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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a regulation of the European Parliament and of the Council on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (Critical Medicines Act) - Four-column table

Delegations will find enclosed the four-column table on the above-mentioned proposal.

This document contains in Annex A the explanations on the layout of the table used in this document and in Annex B the text of the Commission proposal, changes to the proposal approved by the Council on 2 December 2025, and the amendments voted by the European Parliament on 20 January 2026.

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ANNEX A

Explanation of the table layout

	Commission proposal	**EP amendments voted on 20 January 2026**	**Text approved by Council on 2 December 2025**	**Draft agreement**
		Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. ***Text in blue underlined bold italics in this column is text that the EP proposes to add to the Commission proposal.*** *Text in red italics ~~strikethrough~~ in this column is text that the EP proposes to delete.*	Plain text in this column is text from the Commission proposal that Council wishes to maintain. ***Text in bold italics*** in this column is text that Council has agreed to add. Text in ~~*strikethrough*~~ *italics* in this column is text that Council has agreed to delete.	*This column will contain comments, compromise proposals and tentatively agreed text.*

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)

2025/102(COD)
[Version for Trilogue on March 16, 2026]
06-03-2026 at 09h10

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Formula				
1	2025/102 (COD)	2025/102 (COD)	2025/102 (COD)	
Document Stage				
2	Proposal for a	Proposal for a	Proposal for a	
Document Type				
3	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	
Document Purpose				
4	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	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	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	

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	interest, and amending Regulation (EU) 2024/795	interest, and amending Regulation (EU) 2024/795	interest, and amending Regulation (EU) 2024/795	
EEA Relevance				
5	(Text with EEA relevance)	(Text with EEA relevance)	(Text with EEA relevance)	
Formula				
6	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Citation 1				
7	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	
Citation 2				
8	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	
Citation 3				
9	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	
Citation 4				
10	Having regard to the opinion of the European Economic and Social Committee[1],	Having regard to the opinion of the European Economic and Social Committee[1],	Having regard to the opinion of the European Economic and Social Committee[1],	
	_____ 1. OJ C , , p. .	_____ 1. OJ C , , p. .	_____ 1. OJ C , , p. .	
Citation 5				

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11	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	
Formula				
12	Whereas:	Whereas:	Whereas:	
Recital 1				
13	(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.	(1) Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and activities. The availability of safe, efficacious and high-quality medicinal products, ***underpinned by a resilient and competitive pharmaceutical industry and secure, reliable supply chains forming the backbone of the supply of medicinal products,*** is vital to achieving this objective and to safeguarding public health across the Union ***and improving the preparedness and the Union's overall security***.	(1) ***Availability of critical medicinal products is essential for the Union and the functioning of the internal market.*** Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the '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. ***To safeguard the functioning of the internal market it is therefore necessary to create a common Union framework to collectively address the challenges and by strengthening the security of supply and the availability of critical medicinal products.***	
Recital 2				

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14	(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.	(2) In recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages of medicinal products for which insufficient supply ***and lack of transparency of supply chains*** results in serious harm or risk of serious harm to patients ***and healthcare systems***.	(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.	
Recital 2a				
14a		***(2a) A stable and resilient supply of medicines critical to the health of patients in the Union is essential, as shortages can lead to deterioration of patients' health, increased healthcare costs, and significant burdens on healthcare systems and public authorities.***		
Recital 3				
15	(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	(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***, including starting materials,***	(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	

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	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.	***intermediates and other raw pharmaceutical materials and feedstock***. These include existing dependencies on a limited number of suppliers globally and lack of Union capacities to produce certain medicinal products, their active substances or key raw pharmaceutical materials. Through diversification of supply sources and investment in local production, the Union can reduce its risk of exposure to shortages of medicinal products.	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.	
Recital 4				
16	(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 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	(4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in particular, for key raw pharmaceutical materials and active substances. Setting up new, ***expanding*** or modernising existing manufacturing capacities in the Union for critical medicinal products, their key inputs and active substances, which have often been on the market for a long time and are considered to be relatively inexpensive, is currently not seen as	(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 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	

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	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.	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~~***medicinal products whilst upholding the highest social, health and environmental standards***. ***Moreover, strengthening skills and knowledge transfer will help build a resilient and future-ready workforce capable of smoothly embracing innovation and technological advancement. At the same time, developing manufacturing capacity throughout the supply chain requires substantial long-term investment, adequate industrial***	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.	

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		infrastructure, strong research capabilities, regulatory predictability and a skilled workforce.		
Recital 4a				
16a		***(4a) While medicine shortages can occur for any type of product, they disproportionately affect older, off-patent, and generic medicinal products, primarily due to their low profit margins, which reduce incentives for investment in robust manufacturing capacity. Older, off-patent, and generic medicinal products make up the majority of the medicinal products placed on the Union List of Critical Medicinal Products, due to low profit margins that limit investment in manufacturing. Many off-patent and generic medicinal products suppliers have outsourced manufacturing or relocated production of finished products outside the Union, and frequently source their active pharmaceutical ingredients (APIs) from third countries. Consequently, the Union relies on a limited number of API suppliers and manufacturers, many located outside its borders.***		

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Recital 5				
17	(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[1] 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. 1. Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the	(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[1] 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. 1. Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the	(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[1] 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. 1. Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the	

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	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)	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)	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)	
Recital 6				
18	(6) In addition, Regulation (EU) …/… of the European Parliament and of the Council[1] 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. _____ 1. Regulation (EU) …/… of the European Parliament and of the Council laying down Union procedures for the authorisation and	(6) In addition, Regulation (EU) …/… of the European Parliament and of the Council[1] 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. _____ 1. Regulation (EU) …/… of the European Parliament and of the Council laying down Union procedures for the authorisation and	(6) In addition, Regulation (EU) …/… of the European Parliament and of the Council[1] 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. _____ 1. Regulation (EU) …/… of the European Parliament and of the Council laying down Union procedures for the authorisation and	

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

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	there is a high dependency on a single or a limited number of third countries.	single or a limited number of third countries.	single or a limited number of third countries.	
Recital 8				
20	(8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. 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.	(8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care***, and enhance patient's access to the medicinal products they need***. Uncoordinated national measures risk disrupting the internal market, fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for further harmonisation***, while avoiding duplication or overlap of existing structures. Furthermore, existing data infrastructures and***	(8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. 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.	

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		databases should be fully leveraged in order to reduce reporting burdens, streamline the monitoring of medicinal product supply chains, and improve the efficiency of data exchanges between competent authorities and stakeholders. The use of existing structures would also help ensure more stable and predictable data flows.		
Recital 9				
21	(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.	(9) Some medicinal products of common interest which are key for the provision of adapted care to patients, while not affected by supply security issues, may still not be available ***and accessible*** to patients in some Member States. This may be caused by a variety of factors, including ***administrative and budgetary barriers,*** product or geographical demand market size, which can impact the timely availability of medicinal products in certain Member States ***increasing inequalities between patients in the Union and undermining the Union's commitment to achieving universal access to essential medicinal products by 2030 in line with the United Nations sustainable***	(9) Some medicinal products of common interest which are key for the provision of adapted care to patients, while not affected by supply security issues, may still not be available ***and accessible*** to patients in some Member States. This may be caused by a variety of factors, including product or geographical demand market size, which can impact the timely availability of medicinal products in certain Member States.	

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		development goal 3.8**. **This Regulation aims at strengthening the resilience of supply chains, addressing concrete security-of-supply vulnerabilities, and reducing such inequalities among Member States, ensuring more equitable access to medicinal products across the Union, so that patients enjoy the same level of access regardless of their country of residence.		
Recital 10				
22	(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	(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	(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	

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	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.	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.	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.	
Recital 11				
23	(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	(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	(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	

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	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.	responsibility. These measures are aligned with the principles of the internal market. This Regulation is without prejudice to Union competition law, including antitrust, merger and State aid rules. ***The implementation of this Regulation should be coherent with Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space (EHDS) to enhance the interoperability, secure exchange, and real-time monitoring of health data relevant to the availability and supply of medicinal products. Improved integration between this Regulation and the EHDS will contribute to early detection of shortages, cross-border distribution, and streamlined access to critical medicinal products.***	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.	
Recital 12				
Y 24	(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	(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	(12) While the primary objective of this Regulation should be ***to improve the functioning of the internal market by establishing a framework*** to strengthen the security of supply and ensure the availability of critical medicinal	Y

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	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.	can affect the functioning of the economy as a whole, this Regulation should also support the Union's competitiveness by fostering a more stable and predictable market environment, ***reducing administrative barriers,*** encouraging investment and supporting innovation in the pharmaceutical sector***. This should include fostering research and development of innovative treatments, such as alternatives to antimicrobials to address antimicrobial resistance, more targeted cancer therapies, as well as other medicinal products responding to unmet medical needs***. Ensuring the security of supply and availability of critical medicinal products and the availability and accessibility of other medicinal products of common interest should moreover contribute to the Union's preparedness, resilience, ***strategic autonomy*** and economic and overall security, including when cross-border supply chains risk being disrupted***. The past health emergencies and crises, like COVID-19, have demonstrated how***	products and ***the availability and the accessibility*** 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.	

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		the presence of critical infrastructures, including hospitals and community pharmacies, has been fundamental in achieving these objectives. Furthermore, in order to strengthen the functioning of the internal market and to ensure the uninterrupted availability of critical medicinal products across the Union, it is necessary to establish a Union coordination mechanism for critical medicinal products. Such a mechanism would enhance the Union capacity to address shortages, strengthen supply chain resilience, and enable coordinated approaches to national stockpiling and contingency stocks.		
Recital 12a				
24a		***(12a) Contraceptives and abortifacient medicinal products are essential for safeguarding sexual and reproductive health rights, gender equality and the full enjoyment of fundamental rights everywhere in the Union. Shortages and supply disruptions affecting these medicinal products of common interest undermine patient safety and contribute to unequal***		

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		access to healthcare across the Union. In order to safeguard sexual and reproductive health rights and equal access to contraceptive and abortifacient medicinal products for all women in the Union, Member States should ensure the availability, affordability and security of supply of these medicinal products of common interest.		
Recital 13				
G 25	(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.	(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.	(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.	(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. Text Origin: Commission Proposal
Recital 13a				
25a		***(13a) To ensure the effective allocation of administrative and technical resources, the application of Articles 7 to 15 to medicinal products of common interest should not affect the priority***		

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		granted to strategic projects concerning critical medicinal products. Where support measures, such as the processing of building permits or the conduct of dispute-resolution procedures overlap or conflict, requests related to such strategic projects should receive priority.		
Recital 14				
R 26	(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.	(14) The availability and the security of supply of critical medicinal products are essential to safeguard public health***, patients' safety*** and the economic and overall security of the Union and therefore should be considered strategic objectives of the Union.	(14) ~~*The availability and*~~***Ensuring*** the security of supply ***and the availability*** of critical medicinal products ~~*are essential*~~***for patients in the Union*** to safeguard public health and the economic and overall security of the Union ~~*and therefore should be considered*~~***is a*** strategic ~~*objectives*~~***objective*** of the Union. ***To achieve this, it is important that the Member States and the Commission 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. In this effort, the Commission has an important role to support the coordinated efforts of the Members States.***	R

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Recital 14a				
26a		***(14a) Novel antimicrobials are essential for protecting public health and addressing the threat of antimicrobial resistance, which poses a growing threat to human health. Due to their limited and variable use across Member States, novel antimicrobials are not well-suited to volume-based pricing and reimbursement mechanisms and therefore face economic disincentives due to market failure. This could result in low and unpredictable revenues, particularly in smaller markets, and can undermine the ability of manufacturers, including SMEs, to supply these products sustainably. Consequently, the availability of newer antimicrobials has been limited, and some products have been withdrawn from the market. Ensuring a sustainable supply of low-volume, high-value antimicrobials, is therefore necessary.***		
Recital 15				
27	(15) A well-defined list of critical medicinal products is essential to ensure that the	(15) A well-defined list of critical medicinal products is essential to ensure that the measures	(15) A well-defined list of critical medicinal products is essential to ensure that the measures	

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	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.	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.	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.	
Recital 16				
28	(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	(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	(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	

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	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.	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.	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.	
Recital 16a				
28a		***(16a) In order to ensure legal clarity and effective coordination at Union level, it is essential to distinguish between 'contingency stock' and 'national stockpile'. Those two concepts refer to different types of reserves, governed by distinct legal and operational frameworks, and***		

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		serving different purposes within the supply chain and public health preparedness. Thus, a clear differentiation is necessary to avoid confusion in reporting and management, and to support targeted and proportionate Union-level actions during supply disruptions or emergencies. In the context of contingency stocks and national stockpiles, Member States should be encouraged to explore sustainable measures that contribute to reducing waste and improving the efficient use of available medicinal products in line with national law and national needs.		
Recital 16b				
28b		***(16b) The Commission should establish and regularly update a list of medicinal products originating from third countries for which no adequate substitute produced within the Union is available, in order to identify and monitor dependencies and to support measures aimed at ensuring the continuity of supply of medicinal products.***		
Recital 17				

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29	(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.	(17) Certain projects ***and technology*** can have a positive impact on security of supply as they increase the Union's manufacturing capacity for critical medicinal products***, improve efficiencies in the production of those products,*** and strengthen the resilience of the Union's supply chains. In order to encourage private investments in these projects, the concept of ***strategic projects, including cross-border*** strategic projects should be introduced. Given their role in ensuring the Union's security of supply for critical medicinal products, the relevant permitting authority should consider strategic projects to be in the public interest. To ensure their expedient implementation, national authorities should ***be provided with adequate resources to*** ensure that the relevant permit granting processes are carried out in the fastest way possible making available, in particular any form of accelerated procedures that exists in applicable Union and national law***, whilst upholding the highest social, health and environmental standards***. National authorities should consider, when	(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 ***projects recognised as a*** strategic ~~*projects*~~***project by Member States' designated authority*** 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*~~***without undue delay*** 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.	

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		possible, their streamlining as well as enable digital submission of required information. ***To ensure the efficient use of resources and strategic coherence at Union level, the designation of strategic projects should avoid unnecessary duplication of existing or planned manufacturing capacities for the same medicinal product, its active substances, or key inputs, unless such duplication is justified by clearly demonstrated needs.***		
Recital 17a				
29a		***(17a) In order to safeguard the Union's strategic interests and the resilience of its industrial base, strategic projects for manufacturing critical medicinal products must operate without interruption, including during crises or supply chain disruptions. Member States should take all necessary measures to prevent or mitigate unplanned disruptions to essential supplies and to ensure the continued availability of key personnel.***		
Recital 18				
30	(18) To avoid unnecessary delays and the creation of	(18) To avoid unnecessary delays and the creation of additional	(18) ~~*To avoid unnecessary delays and the creation of additional*~~	

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	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.	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*~~***and small mid-cap enterprises (SMCs), as well as entities not engaged in an economic activity, with a view to ensuring that they*** have a fair chance to initiate strategic projects. ***Member States and designated authorities should pay particular attention to minimising the administrative burden on SMEs and SMCs and should provide***	~~*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*~~***The*** designated authority should~~*, when solicited, verify*~~ ***without undue delay assess,*** 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, ***where these procedures already exist in national law,*** 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.	

