275	**0**	**0,545**
Subtotal for objective No 2			**0**	**0,297**	**0**	**0,303**	**0**	**0,600**

TOTALS	**0**	**40,405**	**0**	**41,213**	**0**	**81,618**

EUR million (to three decimal places)

Indicate objectives and outputs			**Year**		**Year**		**TOTAL 2021-2027**	
⇩			**2026**		**2027**			
06 10 03 Union contribution to the European Medicines Agency	**OUTPUTS**							
	Type	Average cost	No	Cost	No	Cost	No	Cost
OBJECTIVE No 1: Security of supply and the availability of critical medicinal products								
A. facilitate investments in manufacturing capacities -	EMA Staff costs			0,524		0,628	**0**	**1,152**
A. facilitate investments in manufacturing capacities	IT			0,100		0,102	**0**	**0,202**
A. facilitate investments in manufacturing capacities	Meetings			0,027		0,028	**0**	**0,055**
Subtotal for objective No 1			**0**	**0,651**	**0**	**0,758**	**0**	**1,408**
TOTALS			**0**	**0,651**	**0**	**0,758**	**0**	**1,408**

3.2.3. *Summary of estimated impact on administrative appropriations*

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. Appropriations from voted budget

EUR million (to three decimal places)

VOTED APPROPRIATIONS	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0,000	0,000	1,793	3,586	5,379
Other administrative expenditure	0,000	0,000	0,035	0,070	0,105
Subtotal HEADING 7	0,000	0,000	1,828	3,656	5,484
Outside HEADING 7					
Human resources	0,000	0,000	0,000	0,000	**0,000**
Other expenditure of an administrative nature	0,000	0,000	0,000	0,000	**0,000**
Subtotal outside HEADING 7	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**
TOTAL	0,000	0,000	1,828	3,656	5,484

3.2.3.3. Total appropriations

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0,000	0,000	1,793	3,586	5,379
Other administrative expenditure	0,000	0,000	0,035	0,070	0,105
Subtotal HEADING 7	0,000	0,000	1,828	3,656	5,484

Outside HEADING 7					
Human resources	0,000	0,000	0,000	0,000	**0,000**
Other expenditure of an administrative nature	0,000	0,000	0,000	0,000	**0,000**
Subtotal outside HEADING 7	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**
TOTAL	0,000	0,000	1,828	3,656	5,484

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☒ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)[1]

VOTED APPROPRIATIONS		Year 2024	Year 2025	Year 2026	Year 2027	POST 2027
• Establishment plan posts (officials and temporary staff)						
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	9	18	18
20 01 02 03 (EU Delegations)		0	0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0	0
Other budget lines (specify)		0	0	0	0	0
• External staff (in Full Time Equivalent unit: FTE)						
20 02 01 (AC, END from the 'global envelope')		0	0	1	2	2
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0	0
Admin. Support line [XX.01.YY.YY] [2]	- at Headquarters	0	0	0	0	0
	- in EU Delegations	0	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0	0
TOTAL		**0**	**0**	**10**	**20**	**20**

[1] Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

3.2.4.2. Financed from external assigned revenues

N/A

3.2.4.3. Total requirements of human resources

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES		Year	Year	Year	Year
		2024	2025	2026	2027
• Establishment plan posts (officials and temporary staff)					
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	9	18
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (in Full Time Equivalent unit: FTE)					
20 02 01 (AC, END from the 'global envelope')		0	0	1	2
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY] [2]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**10**	**20**

The staff required to implement the proposal (in FTEs):

	To be covered by current staff available in the Commission services	**Exceptional additional staff***		
		To be financed under Heading 7 or Research	**To be financed from BA line**	**To be financed from fees**
Establishment plan posts	2026: 9 posts 2027: 18 post Post MMF: 18 posts		N/A	