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		support and clear guidance through application, permitting and regulatory processes. Furthermore, requirements should be applied in a manner that guarantees fair and equal competition among all market players, regardless of their ownership structure. To support the effective implementation of this Regulation, the Commission should provide guidance to national authorities and project promoters, intended as a practical support tool. Such guidance should assist in the preparation, determination and support of strategic projects.		
Recital 18a				
30a		***(18a) To achieve the objective of contributing to the security of supply of critical medicinal products, and where relevant, medicinal products of common interest, Member States should ensure that any accelerated procedure or public funding granted under this Regulation for strategic projects requires enforceable undertakings by the beneficiary regarding security of supply, affordability of end-***		

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		products, and transparency in the use of public funds, and that the resulting medicinal products are made available within the Union.		
Recital 18a				
30b			***(18a) A project promoter is able to request that their application for a permit is granted the status of the highest national significance, if such a status exists in national law, and be treated accordingly. National authorities are to grant the status of the highest national significance to an application for a permit without prejudice to obligations provided for in Union law.***	
Recital 18b				
30c		***(18b) To avoid a fragmented approach across the Union and to ensure coherent and coordinated implementation of this Regulation, the criteria for the determination of strategic projects should be applied in a consistent and transparent manner, while allowing for a degree of flexibility to reflect national specificities and capacities. Such a balanced approach should support a wide***		

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		uptake of strategic projects across the Union.		
Recital 18b				
30d			***(18b) A project promoter is able to 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 and can be applied in disputes of this type, is treated as urgent if and to the extent to which national law concerning permit granting processes provides for such an urgency procedure. The applicable rights of defence of individuals or of local communities are to be respected during such urgency procedures.***	
Recital 19				
31	(19) The production of medicinal products has environmental implications and may negatively impact not only the environment itself but also human health. The environmental	(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	(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	

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	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.	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.	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.	
Recital 19a				
31a		***(19a) Acknowledging the importance of international cooperation in environmental matters, this Regulation respects the obligations arising from the United Nations Economic Commission for Europe (UNECE) Conventions. In particular, it is without prejudice to the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the Aarhus Convention, 1998), as well as the UNECE Convention on***		

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		Environmental Impact Assessment in a Transboundary Context (the Espoo Convention, 1991) and its Protocol on Strategic Environmental Assessment (the Kyiv Protocol, 2003).		
Recital 20				
32	(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.	(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.	(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 ***, where appropriate,*** certain provisions related to strategic projects. Those plans have the potential to help balance the public interest and common good, decreasing the potential for conflict and accelerating the sustainable deployment of strategic projects in the Union.	
Recital 20a				
32a			***(20a) 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***	

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			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.	
Recital 21				
33	(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	(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	(21) Given the capital-intensive nature of pharmaceutical production, including the establishment ~~*or,*~~ expansion ***or modernisation*** 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	

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	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.	support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary. ***Furthermore, any public financial support should ensure full transparency of funding amounts and conditions, be tied to clear supply and access obligations, include effective monitoring measures, and have enforceable sanctions for non-compliance.***	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.	
Recital 22				
34	(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[1], Digital Europe Programme[2] and Horizon Europe[3] (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.	(22) ~~*Union-level funding may be leveraged to facilitate investments in*~~***In order to ensure that the Union can effectively promote*** strategic projects~~*. Strategic projects may benefit from access to existing EU*~~***, it is essential to make full use of the range of Union funding available under the current and future Multiannual Financial Frameworks. Union*** funding instruments, ***including but not limited to regional policy programmes, should therefore be able to support such projects where***	(22) Union-level funding ~~*may*~~***can*** be leveraged to facilitate investments in strategic projects. Strategic projects ~~*may*~~***can*** benefit from access to ~~*existing*~~ EU funding instruments, ~~*such as*~~***including but not limited to*** the EU4Health Programme[1], Digital Europe Programme[2] and Horizon Europe[3] (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	

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	Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 of the European Parliament and of the Council[4] (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. _____ 1. 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) 2. 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) 3. 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	***this is not explicitly excluded by their respective legal bases and where the support is consistent with the objectives laid down in the regulations establishing those instruments. Looking ahead to the future Multiannual Financial Framework, dedicated Union funding should be provided to advance the objectives of this*** ~~*such as the EU4Health Programme[1], Digital Europe Programme[2] and Horizon Europe[3] (relevant, for example, for active substances referred to in Article 5(d) of*~~ Regulation***. Within this framework, and in coordination with other relevant Union instruments, a Union medicinal security fund should be*** ~~*(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*~~***order to reinforce*** the Union ~~*programmes covered by Regulation (EU) 2024/795 of the European Parliament and of the Council[4] (STEP) should in particular consider supporting*~~***'s*** strategic ~~*projects addressing a vulnerability in the*~~***capacity to ensure a secure,***	these instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 of the European Parliament and of the Council[4] (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. _____ 1. 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) 2. 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) 3. 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,	

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	L170, 12.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/695/oj) 4. 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)	***resilient and sustainable*** supply ~~*chains of critical*~~***of*** medicinal products***, thereby strengthening preparedness and safeguarding public health across the Union*** ~~*and therefore Regulation (EU) 2024/795 should be amended*~~. ~~*1. 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)*~~ ~~*2. 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)*~~ ~~*3. 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)*~~ ~~*4. Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic*	12.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/695/oj) 4. 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)	

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		~~*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)*~~		
Recital 23				
35	(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[1]. _____ 1. Communication and visibility rules - Publications Office of the EU	(23) To allow for a more coordinated approach to financial support, it is appropriate that Member States and the Commission exchange the information on financial support to strategic projects. ***In doing so, an appropriate level of confidentiality of sensitive business information and data obtained should be respected and protected, such as details of value chains, the disclosure of which could harm the competitive position of the companies involved. The Commission and the national competent authorities, their officials, employees and other persons working under the supervision of those authorities as well as officials and employees of other authorities of the Member States should not disclose***	(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*~~***received*** EU funding, the beneficiaries should follow the relevant communication and visibility rules[1]. _____ 1. Communication and visibility rules - Publications Office of the EU	

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		information acquired or exchanged by them pursuant to this Regulation where such information is covered by the obligation of professional secrecy. This should also apply to the Critical Medicines Coordination Group. The data collated pursuant to this Regulation should be handled and stored in a secure environment. As regards the strategic projects that have benefitted from EU funding, the beneficiaries should follow the relevant communication and visibility rules[1]. _____ 1. Communication and visibility rules - Publications Office of the EU		
Recital 24				
36	(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	(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	(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*~~***promote resilience of supply in public*** procurement ~~*requirements*~~	

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	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.	Advantageous Tender (MEAT) that take into account the supply security and availability considerations ***as well as support the commercial viability of the procurement procedures in a way that actively encourages the participation of pharmaceutical manufacturers in procurement processes***. Procurement requirements based on such considerations should include ***value-based criteria, such as product quality measured by patient impact and clinical value,*** stockholding obligations, a number of diversified suppliers, state of the art monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery and measures in case of non-timely delivery.	~~*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.*~~***procedures of critical medicinal products falling within the scope of Directive 2014/24/EU.***	
Recital 24a				
36a		***(24a) In order to strengthen the resilience of supply chains for medicinal products and to mitigate the risk of supply disruptions, procurement procedures carried out under this Regulation should, where appropriate, allow for the award of contracts to multiple***		

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		suppliers for the same product. Such multi-winner procurement approaches can promote diversification of supply, enhance security of supply, and ensure that production capacity is distributed across different manufacturers and geographical locations within the Union. In addition, to provide market predictability and support investment in the production of medicinal products, procurement procedures under this Regulation should, where justified, include predictable mix and weighting of qualitative criteria. Those commitments can serve as an incentive for manufacturers to maintain or scale up production capacity, particularly for medicinal products that are essential for public health but may not be commercially attractive under standard market conditions.		
Recital 24a				
36b			***(24a) Resilience can be promoted through various measures depending on market situations and public health considerations. Active use of award criteria acknowledging quality alongside***	

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			price are essential levers. Member States and contracting authorities should retain flexibility to decide the most relevant approach, given the market situations and their specific needs. Resilience requirements could inter alia relate to stockholding obligations, the number of diversified suppliers, state of the art monitoring of supply chains, transparency of the supply chain and contract performance clauses on timely delivery and measures in case of non-timely delivery and could be specified further at national level by Member States. These requirements do not preclude contracting authorities from using public procurement procedures resulting in the award of contracts to more than one winner (multi-winner approaches).	
Recital 25				
37	(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	(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	(25) ~~*Inconsistent*~~***Across Member States, contracting authorities differ in their introduction and*** use of ~~*procurement*~~***resilience*** requirements in public procurement procedures***, which lead to differentiated practices. This could***	

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	order to avoid such negative outcomes, the use of MEAT criteria should be mandatory.	to avoid such negative outcomes, the use of MEAT criteria should be mandatory. ***To minimise market fragmentation and create certainty and predictability for both public health system payers as well as for pharmaceutical manufacturers, the Commission should coordinate and maintain a catalogue of such MEAT criteria, as well as relevant best practices for using them in public procurement, for use by Member States.***	~~*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*~~ ***resilience requirements*** should be mandatory ***and a more streamlined practice supported***.	
Recital 26				
38	(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	(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,	(26) To ensure a high level of ***public*** health protection and security of supply, it is necessary to procure in a way that promotes diversification of suppliers ***and favours European manufactured critical medicinal products or their actives substances,*** where dependency on a single or a limited number of ~~*third*~~ countries ***outside the Union***, 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*~~	

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	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.	when justified by market analysis and public health considerations, ~~may~~***should*** apply procurement requirements that favour suppliers of medicinal products of common interest that manufacture a significant portion of these medicinal products in the EU. These measures should be designed and applied in line with the Union's international obligations including the principles of non-discrimination and proportionality. ***In order to ensure legal certainty and consistency in its application, it is important to determine what constitutes a significant proportion of production within the meaning of this Regulation. In that sense, a significant proportion of the production should take place within the Union or, where appropriate, the EFTA countries, in line with the objective of reinforcing the Union's open strategic autonomy.***	***performed by the Medicines Shortages Steering Group ("MSSG"). This vulnerability evaluation will identify the vulnerabilities with respect to the supply chains*** of critical medicinal products ~~*that manufacture a significant portion of these products in the EU. Moreover, the contracting authorities in*~~***, including the level of dependency on countries outside the Union, that*** the Member States~~, when justified by market analysis and public health considerations, may apply procurement~~ ***can utilise in their efforts to reduce dependencies and promote diversification.*** Requirements that favour~~ suppliers of~~ ***critical*** medicinal products ~~of common interest that manufacture a significant portion of these medicinal products~~***or their active substances manufactured*** in the ~~EU. These measures~~***Union*** should be ~~designed and~~ applied ~~in line with~~***subject to*** the Union~~'~~***'s*** international ~~obligations~~***commitments*** including the ~~principles of non-discrimination and proportionality~~***Government Procurement Agreement in WTO***	

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			and other relevant international agreements of which the Union is bound and which should be assessed in relation to each of these international agreements.	
Recital 26a				
38a	(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. Moved reference text		(~~28~~***27***) ~~*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***, as referred to in Article 168(7) TFEU***. The contracting authorities should therefore retain the ability ***in exceptional cases***, 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. Moved from row 40 [40 - 38a]	
Recital 27				
39	(27) The application of procurement requirements should	(27) The application of procurement requirements should	(~~27~~***28***) The application of ~~*procurement*~~ requirements ***in public***	

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	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.	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.	***procurement procedures*** should take into account the specific market conditions and public health needs of each procurement procedure, whilst bearing in mind the considerations related to affordability of medicinal products. Certain ~~*procurement*~~ requirements may not be justified if they result in disproportionate cost for procurers ~~*or*~~***,*** discourage participation, leading to no bids***, or in case of no suitable tender or no requests to participate have been submitted in response to a similar public procurement procedure launched by the same contracting authority in the two years prior to the commencement of the planned new procurement procedure. Contracting authorities can presume tenders whose price exceeds the contracting authority's budget as determined and documented prior to the launching of the procurement procedure to be considered as tenders with disproportionate costs. Similarly, contracting authorities should be able not to apply the requirements, where it is strictly necessary due to reasons of extreme urgency brought about by events***	

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			unforeseeable by the contracting authority and the circumstances invoked to justify extreme urgency are not attributable to the contracting authority.	
Recital 28				
40	(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.	(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.	Moved to row 38a [40 - 38a]	
Recital 29				
41	(29) The Commission intends to issue guidelines designed to support Member States in implementing their obligations to use procurement requirements including award	(29) The Commission ~~*intends to*~~***should, after consultation with relevant stakeholders such as patients and consumer organisations, healthcare***	(29) The Commission ~~*intends to*~~***should*** issue guidelines designed to support Member States ***and contracting authorities*** in implementing ~~*their*~~***and applying***	

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	criteria beyond price considerations with a view to strengthening the security of supply, building on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate.	***professionals, public healthcare payers and marketing authorisation holders,*** issue guidelines designed to support Member States in implementing their obligations to use procurement requirements including award criteria beyond price considerations with a view to strengthening the security of supply, building on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers and detailing procurement practices that support availability and security of supply is appropriate.	***the*** obligations to use ~~*procurement*~~***resilience*** requirements ~~*including award criteria beyond price considerations*~~***and requirements that favour European manufactured critical medicinal products or their active substances*** with a view to strengthening the security of supply~~*, building on best practices*~~***. The guidelines should include guiding principles on determining whether critical medicinal products or their active substances are manufactured in the Union and address an*** identified ***vulnerability*** 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*~~***chains and dependency on countries outside the Union***. ***The guidelines should be issued at the latest 6 months after the entry into force of this Regulation.***	
Recital 30				
42	(30) The procurement of medicinal products is organised differently across Member States,	(30) The procurement of medicinal products is organised differently across Member States,	(30) The procurement of medicinal products is organised differently across Member States,	

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

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	the various measures put forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality.	the Commission and the Critical Medicines Coordination Group, established by this Regulation, to facilitate the exchange of best practices and coordination between the Member States. This cooperation should enhance the overall effectiveness of the various measures put forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality***, as well as the exchange of best practices in stock management, real1time monitoring, expiry alerts, stock rotation, shelf-life optimisation and waste reduction to further strengthen the Union's preparedness and operational effectiveness. These practices will contribute to greater efficiency, minimise losses, and ensure the availability of critical medicinal products during periods of high demand.***	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.	
Recital 30a				
42a		***(30a) In view of the increasing vulnerabilities in the supply chains of critical medicinal products and the resulting risks of supply***		

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		disruptions and shortages that can seriously endanger public health and disrupt the functioning of the internal market, it is necessary to establish a Union coordination mechanism operated by the Commission. That mechanism should serve as a structured, solidarity-based instrument to monitor availability, coordinate responses, and, where necessary, enable medicinal products to be redistributed equitably across the Union. While safeguarding the principle of subsidiarity, the mechanism should only be activated as a measure of last resort when all other national and voluntary Union-level means have been exhausted and where shortages or disruptions in one or more Member States are likely to result in serious harm to patients or affect other Member States. Binding redistribution decisions should be based on objective risk assessments and real-time data and should ensure that the Member States providing assistance retain adequate minimum stock levels. To support timely and informed decisions, Member States should		

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		report regularly on their national stockpiles and contingency stocks through a harmonised, digital reporting system. Additionally, fair reimbursement and cost-sharing provisions should ensure that solidarity is matched by equity. In order to ensure uniform conditions for the implementation of reporting obligations in relation to national stockpiles and contingency stocks, as well as of procedures for reimbursement or replacement, and for cost-sharing mechanisms between Member States, in the event of a binding redistribution decision, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.		
Recital 30b				
42b		***(30b) To address vulnerabilities in the supply chains of critical medicinal products and medicinal products of common interest, a Union Stockpile may be established as a last-resort mechanism when other national or Union-level***		

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		measures, including the voluntary mechanisms provided for in Union legislation, are insufficient. The Commission should be empowered to adopt delegated acts to define the categories of products, minimum quantities, and operational arrangements for storage, maintenance and deployment. The Union Stockpile should be coordinated with Member States to ensure alignment with national stocks and avoid duplication or disruption. It should be possible for Union budgetary support to be provided where appropriate.		
Recital 30c				
42c		***(30c) In order to promote solidarity, candidate countries should be allowed, on a voluntary basis, to participate in the procedures established by this Regulation where a bilateral agreement with the Union governing the relevant procurement activities is in place. Such participation should be without prejudice to their accession negotiations or to the rights and obligations reserved to Member States under Union law.***		

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Recital 30d				
42d		***(30d) To improve the functioning of the pharmaceutical market in the Union, Member States and the Commission should, when implementing pricing and public procurement practices, take action to achieve the objectives of the 2019 World Health Assembly Resolution on Improving the transparency of markets for medicines, vaccines, and other health products.***		
Recital 31				
43	(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	(31) Obligations imposed by the Member States on companies in the pharmaceutical supply chain to hold contingency stocks can have a serious negative impact on the internal market and other Member States. To avoid such an impact, these obligations should be designed taking into consideration the principles of proportionality, transparency and solidarity ***and non-discrimination***. The Member States should give due consideration to forthcoming Commission guidelines designed to facilitate the fulfilment of Member States' obligations as regards the absence of	(31) ~~*Obligations imposed by the*~~***Some*** Member States ***impose obligations on marketing authorisation holders and other economic operators*** ~~*on companies*~~ in the pharmaceutical supply chain to ***healthcare providers and patients to*** hold contingency stocks ***for the purpose of safeguarding the security of supply of medicinal products within their territory. Contingency stocks are to be distinguished from publicly owned national, regional or local stockpiling in order to anticipate and manage a specific crisis. Contingency stocks can***	

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	the internal market when proposing and defining the scope and timing of any form of requirements for companies to hold such stocks.	any negative impact on the internal market when proposing and defining the scope and timing of any form of requirements for companies to hold such stocks. ***Effective coordination mechanisms at Union level are therefore necessary to address possible conflicts and to ensure that national measures do not delay patient access, distort supply chains, or fragment the internal market.***	***potentially*** ~~*can*~~ have a ~~*serious*~~ negative impact on the internal market ~~*and*~~***including availability of the medicinal products concerned in*** other Member States. ***Any such contingency stocks requirements should take into account that any restriction to the free movement of goods are justified by the purpose of safeguarding public health, thus respecting the Treaties and the case law of the Court of Justice of the European Union.*** To avoid ~~*such and*~~***a negative*** impact ***on the internal market, Member States***~~*, these obligations*~~ should ~~*be designed taking*~~***also, when introducing or changing existing contingency stock requirements for any medicinal products, including determining the medicinal products covered, the size of required stocks and timeline for establishment of the stocks, take*** into consideration the principles of proportionality, transparency and solidarity***. Such requirements should not prevent Member States from assisting other Member States requesting support under the voluntary Solidarity Mechanism launched by the Medicines Shortages Steering***	

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			Group ("MSSG") in 2023. 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*~~***compliance with*** the internal market ***and the free movement of goods*** when proposing and defining ~~*the scope and timing of any form of*~~***contingency stock*** requirements***. Member States should comply with existing obligations under Union law for the notification of technical regulations and technical barriers to the internal market, including those set out in Directive (EU) 2015/1535*** ~~*for companies to hold such stocks*~~.	
Recital 32				
44	(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	(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	(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	

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	powerful tool to improve their security of supply and accessibility.	powerful tool to improve their security of supply and accessibility ***including medicinal products for rare diseases, antimicrobials, and other innovative, high-cost, or specialised treatments across various therapeutic areas, such as oncology. Economic operators participate in collaborative procurement procedures conducted pursuant to this Regulation on a voluntary basis.***	powerful tool to improve their security of supply and accessibility.	
Recital 33				
45	(33) Directive 2014/24/EU of the European Parliament and of the Council[1] 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	(33) Directive 2014/24/EU of the European Parliament and of the Council[1] 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	(33) Directive 2014/24/EU of the European Parliament and of the Council[1] 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	

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	requested, should provide its assistance during the preliminary phase of setting up such a procurement initiative. _____ 1. 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).	requested, should provide its assistance during the preliminary phase of setting up such a procurement initiative. _____ 1. 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).	requested, should provide its assistance during the preliminary phase of setting up such a procurement initiative. ***The involved Member States are able to agree to continue the procedure without the Commission's facilitation, including by agreement on another facilitator in accordance with Directive 2014/24/EU. Any involved Member State can withdraw from the procedure at any stage before the signature of the procurement contract. Withdrawal by one Member State would not in itself affect the continuation of the procedure by the remaining participating Member States, provided that the minimum requirements under this Regulation are still met.*** _____ 1. 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).	
Recital 34				
46	(34) Taking into account experiences resulting from the implementation of joint procurement of medical	(34) Taking into account experiences resulting from the implementation of joint procurement of medical countermeasures	(34) Taking into account experiences resulting from the implementation of joint procurement of medical countermeasures	

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	countermeasures pursuant to Regulation (EU) 2022/2371 of the European Parliament and of the Council[1] and of COVID-19 vaccines, pursuant to Council Regulation (EU) 2016/369[2] 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. _____ 1. 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). 2. 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)	pursuant to Regulation (EU) 2022/2371 of the European Parliament and of the Council[1] and of COVID-19 vaccines, pursuant to Council Regulation (EU) 2016/369[2] 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. _____ 1. 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). 2. 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)	pursuant to Regulation (EU) 2022/2371 of the European Parliament and of the Council[1] and of COVID-19 vaccines, pursuant to Council Regulation (EU) 2016/369[2] 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. _____ 1. 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). 2. 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)	
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47	(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[1] should be provided. _____ 1. 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).	(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[1] should be provided. _____ 1. 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).	(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 ***where the conditions set out in the relevant Articles are met***. For this reason***, derogation*** ~~*derogations*~~ from Article 168 ~~*(2) and*~~ (3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[1] should be provided. _____ 1. 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).	
Recital 36				
48	(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	(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	(36) ***In accordance with Article 168 of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council, the Commission should act only within the limits of the mandate given by the participating Member States,***	

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	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	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	***and any actions outside such mandate remain the sole responsibility of the Commission.*** To ensure transparency, legal clarity, and effective coordination, ***a*** structured agreement between the Member States and the Commission should govern procurement procedures under this Regulation that rely on an active Commission involvement. Such ***an*** 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	

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	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[1] 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. 1. 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)	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[1] 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. 1. 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)	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[1] 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. 1. 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	

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			L 314, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj)	
Recital 37				
49	(37) Ensuring a structured and coordinated approach to strengthening the security of supply of critical medicinal products requires collaboration between the Member States and the Commission. To facilitate this, the Critical Medicines Coordination Group ('the Critical Medicines Group') should be established to facilitate effective coordination across the relevant policy areas. The Critical Medicines Group should be composed of high-level representatives of Member States with expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. The 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.	(37) Ensuring a structured and coordinated approach to strengthening the security of supply of critical medicinal products requires collaboration between the Member States and the Commission. To facilitate this, the Critical Medicines Coordination Group ('the Critical Medicines Group') should be established to facilitate effective coordination across the relevant policy areas. The Critical Medicines Group should be composed of high-level representatives of Member States with expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health, ***the European Medicines Agency ('the Agency') and representatives from patient organisations and healthcare professional organisations***. The Commission should be a member of the group. To ensure structured discussions, the Commission should chair the Critical Medicines Group and perform the functions of its secretariat.	(37) ~~*Ensuring*~~***In order to ensure*** a structured and coordinated approach ***as well as coherent information exchange to strengthen*** ~~*to strengthening*~~ the security of supply of critical medicinal products ~~*requires*~~***,*** collaboration between the Member States and the Commission ***is required***. To facilitate this, the ~~*Critical Medicines Coordination Group ('the Critical Medicines Group')*~~***CMCG*** should be established to facilitate effective coordination across the relevant policy areas. The ~~*Critical Medicines Group*~~ ***CMCG*** should be composed of ~~*high-level representatives of Member States with*~~ ***a permanent representative with strategic*** expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. ***As necessary, Member States may appoint additional expert representatives to accompany the permanent Member State representative in order to support the different tasks of the***	

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			CMCG. The Commission should be a member of the group. To ensure structured discussions~~,~~ ***a representative of the Member States and a representative of*** the Commission should ~~*chair the Critical Medicines Group and*~~***co-chair. The Commission should*** perform the functions of its secretariat.	
Recital 38				
50	(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	(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	(38) To ensure coordinated implementation of this Regulation, the ~~*Critical Medicines Group*~~***CMCG*** 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*~~ ***CMCG*** should also facilitate the exchange of information on national programmes~~*, including on the approach to contingency stock requirements in*~~ ***to promote best practices, and where appropriate, voluntary cooperation on Member States*** public procurement ~~*contracts. When relevant, the*~~***policies with regard to*** critical ~~*Medicines Group should facilitate the coordination of*~~	

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	on the need to launch a collaborative procurement initiative and the need to prioritise the vulnerability evaluation for specific critical medicinal products.	the need to launch a collaborative procurement initiative and the need to prioritise the vulnerability evaluation for specific critical medicinal products. ***In order to ensure solidarity and an effective Union-level response to shortages or supply disruptions of critical medicinal products, it is necessary to establish a clear decision-making process for the redistribution of such products. To that end, the Member States should be included in the decision-making process through the Critical Medicines Group established under this Regulation.***	~~*national programmes. The Critical Medicines Group*~~***medicinal products.. The CMCG*** should furthermore facilitate ***strategic*** discussions on ~~*the need to launch a*~~ collaborative procurement ~~*initiative and*~~***initiatives, exchanges on guiding principles on contingency stocks requirements and discussions on*** the need to prioritise the vulnerability evaluation for specific critical medicinal products. ***The coordination work of the CMCG should be distinct from the work of the MSSG established under Article 3 of Regulation (EU) 2022/123 and whose tasks are set out in Regulation (EU) 2022/123 and Regulation (EU) No …/… [reference to be added after adoption cf. COM(2023) 193 final]. Whereas, the main tasks of the MSSG are to coordinate Union-level responses to actual or potential shortages of medicinal products during public health emergencies or major events, to monitor the supply and demand of critical medicines and to provide recommendations to prevent or mitigate shortages, the focus of the CMCG is to facilitate coordination***	

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			of the measures envisaged in this Regulation creating the necessary conditions on investments and public procurement coordination and collaboration to proactively reduce dependencies and strengthen EU production capacity.	
Recital 38a				
50a		***(38a) In order to strengthen the Union's preparedness and ensure an inclusive, needs-driven, transparent and coordinated approach to future challenges in the supply of critical medicinal products, the Critical medicines group, after consultation with the Commission, the Agency and the Critical Medicines Alliance, should establish a strategic foresight process. This process should identify and assess potential strategic projects, taking into account long-term trends, vulnerabilities, and opportunities for enhancing the resilience and sustainability of supply chains within the Union, specifically based on unmet medical needs.***		
Recital 39				
51	(39) The Union could further enhance the availability and	(39) The Union ~~could~~***should*** further enhance the availability and	(39) The Union could further enhance the availability and security	

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	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.	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~~***should***, to that end, rely on its network of existing trade agreements and additionally pursue strategic partnerships with third countries to further deepen bilateral cooperation, especially with candidate countries. In this context, the Commission should assess whether existing partnerships effectively address the intended aims or could be further improved or upgraded, and what types of potential partnerships could be concluded with the most relevant third countries. This should be done without prejudice to the prerogatives of the Council in accordance with the Treaties. ***As part of these partnerships, the Commission should promote a collaborative innovation ecosystem that integrates small and medium-sized enterprises, start-ups and deep-tech innovators alongside established pharmaceutical companies in order***	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.	