External staff (CA, SNEs, INT)	2026: 1 CA 2027: 2 CA Post MFF: 2 CA			

3.2.4.4. Total requirements of human resources EMA

EMA	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL 2021 - 2027**
Temporary agents (AD+AST)	**0**	**0**	**3**[2]	**3**	
Contract agents	**0**	**0**	**0**	**0**	
Seconded National Experts	**0**	**0**	**0**	**0**	
Total staff	**0**	**0**	**3**	**3**	
Appropriations covered by the EU Budget	0,000	0,000	0,524	0,628	**1,152**
Appropriations covered by fees	0,000	0,000	0,000	0,000	**0,000**
Appropriations co-financed (if applicable)	0,000	0,000	0,000	0,000	**0,000**
TOTAL appropriations	**0,000**	**0,000**	**0,524**	**0,628**	**1,152**

EMA	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**Total 2021-2027 MFF**
Temporary agents (AD Grades)			0,314	0,419	0,733
Temporary agents (AST grades)			0,209	0,209	0,419
Contract staff					0,000

[2] For the 1st year the costs of the 1 AD for the scientific advice is accounted for 50% as it is expected that implementation of strategic projects will not fully kick in in 2026. For the rest of the FTEs the cost is accounted in full.

Seconded National Experts					0,000
Total			0,524	0,628	1,152

Staff requirements (FTE): Total posts Union funded

	Year **2026**	Year **2027**	**TOTAL**
Temporary agents (AD Grades)	2[3]	2	2
Temporary agents (AST grades)	1	1	1
Contract staff as of			
Seconded National Experts			
TOTAL	**3**	**3**	**3**

Description of tasks to be carried out by:

Officials and temporary staff	1 AD to provide scientific advice in accordance to article 11 stating that EMA shall provide dedicated advice to assist project promoters developing projects relying on innovative manufacturing processes , 1 AD and 1 AST to address the increased volume of vulnerability analysis plus provision of aggregated data (AD)
External staff	

[3] For the 1st year the costs of the 1 AD for the scientific advice is accounted for 50% as it is expected that implementation of strategic projects will not fully kick in in 2026. For the rest of the FTEs the cost is accounted in full

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 7 should be presented in the designated line.

The appropriations under Headings 1-6 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021 - 2027**
HEADING 7					
IT expenditure (corporate)	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Policy IT expenditure on operational programmes	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ✠ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

The increase of appropriations for EMA budget line 06.100301 in years 2026 and 2027 by 1,4 million EUR, will be done via internal redeployment within heading 2b, i.e. by an equal reduction of the EU4Health budget line 06.0601 for this period. The appropriations managed by the Commission will be redeployed withing the existing financial envelope of the EU4Health programme.

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation

– ☐ requires a revision of the MFF

3.2.7. Third-party contributions

The proposal/initiative:

– ☐ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	Total
Specify the co-financing body					
TOTAL appropriations co-financed					

3.3. Estimated impact on revenue

- ☐ The proposal/initiative has no financial impact on revenue.
- ☐ The proposal/initiative has the following financial impact:
  - ☐ on own resources
  - ☐ on other revenue
  - ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[4]			
		Year **2024**	Year **2025**	Year **2026**	Year **2027**
Article …….					

For assigned revenue, specify the budget expenditure line(s) affected.

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

Reference to requirement	**Requirement description**	**Stakeholder categories affected**	**High-level processes affected by this requirement**	**Category**	
Article 6 paragraph 1	Recognition of Strategic Projects	Project promoter National authority	Request recognition of Strategic project	Data Digital Public Service	
Article 6 paragraph 2	Member States shall communicate to the Commission which authority is designated for assessing and confirming Strategic Projects;	EC, MS	Notify	Data Digital Public Service	

[4] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

Article 6 paragraph 3	EC publishes online the list of MS designated authorities	EC, MS	Publish	Data	
Article 12	Combination of environmental assessments required under several legal bases via joint or coordinated procedures	Project promoter National authority	Assess strategic projects for more legal bases	Data Digital solution Digital public service	
Article 13 Paragraph 1	Availability of relevant spatial planning data	MS	Make available spatial planning data	Data Digital solution	
Article 13 Paragraph 2	Combination of plans assessments	MS	Assess plans for more legal bases	Data Digital public service	
Article 16	Request assessment of addressing vulnerability Inform on the existence of Strategic projects addressing an existing vulnerability	Project promoter, Designated authority Commission	Request for assessment Inform on addressed vulnerabilities	Data Digital solution Digital public service	
Chapter IV	Public procurement rules for critical medicine products	Member States Public administrations, Economic operator	Launch procurement	Data	
Article 19	Notification of national programmes	Member States Commission CMG	Notification of national programmes	Data	