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		to enhance resilience, foster technological advancement and boost the competitiveness of the Union's pharmaceutical sector. The Commission should specifically consider the inclusion of access to APIs and their starting materials in the scope of international partnerships.		
Recital 40				
52	(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.	(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.	(40) To ensure the application of this Regulation, it is necessary that ~~*economic operators*~~***market actors*** make available information ~~*and data to public*~~***to the competent*** authorities. The ~~*Member States and the Commission*~~***national competent authorities or the Agency, as relevant,*** 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~~***. Information acquired*** in the ~~*supply and distribution chains of critical medicinal products and medicinal products of common interest*~~***course of implementing this Regulation should be used only for the***	

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			purposes of this Regulation and should be protected by the relevant Union and national law. Any obligations on sharing information pursuant to this Regulation should not apply to data that concerns the essential interests of the Member States' security or defence.	
Recital 41				
53	(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	(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	(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 ***at the latest*** 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. ***The evaluation should also include an assessment of the scope, functioning and efficiency of Article 18 as well as coherence of the Regulation with developments within the field of public procurement.*** In particular, the	

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	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.	framework. The results of this evaluation should be presented to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. In order to facilitate this evaluation, national authorities and economic operators should provide relevant data and information upon request to support the Commission's assessment. ***When an evaluation reveals a potential risk to the availability or security of supply of a critical medicinal product in the Union, the Commission should conduct a coordinated, evidence-based assessment and, where appropriate, propose proportionate mitigating measures in consultation with Member States and relevant stakeholders to safeguard continuous supply.***	Commission's evaluation should take into account the views of Member States, ~~*economic operators*~~***markets actors***, ***contracting authorities*** and other relevant stakeholders, ensuring that their feedback contributes to the continuous improvement of the regulatory framework. The results of ~~*this*~~***the*** evaluation should be presented to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. In order to facilitate this evaluation, national authorities***, market actors, contracting authorities and other relevant stakeholders*** ~~*and economic operators*~~ should provide relevant data and information upon request to support the Commission's assessment.	
Recital 42				
54	(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	(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	(42) Since the objectives of this Regulation to ~~*establish*~~***improve the functioning of the internal market by establishing*** a framework to strengthen the availability and security of supply of critical medicinal products within the Union	

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	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.	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.	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.	
Recital 42a				
54a		***(42a) In order to supplement this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the specification and harmonisation of the conditions applicable to the determination of the categories, types and quantities of critical medicinal products to be included in the Union Stockpile, the determination of the specific***		

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

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		to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Formula				
55	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	
Chapter I				
56	Chapter I General provisions	Chapter I General provisions	Chapter I General provisions	
Article 1				
57	Article 1 Objectives and subject matter	Article 1 Objectives and subject matter	Article 1 Objectives and subject matter	
Article 1(1)				
58	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	1. The objective of this Regulation is to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ***reducing its dependency on third countries and thereby*** ensuring a high level of public health protection***, maintaining patient***	1. The objective of this Regulation is ***to improve the functioning of the internal market by establishing a framework*** to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the	

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	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.	***safety*** and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the ***accessibility and*** affordability of medicinal products.	security of the Union. The objective of this Regulation is also to improve the availability and accessibility of ~~*other*~~ medicinal products~~,~~ ***of common interest*** where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the ~~*appropriateness to ensure the*~~ affordability of ***those*** medicinal products.	
Article 1(1a)				
Y	58a		***1a. Strengthening manufacturing capacities and the resilience of supply chains, as well as competitiveness, strategic autonomy and innovation in the Union's pharmaceutical sector, is also an objective of this Regulation.***		Y
Article 1(2)				
Y	59	2. To achieve the objectives referred to in paragraph 1, the Regulation sets out a framework to:	2. To achieve the objectives ~~*referred to in paragraph 1*~~***set out in paragraphs 1 and 1a***, the Regulation sets out a framework to:	2. To achieve the objectives referred to in paragraph 1, ~~*the*~~***this*** Regulation sets out a framework to:	Y
Article 1(2), point (a)				
Y	60	(a) facilitate investments in manufacturing capacity for critical medicinal products, their active	(a) facilitate***, support and incentivise*** investments in ***new manufacturing capacity and***	(a) facilitate investments in manufacturing capacity for critical medicinal products, their active	Y

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	substances and other key inputs in the Union;	***strengthen existing*** manufacturing capacity for critical medicinal products ***and, where applicable, medicinal products of common interest***, their active substances and other key inputs in the Union ***with a priority given to medicinal products that can become critical if vulnerabilities affect their supply chain, by making available any accelerated permit granting processes related to the strategic projects that exist in applicable Union and national law***;	substances and other key inputs in the Union;		
Article 1(2), point (b)					
G	61	(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;	(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;	(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; Text Origin: Commission Proposal	G
Article 1(2), point (ba)					
Y	61a	***(ba) prevent shortages and strengthen availability of medicinal***			Y

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		products by facilitating the adoption of common standards governing contingency stocks and national stockpiles of critical medicinal products and medicinal products of common interest, and by enhancing transparency and coordination among Member States in this regard;		
Article 1(2), point (c)				
62	(c) leverage the aggregated demand of participating Member States through collaborative procurement procedures, and	(c) leverage the aggregated demand of participating Member States through collaborative procurement procedures~~, and~~***;***	(c) leverage the aggregated demand of participating Member States through collaborative procurement procedures, and	
Article 1(2), point (d)				
63	(d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.	(d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships~~.~~ ***with a priority given to medicinal products that can become critical if vulnerabilities affect their supply chain;***	(d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.	
Article 1(2), point (da)				
63a		***(da) facilitate investments in critical distribution infrastructure capacity for critical medicinal products ensuring security of supply, availability and accessibility in the Union; and***		

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	CLEAN	Commission Proposal	VS.EC	EP Mandate	VS.EC	Council Mandate	VS.EC	Draft Agreement	
Article 1(2), point (db)									
Y	63b			***(db) strengthen the resilience of supply chains and promote the sustainable access to and supply of active substances of critical medicinal products, their API starting materials, and other key inputs within the Union insofar as they are used for the manufacture of critical medicinal products.***					Y
Article 2									
G	64	Article 2 Scope		Article 2 Scope		Article 2 Scope		Article 2 Scope Text Origin: Commission Proposal	G
Article 2(1)									
Y	65	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].		1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products referred to in Article 131 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]***, taking into account the distinctive characteristics of each medicinal product's supply chain***.		1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products ~~*referred to in*~~***with the exception of*** Article ~~*131 of Regulation (EU) …/… [reference to be added after adoption cf*~~***21, which only applies to medicinal products of common interest***. ~~*COM(2023) 193 final].*~~			Y
Article 2(1a)									
Y	65a			***1a. Chapter III also applies to active substances of critical***					Y

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		medicinal products, their starting materials, and other key inputs within the Union, insofar as they are used for the manufacture of critical medicinal products.		
Article 2(2)				
R 66	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.	2. ***Chapter III, Articles 5 to 15,*** Chapter IV ***with the exception of its Section Ia new,*** and Article 26(2)***,*** point (c)***,*** also apply to medicinal products of common interest~~. Chapter III does not~~***, where the Critical Medicines Coordination Group has issued a positive recommendation pursuant to Article 26(2)(dj).*** ***Articles 16 and 17*** apply***, mutatis mutandis,*** to medicinal products of common interest ***subject to the condition that the Union funding allocation under Article 16 exceeds EUR 500 million***.	2. ~~*Chapter IV and Article 26(2) point (c)*~~***Articles 1, 22, 24, 26(2) points (c) and (db) and 26(3)*** also apply to medicinal products of common interest. ~~*Chapter III does not apply to medicinal products of common interest.*~~	R
Article 3				
67	Article 3 Definitions	Article 3 Definitions	Article 3 Definitions	
Article 3, first paragraph				
68	For the purpose of this Regulation, the following definitions shall apply:	For the ~~*purpose*~~***purposes*** of this Regulation, ***relevant definitions laid down in Article 4 of Directive (EU)***	For the purpose of this Regulation, the following definitions shall apply:	

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		…/… [reference to be added after adoption cf. COM(2023) 192 final] and in Article 2 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] shall apply mutatis mutandis. The following definitions shall ***also*** apply:		
Article 3, first paragraph, point (1)				
69	(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];	~~*(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];*~~	(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];	
Article 3, first paragraph, point (2)				
70	(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;	(2) 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including primary packaging materials, excipients, solvents and reagents***, raw materials, feedstock and starting materials***;	(2) 'key input' means input material**,** other than an active substance**,** required in the manufacturing process of a given medicinal product, including ***starting materials and raw materials for production of active substances or excipients,*** primary packaging materials, excipients, solvents and reagents;	(2) 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including ~~*primary*~~***immediate*** packaging materials, excipients, solvents~~ *and*~~***,*** reagents ***and starting materials***; Text Origin: Auxiliary 1

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 3, first paragraph, point (3)				
71	(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];	(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];*~~	(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];	
Article 3, first paragraph, point (3a)				
71a			***(3a) 'starting material' means material as defined in Article 4 point (4) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];***	
Article 3, first paragraph, point (3b)				
71b			***(3b) 'excipient' means an excipient as defined in Article 4 point (5) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];***	
Article 3, first paragraph, point (3a)				
71c			***(3c) 'collecting' means collection of substances of human or animal origin for the purpose of being processed into active***	***(3a) 'collecting' means collection of substances of human origin, as defined in Regulation (EU) 2024/1938,***

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			substances of critical medicinal products;	***or of animal origin for the purpose of being used as a starting material for critical medicinal products;*** Text Origin: Auxiliary 1
Article 3, first paragraph, point (4)				
72	(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];	(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];*~~	(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*~~***listed in the Union List of Critical Medicinal Products referred to*** in Article ~~*4 point (13)*~~***131*** of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]~~;~~.	
Article 3, first paragraph, point (4a)				
72a		***(4a) 'substance of human origin' or 'SoHO' means a 'substance of human origin' or 'SoHO', as defined in Regulation (EU) 2024/1938;[1a]*** ***1a. Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC***		
Article 3, first paragraph, point (5)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
R 73	(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;	(5) 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability, ***affordability*** and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States ***or is designated as an orphan medicinal product pursuant to Article 67 of Regulation (EU) .../... [reference to be added after adoption cf. COM(2023)193 final)], or as a contraceptive or abortifacient medicinal product***;	(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;	R
Article 3, first paragraph, point (5a)				
73a		***(5a) 'API starting material' means a raw material, an intermediate product, or an active substance that is used in the production of an active pharmaceutical ingredient (API) and that is incorporated as a significant structural fragment into the structure of the API;***		
Article 3, first paragraph, point (5b)				
73b		***(5b) 'systemic wholesaler' means a wholesaler of medicinal***		

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		products that holds a wholesale distribution authorisation and fulfils all obligations laid down in Article 166 of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final]. They wholesale and continuously distribute either the full range of prescription medicines, meaning more than 80% of the prescription medicines available for retail sale in a Member State market, or above 20% of the total market share of prescription medicines available for retail sale in a Member State market;		
Article 3, first paragraph, point (6)				
74	(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	(6) 'vulnerability in the supply chains' means ***structural and non-structural*** risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level, taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation, ***and the specific features of the supply chains of each product,*** that	(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*~~ ***Union*** 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;	

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	medicinal products to patients in the Union;	compromise the continuous supply of such medicinal products to patients in the Union;		
Article 3, first paragraph, point (7)				
75	(7) 'vulnerability evaluation' means the evaluation of the supply chains of critical medicinal products to identify their vulnerabilities performed by the MSSG in accordance with Regulation (EU) …/… of the European Parliament and of the Council[1] [reference to be added after adoption cf. COM(2023) 193 final]; _____ 1. Regulation (EU) …. of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ …) [D.G.: Title according to COM(2023) 193 final. Please check against latest version of this draft Regulation].	(7) 'vulnerability evaluation' means the evaluation of the supply chains of critical medicinal products to identify their vulnerabilities performed by the MSSG in accordance with Regulation (EU) …/… of the European Parliament and of the Council[1] [reference to be added after adoption cf. COM(2023) 193 final]; _____ 1. Regulation (EU) …. of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ …) [D.G.: Title according to COM(2023) 193 final. Please check against latest version of this draft Regulation].	(7) 'vulnerability evaluation' means the evaluation of the supply chains of critical medicinal products ***in order*** to identify their vulnerabilities performed by the ***Medicines Shortages Steering Group ("MSSG")*** ~~*MSSG*~~ in accordance with Regulation (EU) …/… of the European Parliament and of the Council[1] [reference to be added after adoption cf. COM(2023) 193 final]; _____ 1. Regulation (EU) …. of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ …) [D.G.: Title according to COM(2023) 193 final. Please check against latest version of this draft Regulation].	
Article 3, first paragraph, point (8)				
76	(8) 'common name' means a common name as defined in Article	(8) 'common name' means a common name as defined in Article	(8) 'common name' means a common name as defined in Article	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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];	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];	4 ***(1),*** 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];	
Article 3, first paragraph, point (9)				
77	(9) 'contracting authorities' means contracting authorities as defined in Article 2(1) point (1) of Directive 2014/24/EU;	(9) 'contracting authorities' means contracting authorities as defined in Article 2(1) point (1) of Directive 2014/24/EU;	(9) 'contracting authorities' means contracting authorities as defined in Article 2(1) point (1) of Directive 2014/24/EU;	
Article 3, first paragraph, point (10)				
78	(10) 'strategic project' means an industrial project identified pursuant to the criteria set out in Article 5;	(10) 'strategic project' means ~~*an industrial*~~***a strategic*** project identified pursuant to the criteria set out in Article 5 ***of this Regulation***;	(10) 'strategic project' means an industrial project ~~*identified*~~***recognised as a strategic project by a designated authority as referred to in Article 6*** pursuant to the criteria set out in Article 5;	
Article 3, first paragraph, point (10a)				
78a		***(10a) 'cross-border strategic project' means a strategic project identified pursuant to the criteria set out in Article 5 of this Regulation, which may be carried out by a minimum of two Member States;***		
Article 3, first paragraph, point (11)				
79	(11) 'project promoter' means any undertaking or consortium of	(11) 'project promoter' means any undertaking or consortium of	(11) 'project promoter' means any undertaking or consortium of	

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	undertakings developing a strategic project;	undertakings developing a strategic project;	undertakings developing a strategic project;	
Article 3, first paragraph, point (11a)				
79a		***(11a) 'economic operator' means an economic operator as defined in Directive 2014/24/EU;***		
Article 3, first paragraph, point (12)				
80	(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 and environmental assessments and authorisations where those are required and encompassing all applications and procedures;	(12) 'permit granting process' means a process covering all relevant permits to build***, expand, convert*** and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures;	(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 and environmental assessments and authorisations where those are required and encompassing all applications and procedures;	
Article 3, first paragraph, point (13)				
81	(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;	(13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, ***automation, yield improvements or other chemistry or biotechnology process that contribute to increase the level of security, energy and environmental***	(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;	

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		performance of the production, and use of Artificial Intelligence, platform ~~*techniques,*~~ ~~*3D*~~***technologies or 3D technologies in*** manufacturing;		
Article 3, first paragraph, point (13a)				
81a		***(13a) 'contingency stock' means the quantity of critical medicinal products or, where applicable, medicinal products of common interest that manufacturers and wholesalers might be required to hold under national law in order to have a buffer when shortages or supply disruptions occur, including because of fluctuations in demand or supply;***		
Article 3, first paragraph, point (13b)				
81b		***(13b) 'contingency stock requirement' means an obligation imposed by a Member State law on manufacturers and wholesalers in the supply chain to establish buffer stocks of certain medicinal products to mitigate the risk of shortages or supply disruptions;***		
Article 3, first paragraph, point (13c)				
81c		***(13c) 'national stockpile' means the reserves of a quantity of critical medicinal products or medicinal***		

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		products of common interest established under national law by a Member State for a public health use, such as national strategic reserves;		
Article 3, first paragraph, point (13d)				
81d		***(13d) 'redistribution' means the transfer of critical medicinal products from a contingency stock or national stockpile from one or several Member States to other Member States following a decision of the Commission in response to shortages or supply disruptions in one or more Member States;***		
Article 3, first paragraph, point (14)				
82	(14) 'Member States' cross-border procurement' means a procurement procedure initiated between the contracting authorities from different Member States on the basis of Article 39 of Directive 2014/24/EC;	(14) 'Member States' cross-border procurement' means a procurement procedure initiated between the contracting authorities from different Member States on the basis of Article 39 of Directive 2014/24/EC;	(~~14~~***15***) 'Member States' cross-border procurement' means a procurement procedure initiated ~~*between the*~~ ***at the request of Member States and involving*** contracting authorities from different Member States ~~*on the basis of*~~ ***pursuant to*** Article 39 of Directive ~~*2014/24/EC*~~***2014/24/EU***;	
Article 3, first paragraph, point (15)				
83	(15) 'procurement on behalf of or in the name of the Member States' means a procurement procedure initiated at the request of	(15) 'procurement on behalf of or in the name of the Member States' means a procurement procedure initiated at the request of	(~~15~~***16***) 'procurement on behalf of or in the name of the Member States' means a procurement procedure initiated at the request of	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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;	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;	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, ***Euratom***) 2024/2509 ***of the European Parliament and of the Council***;	
Article 3, first paragraph, point (16)				
84	(16) 'joint procurement' means a procurement procedure carried out jointly by the Commission and Member States, as provided for in Article 168(2) of Regulation (EU) 2024/2509;	(16) 'joint procurement' means a procurement procedure carried out jointly by the Commission and Member States, as provided for in Article 168(2) of Regulation (EU) 2024/2509;	~~*(16) 'joint procurement' means a procurement procedure carried out jointly by the Commission and Member States, as provided for in Article 168(2) of Regulation (EU) 2024/2509;*~~	
Article 3, first paragraph, point (17)				
85	(17) 'supplier' means the manufacturer or marketing authorisation holder of finished dosage forms, or manufacturer of key inputs or active substances;	(17) 'supplier' means the manufacturer or marketing authorisation holder of finished dosage forms, or manufacturer of key inputs or active substances;	~~*(17) 'supplier' means the manufacturer or marketing authorisation holder of finished dosage forms, or manufacturer of key inputs or active substances;*~~	
Article 3, first paragraph, point (17a)				
85a			***(18b) 'contingency stocks requirement' means an obligation imposed by a Member State on marketing authorisation holders and other economic operators in the supply chain of medicinal products to healthcare providers***	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			and patients to hold stocks of certain medicinal products to safeguard the security of supply and which obligation is imposed by law, regulations or administrative provisions, including stockholding obligations in public procurement procedures.	
Article 3, first paragraph, point (18)				
86	(18) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products 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.	(18) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products ***or its supply chain, their active substances and key inputs*** that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation~~.~~ ***;***	(~~18~~***19***) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation.	
Article 3, first paragraph, point (18a)				
86a		***(18a) 'resilience of supply chains' means the ability of the supply chain to maintain a continuous and demand-oriented supply of medicinal products, active substances, API starting materials,***		

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		and key inputs in the Union, even during disruptions or external shocks;		
Article 3, first paragraph, point (18b)				
86b		***(18b) 'diversification of supply chains' means the existence of several independent sources or production sites, so that the supply of a medicinal product, active substances, API starting materials, and key inputs does not depend on a single supplier or third country of supply.***		
Chapter II				
R 87	Chapter II Strengthening the Union's security of supply	Chapter II Strengthening the Union's security of supply	~~*Chapter II*~~ ~~*Strengthening the Union's security of supply*~~	R
Article 4				
R 88	Article 4 Strategic objective of the Union	Article 4 Strategic objective of the Union	~~*Article 4*~~ ~~*Strategic objective of the Union*~~	R
Article 4(1)				
R 89	1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.	1. The security of supply ~~*and*~~, availability ***and affordability*** of critical medicinal products ***and, where applicable, medicinal products of common interest,*** for patients ~~*is*~~***shall be considered*** a strategic objective of the Union. ***In order to achieve such an objective,***	~~*1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.*~~	R

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		the determination of strategic projects that meet the criteria laid down in Article 5 shall be made in accordance with Article 6.		
Article 4(2)				
R 90	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.	2. The Member States and the Commission shall work together ***to achieve the strategic objective of the Union referred to in paragraph 1 including by gathering information from healthcare professional organisations, patient organisations and economic operators including marketing authorisation holders,*** to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures ***provided for in Sections II and III of this Chapter*** that take full advantage of the potential of the internal market, ***reflecting the principles of solidarity and coordination between Member States and reducing dependencies on third countries, while ensuring predictability for project promoters***.	~~*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.*~~	R
Article 4(3)				

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R 91	3. The Commission shall support the coordinated efforts of the Members States.	3. The Commission shall support the coordinated efforts of the Members States ***and foster a secure cross-border exchange of relevant information and facilitate the distribution of critical medicinal products throughout the Union***.	~~*3. The Commission shall support the coordinated efforts of the Members States.*~~		R
Chapter III					
92	Chapter III Enabling conditions for investment	Chapter III Enabling conditions for investment	Chapter III Enabling conditions for investment		
Section I					
93	Section I Criteria and procedure for the recognition of strategic projects	Section I Criteria and procedure for the recognition of strategic projects	Section I Criteria and procedure for the recognition of strategic projects		
Article 5					
94	Article 5 Strategic Projects	Article 5 Strategic Projects	Article 5 Strategic Projects		
Article 5, first paragraph					
G 95	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:	***1.*** A project located in the Union and related to creating***,*** ***modernising,*** ~~*or*~~ increasing ***or improving*** manufacturing capacity***,*** ***as well as decreasing Union dependency in relation to key inputs or otherwise contributing to the security of supply or availability of medicinal products,*** shall be considered as a strategic project if it	A project located in the Union and related to creating***, modernising*** or increasing manufacturing capacity ***of critical medicinal products*** shall be ~~*considered*~~***recognised*** as a strategic project if ~~*it*~~ meets at least one of the following criteria:	A project located in the Union and related to creating***,*** ***modernising*** or increasing manufacturing capacity shall be ~~*considered*~~***recognised*** as a strategic project if it meets at least one of the following criteria:	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		meets at least one of the following criteria:		Text Origin: Auxiliary 1
Article 5, first paragraph, point (a)				
96	(a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances;	(a) it creates or increases manufacturing capacity***, including through new technologies and innovative manufacturing processes,*** for one or more critical medicinal products ***or, where applicable, medicinal products of common interest,*** or for collecting or manufacturing their active substances***, or it creates capacity for compounding techniques within pharmacies or hospitals***;	(a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances;	
Article 5, first paragraph, point (b)				
97	(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;	(b) it modernises an existing manufacturing site***, including through new technologies and innovative manufacturing processes,*** for one or more critical medicinal products or ***where applicable, medicinal products of common interest,*** their active substances ***or key inputs to strengthen supply chain resilience,*** to ensure greater sustainability or increased efficiency;	(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;	
Article 5, first paragraph, point (c)				

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Y	98	(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;		(c) it creates ~~or~~, increases ***or modernises*** manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or, ***where applicable, medicinal products of common interest,*** their active substances ***or key inputs***;		(c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances ***where it is demonstrated that there are supply constraints or limited manufacturing capacity in the Union***;			Y
Article 5, first paragraph, point (d)									
Y	99	(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.		(d) it contributes to the roll-out ***or transfer*** of a technology that plays a key role in enabling the manufacturing ***or supply*** of one or more critical medicinal products, ***or, where applicable, medicinal products of common interest,*** their active substances or key inputs~~.~~***;***		(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.			Y
Article 5, first paragraph, point (da)									
Y	99a			***(da) it reserves a defined portion of manufacturing capacity, within a fixed timeframe, to produce specific critical medicinal products or, where applicable, medicinal products of common interest, their pharmaceutical forms, their active substances, key inputs, or enabling technologies, at the request of the Critical Medicines Coordination***					Y

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			Group, in order to address current, emerging or potential shortages.			
Article 5, first paragraph a						
Y	99b		***Notwithstanding paragraph 1, a project shall not receive financial support from the Union pursuant to Article 16 if it results in unnecessary duplication of existing or planned manufacturing capacities for the same medicinal product, its active substances or key inputs within the Union, unless the Critical Medicines Group has assessed the need and such duplication is justified by clearly demonstrated needs related to security of supply, geographical distribution of production sites, or the overall resilience of the Union's pharmaceutical supply chain.***			Y
Article 6						
G	100	Article 6 Recognition of Strategic Projects	Article 6 ~~*Recognition*~~***Determination*** of Strategic Projects	Article 6 Recognition of Strategic Projects	Article 6 Recognition of Strategic Projects Text Origin: Commission Proposal	G
Article 6(1), first subparagraph						
Y	101	1. Each Member State shall designate an authority ('the	1. ***Within three months of the entry into force of this Regulation,***	1. Each Member State shall designate an authority ('the		Y

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		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.	each Member State shall designate an authority ('the designated authority') ~~*that shall assess and verify*~~***to be in charge of assessing and verifying*** whether or not a project meets at least one of the criteria set out in Article 5 and ***is*** therefore ~~*constitutes*~~***to be considered*** a strategic project.	designated authority') that shall assess ~~*and verify*~~ whether ~~*or not a*~~ ***an industrial*** project meets at least one of the criteria set out in Article 5 and therefore ***shall be recognised as*** ~~*constitutes*~~ a strategic project. ***A Member State may designate more than one designated authority.***	
	Article 6(1), second subparagraph				
Y	102	A promoter may request the designated authority to assess whether a project is a strategic project.	A promoter may request the designated authority to assess whether a project ~~*is*~~***constitutes*** a strategic project.	***2. In order for a project to be recognised as a strategic project*** a promoter ~~*may*~~***of an industrial project shall*** request the designated authority to assess whether ~~*a*~~***the*** project is a strategic project. ***The request shall contain justification and relevant evidence related to the fulfilment of at least one of the criteria set out in Article 5. The designated authority shall provide its assessment to the promoter without undue delay.***	Y
	Article 6(1), third subparagraph				
G	103	Any Member State authority may request the designated authority to verify its determination of 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*~~***as*** a strategic project.	***2a.*** ~~*Any Member State authority may*~~***The submission of a*** request ~~*the designated authority to verify its determination of whether*~~***for*** a project ~~*is*~~***to be recognised as*** a strategic project ***as provided for in***	***2a.*** ~~*Any Member State authority may*~~***The submission of a*** request ~~*the designated authority to verify its determination of whether*~~***for*** a project ~~*is*~~***to be*** G

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			paragraph 2 does not preclude the promoter of the project from simultaneously initiating application procedures with other authorities for the permits needed for the project.	***recognised as*** a strategic project ***as provided for in paragraph 2 does not preclude the promoter of the project from simultaneously initiating application procedures with other authorities for the permits needed for the project***. Text Origin: Council Mandate
Article 6(2)				
104	2. Member States shall communicate to the Commission what is the designated authority for the purposes of paragraph 1.	2. Member States shall communicate to the Commission what is the designated authority for the purposes of paragraph 1.	~~***23***~~. Member States shall communicate to the Commission ~~*what is*~~ the designated ~~*authority*~~***authorities*** for the purposes of paragraph 1 ***of this article and Article 16(2)***.	
Article 6(3)				
G 105	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.	3. The Commission shall provide a simple, accessible***, and user-friendly*** webpage ***serving as the central hub for project promoters*** on which ~~*the contact details and other relevant information on the Member States' designated authorities*~~***at least the following elements*** shall be clearly listed~~.~~***:***	~~***34***~~. The Commission shall provide a simple, accessible webpage on which the contact details and other relevant information on the ***tasks of*** Member States' designated authorities shall be clearly listed.	3. The Commission shall provide a simple, accessible***, and user-friendly*** webpage ***for project promoters*** on which ~~*the contact details and other relevant information on the Member States' designated authorities*~~***at least the following elements*** shall be clearly listed~~.~~***:*** G

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				Text Origin: Auxiliary 1	
Article 6(3), point (a)					
G 105a		***(a) the contact details and other relevant information on the Member States' designated authorities;***		***(a) the contact details and other relevant information on the tasks of Member States' designated authorities;*** Text Origin: Auxiliary 1	G
Article 6(3), point (b)					
G 105b		***(b) information on available administrative or financial support from the Union; and***		***(b) information on dedicated Union support for strategic projects; and*** Text Origin: Auxiliary 1	G
Article 6(3), point (c)					
G 105c		***(c) a standard template for the project promoter's request available in all official languages of the Union.***		***(c) a standard template for the project promoter's request referred in paragraph 2 available in all official languages of the Union.*** Text Origin: Auxiliary 1	G
Article 6(3), first subparagraph a					
G 105d		***The Commission shall adopt implementing acts to provide for a standard template for the project promoter's request referred to in***		***(d) The Commission shall adopt implementing acts to provide for a standard template for the***	G

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		point (c) of the first subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20e(2).		***project promoter's request referred to in point (c) of the first subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20e(2).*** Text Origin: EP Mandate	
Article 6(3a)					
Y	105e	***3a. The designated authority shall assess the project promoter's request referred to in paragraph 1, second subparagraph, within three months of that submitted request.***			Y
Article 6(4)					
Y	106	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.	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.	~~*45*~~. Any other ***authority in the*** Member State ~~*authority*~~ that receives a request from a promoter concerning Articles ~~*8 to 14*~~***7, 8, 11, 12, 13 and 15*** shall ~~*assess*~~ ***rely on the decision of the designated authority pursuant to paragraph 1 as to*** whether that given project ~~*meets the criteria to be considered*~~ ***is recognised as*** a strategic project ~~*as provided for in Article 5 and where necessary, request the verification of its determination from the designated authority*~~.	Y
Article 6(5)					

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107	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.	5. Where the verification whether a project ~~is~~***constitutes*** a strategic project has been performed by ~~an~~***a designated*** authority in accordance with this Article, any other authority shall rely on that verification.	~~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.*~~	
Article 6(5a)				
107a		***5a. In order to promote a consistent and coordinated approach across the Union and to ensure legal certainty for project promoters, the Commission shall adopt guidelines setting out common criteria and procedural principles for the assessment and determination of projects as strategic projects for critical medicinal products and, where applicable, medicinal products of common interest. Designated authorities shall take into consideration those guidelines, as appropriate, when assessing and determining projects as strategic.***		
Article 6(5b)				
107b		***5b. The guidelines referred to in paragraph 5a shall, in particular, specify:*** ***(a) measurable criteria for the assessment of strategic relevance,***		

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		including the project's potential to address supply vulnerabilities, enhance manufacturing capacity or resilience, ensure security of supply, or contribute to Union-wide public health preparedness; ***(b) indicative timelines for operational readiness, transparency requirements, and steps for submission and assessment of requests;*** ***(c) available mechanisms for cooperation and exchange of information between the Commission and the designated authority to allow for consistent application of the guidelines.***		
Article 6(5c)				
107c		***5c. The Commission shall act as a coordinator for cross-border strategic projects and shall ensure effective cooperation between the designated authorities of the Member States concerned, to avoid duplication of efforts in bordering Member States and to promote complementarity and efficiency in the implementation of such projects.***		
Article 6(5d)				

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107d		***5d. Prior to the determination of a project as strategic, the designated authority shall notify the Critical Medicines Coordination Group of its intention to make such a determination. Within one month of receipt of such notification, the Critical Medicines Coordination Group shall assess whether the project would result in a significant duplication of existing or planned manufacturing capacities within the Union. Where the Critical Medicines Coordination Group does not complete the assessment within that period, the project shall be presumed not to result in significant duplication.*** ***Where the Critical Medicines Coordination Group considers that the project would result in a significant duplication of existing or planned manufacturing capacities within the Union, it shall inform the designated authority thereof. Such projects shall not be eligible to receive financial support from the Union pursuant to Article 16.***		
Section II				

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108	Section II Facilitating administrative and permit-granting processes	Section II Facilitating administrative and permit-granting processes	Section II Facilitating administrative and permit-granting processes ***for strategic projects***	
Article 7				
109	Article 7 Priority status of strategic projects	Article 7 Priority status of strategic projects	Article 7 Priority status of strategic projects	
Article 7, first paragraph				
110	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.	Strategic projects shall be considered as contributing to the security of supply of critical medicinal products***, or where applicable, medicinal products of common interest,*** in the Union and, therefore, to be in the public interest ***as serving the objectives of public health, safety and the protection of patients' interests***.	***1.*** Strategic projects shall be considered as contributing to the security of supply of critical medicinal products in the Union and, therefore, to be in the public interest.	
Article 7, second paragraph				
111	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.	The Member States' authorities shall ensure that the relevant permit granting processes ***and corresponding certification and inspection processes*** related to strategic projects are ~~*carried out in the fastest way possible*~~***fast tracked***, making available, in particular, any form of accelerated procedures that exists in applicable Union and national law***, while ensuring the quality and robustness of***	***2.*** The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects are carried out ~~*in the fastest way possible*~~***without undue delay*** , making available, in particular, any form of accelerated procedures that exists in applicable Union and national law.	