4.2. Data

Type of data	Reference requirements	Standard and/or specification
List of MS Authorities designated for assessing and confirming Strategic Projects;	Article 6	Standard list of MS
Strategic Project	Article 6	Not defined
Status of the highest national significance for Strategic Projects	Article 9	Not defined
Combined environmental assessment	Article 12	Defined under other legal bases
Spatial planning data	Article 13 Paragraph 1	Not defined
Combined urbanistic assessments	Article 13 Paragraph 2	Not defined

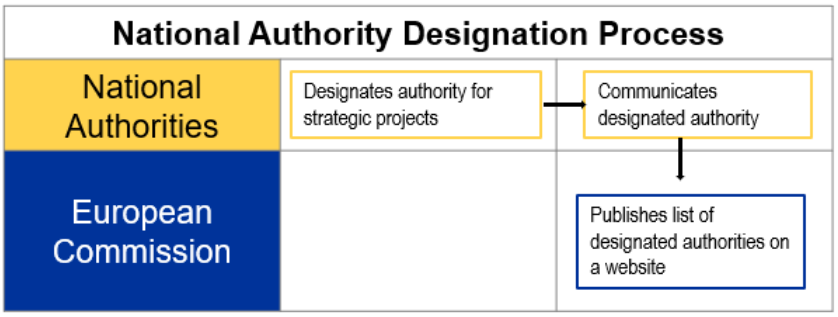
Assessment whether strategic projects address a supply chain vulnerability	Article 16	Not defined
National programmes	Article 19	Not defined

The list of Member States' Authorities designated for assessing and confirming Strategic Projects will be published on the ec.europa.eu website, relying on its standards for being findable and accessible.

The act follows the only-once principle by not duplicating data collection for identification of critical medicines and evaluation of vulnerabilities in their supply chains, by re-using data collected under the Revision of the General Pharmaceutical Legislation.

Data related to assessments are governed by the relevant legal basis that trigger the assessments.

Data flows



Type of data	Reference(s) to the requirement(s)	Actor who provides the data	Actor who receives the data	Trigger for the data exchange	Frequency (if applicable)
List of MS Authorities designated for assessing and confirming Strategic Projects	Article 6	Member States	Commission	Not defined	NA
Project	Article 6	Project promoter	Designated authority	at the initiative of the project promoter	
Strategic Project	Article 6	Designated authority	Project promoter	At Project promoter request	No deadline se
Status of the highest national significance for Strategic Projects	Article 9	National authorities	Strategic Project promoter	No deadline set	
Combined environmental assessment	Article 12	Competent authority	Strategic Project promoter	Within 45 days after receiving all necessary information and subject to exceptions	

Spatial planning data	Article 13 paragraph 1	Member States	General public			
Combined urbanistic assessments	Article 13 paragraph 2	Member States competent authorities	Strategic Project promoter	No deadline set		
Request for assessment of addressing vulnerability by Strategic Projects	Article 16 paragraph 2	Strategic Project promoter	Designated authority	At the initiative of the project promoter		
Assessment of addressing vulnerability by Strategic Projects	Article 16 paragraph 2	Designated authority	Strategic Project promoter	Within 15 working days		
Assessment of addressing vulnerability by Strategic Projects	Article 16 paragraph 2	Designated authority	The Commission	If Strategic project addresses an existing vulnerability in the supply chain. No deadline set		
National programmes	Article 19 paragraph 2	Member States	Commission	By 6 months after entry into force of this Regulation		

4.3. Digital solutions

No new digital solution is foreseen.

4.4. Interoperability assessment

Reference to the legal provision	Description of the requirement	Interaction across Member State borders, among EU entities or between EU entities and public sector bodies	Effect on 'cross-border interoperability'

Article 6 paragraph 2	Member States shall communicate to the Commission which authority is designated for assessing and confirming Strategic Projects;	No interaction just one simple notification and/or publishing
Article 6 paragraph 3	EC publishes online the list of MS designated authorities	

4.5. Measures to support digital implementation