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		assessments and upholding the relevant environmental, health and work safety standards.		
Article 8				
112	Article 8 Administrative support	Article 8 Administrative ***and technical*** support	Article 8 Administrative support	
Article 8(1)				
113	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:	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:	1. Upon request of a project promoter, a Member State***'s authorities*** shall ***with regard to the relevant permit-granting processes related to strategic projects*** provide to a strategic project located on its territory ~~*all*~~ the administrative support ~~*necessary*~~ to facilitate its ~~*timely and effective*~~ implementation, including assistance ***in accordance with national law***:	
Article 8(1), point (a)				
G 114	(a) with regard to compliance with applicable administrative and reporting obligations;	(a) with regard to compliance with applicable administrative and reporting obligations;	(a) with regard to ***the project promoter's*** compliance with applicable administrative and reporting obligations;	(a) with regard to ***the project promoter's*** compliance with applicable administrative and reporting obligations; Text Origin: Auxiliary 1 G
Article 8(1), point (b)				

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115	(b) with regard to informing the public, with the aim of increasing public acceptance of the strategic project;	(b) with regard to informing the public, with the aim of increasing public acceptance of the strategic project ***and, where relevant, facilitating required consultations of local communities, organisations and social partners***;	~~*(b) with regard to informing the public, with the aim of increasing public acceptance of the strategic project;*~~	
Article 8(1), point (c)				
116	(c) along the permit-granting process.	(c) along the permit-granting process.	~~*(c)*~~***(b) to the project promoter*** along the permit-granting process.	(c) ***to the project promoter*** along the permit-granting process. Text Origin: Council Mandate
Article 8(2)				
117	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.	2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs)***, small mid-cap enterprises (SMCs), as well as to entities not engaged in an economic activity*** and, where appropriate, establish a dedicated channel for communication with ~~*SMEs*~~***them*** to provide guidance and respond to queries related to the implementation of this Regulation.	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*~~***necessary*** , ***may*** establish a dedicated channel for communication with SMEs to provide guidance and respond to queries related to the implementation of this Regulation.	2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs)***, small mid-cap enterprises (SMCs), as well as not for profit entities*** and, where ~~*appropriate*~~***necessary***, establish a dedicated channel for communication with ~~*SMEs*~~***them*** to provide guidance and respond to queries related to the

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								implementation of this Regulation. Text Origin: Auxiliary 1
Article 8(2a)								
Y	117a			***2a. Member States shall ensure that a strategic project located within its territory is provided with the administrative and technical support necessary to prevent or mitigate unplanned interruptions in the supply of energy, gas or heat required for the establishment or expansion of manufacturing capacity, including facilitating timely access to relevant network connections and capacity, and coordinating with the competent network operators to ensure the stability and continuity of supply.***				Y
Article 8(2b)								
Y	117b			***2b. Member States shall ensure that their authorities providing administrative support and authorities involved in the permit-granting process have a sufficient number of qualified staff and sufficient financial, technical and technological resources necessary for the effective performance of their tasks under this Regulation.***				Y

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Article 9						
Y	118	Article 9 Request for granting the status of highest national significance	Article 9 Request for granting the status of highest national significance	~~*Article 9*~~ ~~*Request for granting the status of highest national significance*~~		Y
Article 9(1)						
Y	119	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.	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.	~~*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.*~~		Y
Article 9(2)						
Y	120	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.	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.	~~*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.*~~		Y
Article 10						
Y	121	Article 10 Procedures relating to dispute resolution	Article 10 Procedures relating to dispute resolution	~~*Article 10*~~ ~~*Procedures relating to dispute resolution*~~		Y
Article 10, first paragraph						
Y	122	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	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	~~*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*~~		Y

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	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.	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.	~~*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.*~~	
Article 10, second paragraph				
Y	123 The project promoter shall participate in such urgency procedures, where applicable.	The project promoter shall participate in such urgency procedures, where applicable.	~~*The project promoter shall participate in such urgency procedures, where applicable.*~~	Y
Article 11				
Y	124 Article 11 Regulatory and scientific support from medicines agencies and pharmaceutical inspectorates	Article 11 Regulatory and scientific support from medicines agencies and pharmaceutical inspectorates	Article 11 Regulatory ~~*and scientific*~~ support from ~~*medicines agencies and pharmaceutical inspectorates*~~***competent authorities for medicinal products***	Y
Article 11(1)				
Y	125 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	1. Upon request of a project promoter, a Member State***, with support of the Agency as necessary and through a single point of contact,*** shall provide regulatory support to a strategic project located	1. Upon request of a project promoter, a Member State***'s competent authority for medicinal products*** shall provide regulatory support to a strategic project located on its territory, ~~*including by*~~	Y

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	inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project.	on its territory, including by prioritising Good Manufacturing ***and Good Distribution*** Practices inspections for approval of new ~~and~~***or*** extended manufacturing sites ~~and for~~***or modernisation of*** the manufacturing sites modernised in the context of the concerned strategic project.	~~prioritising~~***where relevant. Such support shall include administrative support for obtaining the necessary authorisations from the competent authority.*** ***A Member State's competent authority shall, when feasible, prioritise*** 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.	
Article 11(2)				
126	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.	2. Upon request of a project promoter, the European Medicines Agency ('the Agency') shall***, where appropriate, with the support of national competent authorities for medicinal products,*** provide dedicated advice to assist project promoters***, including those*** developing projects relying on innovative manufacturing processes.	2. Upon request of a project promoter, the European Medicines Agency ('the Agency') shall provide dedicated ***regulatory*** advice to assist project promoters developing projects relying on innovative manufacturing processes. ***Where this advice includes aspects related to Good Manufacturing Practices, which would be subject to review during inspections for manufacturing sites in a Member State, the Agency shall involve the relevant national competent***	Text Origin: Council Mandate

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						authority for medicinal products in the provision of this advice.			
Article 11(2a)									
G	126a					***2a. For the purposes of paragraphs 1 and 2, the competent authorities and the Agency shall act within the limits of the competences conferred upon them.***		*deleted*	G
Article 12									
G	*127*	Article 12 Environmental assessments and authorisation		Article 12 Environmental assessments and authorisation		Article 12 Environmental assessments and authorisation		Article 12 Environmental assessments and authorisation Text Origin: Commission Proposal	G
Article 12(1), first subparagraph									
Y	128	1. A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[1], Directive 2000/60/EC of the European Parliament and of the Council[2], Directive 2001/42/EC of the European Parliament and of the Council[3], Directive 2008/98/EC of the European Parliament and of the Council[4], Directive 2009/147/EC of the European Parliament and of the		1. A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[1], Directive 2000/60/EC of the European Parliament and of the Council[2], Directive 2001/42/EC of the European Parliament and of the Council[3], Directive 2008/98/EC of the European Parliament and of the Council[4], Directive 2009/147/EC of the European Parliament and of the		1. A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[1], Directive 2000/60/EC of the European Parliament and of the Council[2], Directive 2001/42/EC of the European Parliament and of the Council[3], Directive 2008/98/EC of the European Parliament and of the Council[4], Directive 2009/147/EC of the European Parliament and of the			Y

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	Council[5], Directive 2010/75/EU of the European Parliament and of the Council[6], Directive 2011/92/EU of the European Parliament and of the Council[7] or Directive 2012/18/EU of the European Parliament and of the Council[8], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied. _____ 1. Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj). 2. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj). 3. Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj). 4. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj). 5. Directive 2009/147/EC of the European Parliament and of the Council of 30	Council[5], Directive 2010/75/EU of the European Parliament and of the Council[6], Directive 2011/92/EU of the European Parliament and of the Council[7] or Directive 2012/18/EU of the European Parliament and of the Council[8], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts ~~are~~***is*** applied. ***The application of the joint or coordinated procedure shall not affect the content or quality of the environmental impact assessment.*** _____ 1. Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj). 2. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj). 3. Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj). 4. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p.	Council[5], Directive 2010/75/EU of the European Parliament and of the Council[6], Directive 2011/92/EU of the European Parliament and of the Council[7] or Directive 2012/18/EU of the European Parliament and of the Council[8], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied. _____ 1. Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj). 2. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj). 3. Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj). 4. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj). 5. Directive 2009/147/EC of the European Parliament and of the Council of 30	

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		November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj). 6. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj). 7. Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj). 8. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2012/18/oj).		3, ELI: http://data.europa.eu/eli/dir/2008/98/oj). 5. Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj). 6. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj). 7. Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj). 8. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2012/18/oj).		November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj). 6. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj). 7. Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj). 8. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2012/18/oj).		
Article 12(1), second subparagraph								
G	129	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 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 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 coordinated procedure referred to in the first subparagraph, a competent authority shall coordinate the various individual assessments of the environmental impact of a	G

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					particular project required by the relevant Directive. Text Origin: Commission Proposal	
Article 12(1), third subparagraph						
G	130	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.	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.	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.	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. Text Origin: Commission Proposal	G
Article 12(2)						
Y	131	2. Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information.	2. Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information ***pursuant to Articles 5, 6 and 7 of that Directive and after completing the consultations referred to in Articles 6 and 7 of that Directive, with a possibility of extension by a***	2. Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within ~~***45***~~***90*** days of receiving all necessary information.		Y

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				maximum of 45 days in duly justified cases.					
Article 12(3)									
Y	132	3. In exceptional cases, where the nature, complexity, location or size of the proposed project so requires, Member States may extend the time limit referred to in paragraph 2 once by a maximum of 15 days, before its expiry and on a case-by-case basis. In that event, the competent authority shall inform the project promoter in writing of the reasons justifying the extension and of the deadline for its reasoned conclusion.		3. In exceptional cases, where the nature, complexity, location or size of the proposed project so requires, Member States may extend the time limit referred to in paragraph 2 once by a maximum of 15 days, before its expiry and on a case-by-case basis. In that event, the competent authority shall inform the project promoter in writing of the reasons justifying the extension and of the deadline for its reasoned conclusion.		3. In exceptional cases, where the nature, complexity, location or size of the proposed project so requires, Member States may extend the time limit referred to in paragraph 2 once by a maximum of ~~*15*~~***20*** 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.		Y
Article 12(4)									
G	133	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.		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.		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.		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	G

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				referred to in Article 6(7) of that Directive. Text Origin: Commission Proposal
Article 12(5)				
G 134	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.	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.	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.	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. Text Origin: Commission Proposal G
Article 12(5a)				

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Y	134a		***5a. Member States shall ensure that their competent authorities and other authorities designated pursuant to Article 6(1) of Directive 2011/92/EU have a sufficient number of qualified staff and sufficient financial, technical and technological resources necessary to fulfil their obligations under this Article.***			Y
	Article 13					
G	135	Article 13 Planning	Article 13 Planning	Article 13 Planning	Article 13 Planning Text Origin: Commission Proposal	G
	Article 13(1)					
Y	136	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.	1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant ***planning authorities have the resources needed to decide upon, in a timely manner, any***	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.		Y

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		planning application and that all relevant spatial planning data ~~*is*~~***are*** available ***and accessible, including online***.		
Article 13(2)				
137	2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[1], the combined assessment shall also cover those impacts. _____ 1. 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	2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[1], the combined assessment shall also cover those impacts. ***The fact that assessments are combined pursuant to this paragraph shall not affect their***	2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council[1], the combined assessment shall also cover those impacts. _____ 1. 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	

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	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).	***content, or quality or robustness of the assessment.*** _____ 1. 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).	2014 establishing a framework for maritime spatial planning (OJ L 257, 28.8.2014, p. 135, ELI: http://data.europa.eu/eli/dir/2014/89/oj).	
Article 13(2a)				
137a		***2a. Where the development of Strategic Projects or their related infrastructure has potential cross-border implications, the Member States concerned shall coordinate their planning and assessment procedures, with the support of the Commission, in order to avoid duplication of efforts, ensure complementarity, and reflect the principles of solidarity and cooperation between Member States.***		
Article 14				
138	Article 14 Applicability of UNECE Conventions	Article 14 Applicability of UNECE Conventions	~~*Article 14*~~ ~~*Applicability of UNECE Conventions*~~	
Article 14(1)				
139	1. This Regulation is without prejudice to the obligations under	1. This Regulation is without prejudice to the obligations under	~~*1.*~~ ~~*This Regulation is without prejudice to the obligations under*~~	

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	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.	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.	~~*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.*~~	
Article 14(2)				
Y	140	2. All decisions adopted pursuant to the Articles in this section shall be made publicly available.	2. All decisions adopted pursuant to the Articles in this section shall be made publicly available ***in an easily understandable manner, including online, and all decisions concerning one project shall be available on the same website***.	~~*2. All decisions adopted pursuant to the Articles in this section shall be made publicly available.*~~	Y
Section III				
G	141	Section III Financial incentives	Section III Financial incentives	Section III Financial incentives	Section III Financial incentives Text Origin: Commission Proposal	G
Article 15				

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142	Article 15 Financial support by Member States	Article 15 Financial support by Member States	Article 15 Financial support by Member States	Article 15 Financial support by Member States Text Origin: Commission Proposal
Article 15(1)				
143	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).	1. Without prejudice to Articles 107 and 108 TFEU, Member States ~~may~~ ***shall*** prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products***, and, where applicable, medicinal products of common interest,*** identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines Group referred to in Article 26(2) point (a). ***Financial support shall be proportionate to the financing needs of the strategic project and shall be subject to transparency requirements.***	1. Without prejudice to ***Union state aid rules as set out in*** Articles 107 and 108 ***Treaty of the Functioning of the European Union (TFEU)*** ~~TFEU~~, Member States may prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines ***Coordination*** Group ***('CMCG')*** referred to in Article 26(2) point (a).	
Article 15(1a)				
143a		***1a. Member States may, at the request of the Critical Medicines Group, establish contractual arrangements with economic operators on strategic projects to***		

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		dedicate a portion of their manufacturing capacity to produce specific medicinal products, their pharmaceutical forms, their active substances and key inputs or technologies, or categories thereof, in order to address current, emerging or potential shortages within a fixed timeframe, determined by the Critical Medicines Group.		
Article 15(1a)				
G 143b		***1b. The Commission shall facilitate the consistent application of this Article by providing sufficient guidance to Member States on the possibilities offered under existing State aid rules for the granting of State aid to strategic projects that meet the criteria of Article 5. This guidance shall in particular facilitate the financing of strategic projects that are aimed to improve the security of supply of medicinal products in the Union, both in terms of manufacturing capacity and in terms of innovative manufacturing processes.***		***1b. The Commission shall facilitate the consistent application of this Article by providing sufficient guidance to Member States on the possibilities offered under existing State aid rules for the granting of State aid to strategic projects that meet the criteria of Article 5.*** Text Origin: EP Mandate G
Article 15(2)				

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Y	144	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.	2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, ~~*an undertaking*~~***a project promoter*** that has benefitted from financial support ***by a Member State*** for a strategic project shall prioritise ***appropriate and continued*** supply to the Union market ***so that the needs of patients in the Member State in question are covered*** and ~~*use its very best efforts to*~~ ensure that the critical medicinal product remains available in the Member States where it is being marketed. ***This paragraph applies mutatis mutandis to medicinal products of common interest.***	2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from financial support for a strategic project shall prioritise supply to the Union market and use its very best efforts to ensure that the critical medicinal product remains available in ***all*** the Member States where it is being marketed. ***Where appropriate, the terms of the financial support shall stipulate for how long the obligation shall continue to apply in case the critical medicinal product is removed from the Union List of Critical Medicinal Products.***		Y
Article 15(2a)					
Y	144a		***2a. The Member State providing financial support to a strategic project shall require the beneficiary economic operator to adopt measures that contribute to the availability and affordability of the critical medicinal product and medicinal product of common interest in the Union market, following guidelines referred to in Article 26(2)(ca).***		Y
Article 15(3), first subparagraph					

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145	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.	3. The Member State that provided financial support to a strategic project may request such ~~*undertaking to*~~***project promoter to prioritise and*** provide the necessary supplies of a critical medicinal product***, or, where applicable, medicinal product of common interest***, active substance or key inputs, as applicable, to the Union market ***as a priority*** to avoid shortages in one or several Member States.	3. The Member State that provided financial support to a strategic project may ~~*request*~~***require*** such undertaking to ***prioritise supply and*** provide the necessary supplies of a critical medicinal product, active substance or key inputs, as applicable, to the Union market to avoid shortages in one or ~~*several*~~***more*** Member States.	
Article 15(3), second subparagraph				
146	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.	Any Member State that encounters a threat of shortages of the critical medicinal product ***or medicinal product of common interest*** in question may demand the Member State that provided financial support to submit a request on its behalf. ***The project promoter shall undertake its very best efforts to supply such products in the requesting Member State.***	Any Member State that encounters a threat of shortages of the critical medicinal product in question may ~~*demand*~~***request*** the Member State that provided financial support to submit a request on its behalf.	
Article 15(3a)				
146a		***3a. Where a project promoter that receives financial support fails to comply with the obligations in paragraphs 2 and 3, the financial support granted to the strategic***		

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		project may be suspended, revoked or recovered, in whole or in part, by the Member State concerned. In addition, the project promoter may be subject to an effective, proportionate and dissuasive financial penalty in accordance with national law of the Member State concerned or an exclusion from funding proportionate to the impact and severity of non-compliance.		
Article 15(3b)				
146b		***3b. Where there is a substantiated risk that export of a critical medicinal product or, where applicable, medicinal product of common interest, would undermine supply within the Union, and upon request by at least one Member State, the Commission may require the project promoter benefiting from financial support to obtain an export authorisation before transferring such products outside the Union. This measure shall be proportionate, time-limited and targeted to safeguard public health within the Union.***		
Article 15(3c)				

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146c		***3c. Where financial support has been granted, the project promoter shall demonstrate that the funds have been used within the territory of the Union.***		
Article 16				
147	Article 16 Financial support from the Union	Article 16 Financial support from the Union	Article 16 Financial support from the Union	Article 16 Financial support from the Union Text Origin: Commission Proposal
Article 16(1)				
148	1. For the duration of the Multiannual Financial Framework 2021-2027[1] strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme[2], Horizon Europe[3], and the Digital Europe Programme[4] provided that such support is in line with the objectives set out in the regulations establishing those programmes. 1. 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)	1. ~~*For the duration of the*~~***All the Union funding under the current and future*** Multiannual Financial ~~*Framework 2021-2027*~~[1] ***Frameworks, including regional policy funding programmes, may support*** strategic projects ~~*may be supported by Union funding, including but not limited to such Union*~~***unless explicitly excluded by the legal basis or the scope of relevant*** programmes ~~*as the EU4Health Programme[2], Horizon Europe[3], and the Digital Europe Programme[4]*~~***and*** provided that such support is in line with the objectives set out in the regulations establishing those programmes.	1. ***Financial support for strategic projects under*** ~~*For the duration of*~~ the Multiannual Financial Framework 2021-2027[1] ~~*strategic projects*~~ may be ~~*supported by*~~***provided by the*** Union ~~*funding.*~~***from Union programmes*** including but not limited to ~~*such Union programmes as,*~~ the EU4Health Programme[2]~~,~~ ***established by Regulation (EU) 2021/522,*** Horizon Europe[3] ***established by Regulation (EU) 2021/695***, and the Digital Europe Programme[4] ***established by Regulation (EU) 2021/694,*** provided that such support is in line with the objectives set out in the	

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	2. 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) 3. 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) 4. 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)	~~1. 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)~~ ~~2. 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)~~ ~~3. 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)~~ ~~4. 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)~~	***respective*** regulations establishing those programmes. ***The amount of Union financial contribution provided under this Article shall be established in accordance with the rules of the respective Union programmes as part of the annual budgetary procedure, subject to the availability of funding.*** 1. 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) ~~2. 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)~~ ~~3. 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)~~	

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						~~4. 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)~~			
Article 16(1), second subparagraph									
R	148a			***Subject to a Council regulation laying down the multiannual financial framework for the years 2028 to 2034 (MFF 2028–2034), strategic projects may be supported by Union funding, including any relevant Union instrument financed within the limits of the ceilings established in the MFF 2028–2034, provided that such support is in line with the objectives set out in the regulations establishing any such relevant instrument. A critical medicines security fund shall be established within the framework of MFF 2028–2034, in coordination with other relevant Union instruments, to support the achievement of the objectives of this Regulation.***					R
Article 16(1), third subparagraph									
R	148b			***If a project promoter has received financial support for a strategic***					R

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		project from Union funding, it shall prioritise supply to the Union market and shall ensure that the critical medicinal product or, where applicable, medicinal product of common interest, remains available in the Member States where it is being marketed.		
Article 16(2)				
149	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.	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.	2. At the request of a project promoter, justified by ***the*** necessity to provide results of vulnerability evaluation for the purpose of an application for Union funding, the designated authority shall ~~*assess*~~***verify*** 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*~~ ***the verification to the*** project promoter within 15 working days of ~~*its*~~***receiving the*** request. The designated authority shall inform the Commission about the strategic projects identified as addressing an existing vulnerability in the supply chains without delay.	

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						Where the designated authority considers that the submitted particulars accompanying the request referred to in the first subparagraph is incomplete, it shall inform the project promoter accordingly and shall set a timeline for submitting the missing information and documentation. In case the designated authority sets such a timeline, the timeline referred to in the first subparagraph shall be suspended until such time as the supplementary information and documentation required has been provided for.		
	Article 16(2a)							
G	149a			***2a. A project promoter receiving Union financial support under this Article shall comply with any obligations linked to such support including any reporting obligations pursuant to Article 57 of Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final]. Where a project promoter fails to comply with those***				Deletion of EP amendment	G

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				obligations, the Commission may suspend, revoke or recover the funding, in whole or in part, in accordance with the applicable rules. In addition, the Commission may impose a financial penalty or exclusion from future funding that is proportionate to the impact of the non-compliance, time-limited, and targeted to safeguard public health within the Union.				
	Article 16(2b)							
Y	149b			***2b. Where there is a substantiated risk that export of a critical medicinal product would undermine supply within the Union, and upon request by at least one Member State, the Commission may require the project promoter benefiting from financial support to obtain an export authorisation before transferring such products outside the Union. This measure shall be proportionate, time-limited, and targeted to safeguard public health within the Union.***				Y
	Article 16(2c)							
Y	149c			***2c. The Commission shall establish a 'one-stop-shop' to coordinate the award of Union funds pursuant to this Article and***				Y

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		to support Member States' authorities with the prioritisation of financial support to strategic projects pursuant to Article 15.		
Article 16(2d)				
149d		***2d. Where financial support has been granted, the project promoter shall demonstrate that the funds have been used within the territory of the Union.***		
Article 17				
150	Article 17 Exchange of information on funded projects	Article 17 Exchange of information on funded projects	Article 17 Exchange of information on ~~*funded projects*~~***financial support***	
Article 17(1)				
151	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.	1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article ~~24~~***25*** of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article ~~25~~***26***. ***This information shall include a description of how the project meets one or more of the criteria listed in Article 5.***	1. Member States shall ~~*inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article 24 of the intention*~~***, without prejudice to their right to decide whether*** to provide financial support to strategic projects***, inform the CMCG, referred to in Article 25, of the intention to provide such financial support*** sufficiently in advance to ~~*allow the group*~~***enable the CMCG*** to carry out its coordination task as set out in Article ~~25~~***26***.	

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Article 17(2), first subparagraph				
152	2. The Commission shall inform periodically the Critical Medicines Group of the strategic projects that benefited from financial support from the Union.	2. The Commission shall ***regularly*** inform ~~*periodically*~~ the Critical Medicines Group of the strategic projects that benefited from financial support from the Union ***including information on how these projects meet the criteria listed in Article 5***.	2. The Commission ***and Member States*** shall ***regularly*** inform ~~*periodically the Critical Medicines Group*~~***the CMCG*** of the strategic projects ~~*that benefited from*~~***receiving*** financial support from the Union ***and Member States respectively to enable the CMCG to carry out its coordination task***.	
Article 17(2), second subparagraph				
153	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.	The Commission ~~*may*~~***shall*** inform the Critical Medicines Group of ~~*the*~~***its*** intention to propose the establishment of funding possibilities ~~*specifically designed to address vulnerabilities in the supply chains as well as*~~***to support strategic projects. It shall also*** inform ***the Critical Medicines Group*** of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes.	***3.*** The Commission ~~*may*~~***shall*** inform the ~~*Critical Medicines Group of the intention to propose*~~***CMCG of planned proposals for*** the establishment of funding possibilities specifically designed to address vulnerabilities in the supply chains as well as inform of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes.	
Chapter IV				
154	Chapter IV Demand side measures	Chapter IV Demand side measures	Chapter IV Demand side measures	
Section I				

Public Register

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
155	Section I Award criteria and other procurement requirements and related measures	Section I Award criteria and other procurement requirements and related measures	Section I ~~*Award criteria and other*~~***Requirements for public*** procurement ~~*requirements*~~***procedures*** and related measures	
Article 18				
156	Article 18 Incentivising resilience, sustainability and positive social impacts in public procurement procedures	Article 18 Incentivising resilience, sustainability and positive social impacts in public procurement procedures	Article 18 Incentivising resilience~~,~~ ~~*sustainability and positive social impacts*~~ in public procurement procedures	
Article 18(1)				
157	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	1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall ***implement multi-winner procurements, wherever feasible, the scope of which is designed based on clinical needs and the size of the patient population in consultation with healthcare professionals, with predictable procurement timelines and predictable mix and weighting of qualitative criteria, and shall*** apply procurement requirements other than price-only award criteria ~~*such as procurement*~~***. Those***	1. For ***public procurement*** ~~*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~~ ***for these critical medicinal products.*** ***These resilience*** requirements shall ~~*be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers,*~~	

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	authority and contract performance clauses on timely delivery.	requirements ***shall include award criteria*** that promote the resilience of supply in the Union***, support the diversification of supply sources, and take into account the distance between manufacturing sites and points of delivery within the Union. Such criteria shall form the main basis for award decisions and shall, in any case, be given greater weight than price in the evaluation of tenders***. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may ~~*relate to stockholding obligations*~~***also include innovation, supply chain robustness***, the number of diversified suppliers, ***obligations on the*** monitoring of supply chains, ~~*their*~~ transparency ~~*to*~~***of supply chains upon request of*** the contracting authority and contract performance clauses on timely delivery.	~~*monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery.*~~***take the form of at least one of the following:***	
Article 18(-1), first subparagraph, point (a)				
157a			***(a) selection criteria within the meaning of Article 58 of Directive 2014/24/EU; or***	
Article 18(-1), first subparagraph, point (b)				

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157b			***(b) technical specifications within the meaning of Article 42 of Directive 2014/24/EU; or***	
Article 18(-1), first subparagraph, point (c)				
157c			***(ba) best price-quality ratio as contract award criteria within the meaning of Article 67 of Directive 2014/24/EU; or***	
Article 18(-1), first subparagraph, point (d)				
157d			***(c) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU.***	
Article 18(-1), second subparagraph				
157e			***The resilience requirements may, inter alia, relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, transparency of the supply chains and contract performance clauses on timely delivery.***	
Article 18(1a)				
157f		***1a. In contracts which provide for the possibility of unilateral prolongation by the contracting authority, suppliers shall have, where duly justified, a mechanism allowing for price adjustments.***		
Article 18(2)				

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158	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.	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***, while taking into account the distinctive characteristics of the supply chains of different medicinal products. Those*** ~~*. These*~~ requirements shall be applied in compliance with the Union's international commitments.	2. ~~*With regard to*~~ ***For public procurement procedures of*** critical medicinal products for which a vulnerability in the supply chains has been ~~*confirmed*~~ ***identified*** through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of ~~*third*~~ countries ***outside the Union***, the contracting authorities shall~~*, where justified, apply procurement requirements that*~~ favour ~~*suppliers that manufacture a significant proportion of these*~~ critical medicinal products ***or their active substances manufactured*** in the Union~~*. These requirements shall be applied in compliance with the Union's international commitments*~~ ***that address the vulnerability and dependency identified***.	
Article 18(2), second subparagraph				
158a		***For the purposes of this paragraph, a 'significant proportion' of the manufacture of a critical medicinal product shall be considered to take place within the Union if at least one of the following conditions is met:***		
Article 18(1b), second subparagraph, point (a)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
158b		***(a) at least 50% of the active substance used in the manufacture of the product is produced within the Union or, where appropriate, the EFTA countries;***		
Article 18(1b), second subparagraph, point (b)				
158c		***(b) at least 50 % of the value of the final medicinal product results from manufacturing or processing operations carried out within the Union or, where appropriate, the EFTA countries;***		
Article 18(1b), second subparagraph, point (c)				
158d		***(c) essential manufacturing steps, including the synthesis or biological production of active substances, are carried out within the Union or, where appropriate, the EFTA countries.***		
Article 18(-1a), second subparagraph				
158e			***Contracting authorities shall favour the critical medicinal products or their active substances referred to in the first subparagraph by applying requirements that take the form of at least one of the following:***	
Article 18(-1a), second subparagraph, point (a)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
158f			***(-a) technical specifications or requirements within the meaning of Article 42 of Directive 2014/24/EU; or***	
Article 18(-1a), second subparagraph, point (b)				
158g			***(a) best price-quality ratio as contract award criteria within the meaning of Article 67 of Directive 2014/24/EU which may be assessed on the basis of criteria also relating to delivery condition for the critical medicinal products or their active substances; or***	
Article 18(-1a), second subparagraph, point (c)				
158h			***(b) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU.***	
Article 18(-1a), third subparagraph				
158i			***These requirements shall be applied subject to the Union's international commitments.***	
Article 18(3)				
159	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	3. With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities ~~*may*~~***shall*** apply procurement requirements that	3. ~~*With regard to other medicinal*~~***The requirements set out in paragraphs 1 and 2 shall apply irrespective of whether*** products ~~*of common interest, where justified by market analysis and public health considerations,*~~ ***are supplied or***	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	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.	favour suppliers that manufacture at least a significant proportion of these medicinal products in the Union ***and shall take into account the distinctive characteristics of the supply chains of different medicinal products***. These requirements shall be applied in compliance with the Union's international commitments.	***provided by*** the ***successful tenderer or by a subcontractor. These requirements do not preclude*** 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.*~~ ***from using multi-winner approaches.***	
Article 18(1c), second subparagraph				
159a		***For the purposes of this paragraph, a 'significant proportion' of the manufacture of a medicinal product of common interest shall be considered to take place within the Union if at least one of the following conditions is met:***		
Article 18(1c), second subparagraph, point (a)				
159b		***(a) at least 50 % of the active substance used in the manufacture of the product is produced within the Union or, where appropriate, the EFTA countries; or, in the case of medicinal products of common interest for which no relevant substitute is produced within the Union, any third country with***		

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		which the Union has established a strategic partnership within the meaning of Article 27 of this Regulation;		
Article 18(1c), second subparagraph, point (b)				
159c		***(b) at least 50 % of the value of the final medicinal product results from manufacturing or processing operations carried out within the Union or, where appropriate, the EFTA countries; or, in the case of medicinal products of common interest for which no relevant substitute is produced within the Union, any third country with which the Union has established a strategic partnership within the meaning of Article 27 of this Regulation;***		
Article 18(1c), second subparagraph, point (c)				
159d		***(c) essential manufacturing steps, including the synthesis or biological production of active substances, are carried out within the Union or, where appropriate, the EFTA countries; or, in the case of medicinal products of common interest for which no relevant substitute is produced within the Union, any third country with which the Union has established a***		

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		strategic partnership within the meaning of Article 27 of this Regulation.		
Article 18(3a)				
159e			***3b. This Article shall not preclude Member States from specifying the requirements set out in paragraphs 1 and 2 and laying down additional requirements in accordance with Directive 2014/24/EU in national laws, regulations, administrative provisions or in their national programmes referred to in Article 19 of this Regulation.***	
Article 18(3a)				
159f				
Article 18(4)				
160	4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights.	4. ***Procurement procedures under this Chapter*** ~~*This Article*~~ shall ~~*not preclude contracting authorities from using*~~***, include*** additional qualitative ~~*requirements*~~***criteria***, ~~*including in relation*~~ ***in particular criteria relating*** to environmental sustainability and ***the promotion of*** social rights.	4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social ~~*rights*~~***considerations***.	
Article 18(5)				

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161	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.	5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2, ***3 and 4*** ~~*and 3*~~ where ***such a decision is duly*** justified ~~*by*~~***on the basis of a documented*** market analysis***, or where the application of those paragraphs would result in a disproportionately high price in a specific procurement procedure*** ~~*or considerations related to the financing of health services*~~. ***Such derogation shall be accompanied by a written justification specifying the relevant reasons and circumstances, and shall be subject to ex post verification by the competent supervisory authority designated by the Member State.***	5. Contracting authorities may exceptionally decide not to apply paragraphs 1, ~~*2 and 3*~~ ***and 2*** where ~~*justified by market analysis or considerations related to the financing of health services.*~~***:***	
Article 18(5), point (a)				
161a			***(a) the required critical medicinal product can only be supplied by a specific economic operator as defined in Article 2(1) point (10) of Directive 2014/24/EU and no reasonable alternative or substitute exists and the absence of competition is not the result of an artificial narrowing down of the parameters of the public procurement procedure; or***	

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Article 18(5), point (b)				
161b			***(b) no suitable tenders or no suitable requests to participate have been submitted in response to a similar public procurement procedure launched by the same contracting authority in the two years prior to the commencement of the planned new procurement procedure; or***	
Article 18(5), point (c)				
161c			***(c) their application would oblige that contracting authority to acquire critical medicinal products having disproportionate costs; or***	
Article 18(5), point (d)				
161d			***(d) it is strictly necessary due to reasons of extreme urgency brought about by events unforeseeable by the contracting authority and the circumstances invoked to justify extreme urgency are not attributable to the contracting authority.***	
Article 18(5a)				
161e		***5a. To support the implementation of this Article by Member States, the Commission shall develop guidelines for the***		

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		application of non-price award criteria by ... [18 months from the date of entry into force of this Regulation].		
Article 18(5a)				
161f			***6. By [6 months after the date of entry into force of this Regulation], the Commission shall issue guidelines designed to support Member States in implementing the obligations of this Article and to facilitate the application of these obligations by contracting authorities. The guidelines shall inter alia include guidance on determining whether critical medicinal products or their active substances are manufactured in the Union and address an identified vulnerability and dependency for the purposes of the requirements set out in paragraph 2.*** ***The guidelines shall respect the responsibilities of the Member States for the management of health services and medical care and the allocation of the resources assigned to them.***	
Article 19				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
162	Article 19 Programmes supporting sustainability and resilience in public procurement procedures	Article 19 Programmes supporting sustainability and resilience in public procurement procedures	Article 19 ***National*** programmes supporting ~~*sustainability and*~~ resilience in public procurement procedures	
Article 19(1)				
163	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.	1. By 6 months after entry into force of this Regulation each Member State shall establish***, after having consulted patient and consumer organisations and healthcare professional organisations,*** a national programme supporting security of supply of critical medicinal products, including in public procurement procedures***. National programmes shall include measures to promote the use of procurement award criteria relating to supply chain resilience and diversification of supply sources in accordance with Article 18***. Such programmes shall promote the consistent use of procurement requirements by contracting authorities within a given Member State as well as multi-winner approaches, where beneficial in light of the market analysis ***and shall align reporting and shortage signals with mechanisms operated***	1. By ~~*6*~~***12*** months after entry into force of this Regulation each Member State shall***, with due respect to the organisation of the procurement of medicinal products within the Member State,*** establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of ~~*procurement*~~ requirements ***in public procurement procedures*** by contracting authorities within a given Member State ~~*as well as*~~***. Such programmes may also promote the consistent use of*** multi-winner approaches, where beneficial in light of the market analysis~~*. Such programmes may also*~~***, and may*** include measures ~~*for pricing and reimbursement*~~ supporting security of supply of ~~*those*~~ critical medicinal products that are not purchased	

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		by MSSG to avoid duplication. Such programmes ~~*may also*~~***shall also, where appropriate,*** include measures for pricing and reimbursement supporting security of supply of those critical medicinal products that are not purchased through public procurement procedures ***as well as review any price freezes, cost containment measures or stockholding obligations applicable. Member States may involve their national pricing and reimbursement authorities in the planning and evaluation of such programmes.***	through public procurement procedures.	
Article 19(2)				
164	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	2. Member States shall notify their programmes to the Commission in its role of the secretariat of the Critical Medicines Group. The Commission shall ensure the distribution to all members of the Critical Medicines Group forthwith. The Critical Medicines Group shall facilitate a discussion***, involving representatives of marketing authorisation holders, patient and consumer organisations and healthcare professional***	2. Member States shall ~~*notify their programmes to*~~ ***inform*** the Commission in its role of the secretariat of the ~~*Critical Medicines Group*~~ ***CMCG about their programmes***. The Commission shall ensure the distribution to all members of the ~~*Critical Medicines Group*~~ ***CMCG*** forthwith. The ~~*Critical Medicines Group*~~ ***CMCG*** shall facilitate a discussion ***as referred to in Article 26(2), point (b) on the national programmes*** aiming to ensure coordination of	

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	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.	***organisations, and other relevant actors in the supply chain,*** aiming to ensure coordination of national programmes including as regards the application of criteria mentioned in Article 18(2) and may issue opinions. Where the Critical Medicines Group issues an opinion concerning the national programmes, Member States shall give it due consideration and may take it into account when revising their programmes.	national programmes including as regards the application of ~~*criteria mentioned*~~***the requirements set out*** 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				
165	Article 20 Safeguards related to Member States' contingency stocks requirements and other security of supply measures	Article 20 Safeguards related to Member States' contingency stocks requirements and other security of supply measures	Article 20 Safeguards related to Member States' contingency stocks requirements~~*and other security of supply measures*~~	
Article 20, first paragraph				
166	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.	Measures ~~*on*~~***relating to*** security of supply applied in one ***or more*** Member ~~*State*~~***States*** shall not result in any negative impact ***on the availability of critical medicinal products and medicinal products of common interest*** in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of	***1.*** ~~*Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of*~~***When imposing*** requirements ~~*for companies*~~***on marketing authorisation holders and other***	

PROOF

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		requirements for ~~companies~~***economic operators*** to hold contingency stocks.	***economic operators in the supply chain to healthcare providers and patients*** to hold contingency stocks ***for the purpose of safeguarding the security of supply of critical medicinal products within their territory, or making changes to existing requirements, Member States shall aim at avoiding that any form of such requirements negatively impacts the security of supply in other Member States in compliance with the internal market provisions of the TFEU***.	
Article 20, second paragraph				
167	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.	Member States shall ensure that any ***national measures or*** requirements they impose on ~~companies~~***economic operators*** in the supply chain to hold contingency stocks are proportionate***, targeted, evidence-based*** and respect the principles of transparency ~~and~~***,*** solidarity ***and non-discrimination***.	***2.*** Member States shall ensure that any ***contingency stock*** requirements ~~*they impose on companies in the supply chain to hold contingency stocks*~~***referred to in paragraph 1 , including the extent and implementation timeline,*** are proportionate and respect the principles of transparency and solidarity.	
Article 20, second paragraph a				
167a		***Where Member Stats impose contingency stock requirements on economic operators, they shall notify the Commission and the Agency. Member States shall also***		

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		encourage the implementation of rolling stockpiling systems amongst manufactures.		
Article 20, second paragraph a				
167b			***3a. Member States shall, without prejudice to their right to decide to impose contingency stocks requirements, inform the CMCG of their intention to impose such requirements or make significant changes to existing requirements, for the purpose of transparency and to enable exchanges on the guiding principles of proportionality and solidarity referred to in paragraph 2.*** ***The Commission shall, based on data available to the Commission, regularly inform the CMCG of contingency stocks requirements imposed by Member States, for the purpose of transparency.***	
Article 20, second paragraph b				
167c		***All contingency stock requirements and other security of supply measures shall be implemented in a manner that minimises waste and environmental impact, including through effective stock rotation***		

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		based on the 'first expired, first out' system to prevent the destruction of medicinal products.		
Article 20, second paragraph b				
167d			***4. This Article is without prejudice to obligations under Union law for the notification of technical regulations and technical barriers to the internal market, including those set out in Directive (EU) 2015/1535.***	
Article 20, second paragraph c				
167e		***The Commission shall, following a consultation with relevant stakeholders, including patient and consumer organisations, healthcare professional organisations, public healthcare payers, and marketing authorisation holders, issue Union guidelines recommending the establishment of common standards for contingency stocks and national stockpiles to support Member State activities, ensuring predictability for economic operators. Those common standards may include:***		
Article 20, second paragraph c, point (a)				

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167f		***(a) the establishment of maximum quantitative thresholds for contingency stocks at both national and aggregated Union level, to be determined in cooperation with economic operators and reviewed periodically in light of evolving risk assessments;***		
Article 20, second paragraph c, point (b)				
167g		***(b) provisions allowing for the holding of contingency stocks in the form of white-label semi-finished or bulk products, where appropriate to ensure flexibility and timely deployment;***		
Article 20, second paragraph c, point (c)				
167h		***(c) the use of harmonised packaging formats, including multi-language or Union-wide packs, with a view to facilitating cross-border supply and reducing relabelling burdens;***		
Article 20, second paragraph c, point (d)				
167i		***(d) practices on sustainable stockpiling, including practices to reduce emissions, improve packing, including leaflet, manager expiry dates, and ensure responsible***		

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		disposal of unused or obsolete medicinal products.		
Article 20, second paragraph d				
167j		***During health emergencies and crises, Member States authorities and Union preparedness authorities shall closely coordinate the distribution of critical medicinal products, in particular with systemic wholesalers, in order to ensure equitable and fair distribution. Member States may also undertake the distribution of critical medicinal products via their civil preparedness authorities or military authorities if deemed necessary in accordance with national law.***		
Section Ia				
167k		***Section Ia UNION COORDINATION MECHANISM FOR CRITICAL MEDICINAL PRODUCTS***		
Article 20a				
167l		***Article 20a Establishment of a Union coordination mechanism for critical medicinal products***		
Article 20a(1)				

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167m		***A Union coordination mechanism for national stockpiles and contingency stocks of critical medicinal products is hereby established. It shall be operated by the Commission in collaboration with the Agency and the Critical Medicines Coordination Group. Through that coordination mechanism, the Commission shall:***		
Article 20a(1), point (a)				
167n		***(a) monitor the availability and distribution of critical medicinal products across the Union;***		
Article 20a(1), point (b)				
167o		***(b) enable effective and equitable redistribution in cases of a shortage or a supply disruption in one or more Member States that has a negative impact on the internal market or on other Member States.***		
Article 20b				
167p		***Article 20b Redistribution decisions***		
Article 20b(1)				
167q		***1. Where a shortage or a supply disruption of a critical medicinal product is identified in***		

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		one or more Member States, the Commission shall, as a last resort and only after all other measures have been exhausted, including the voluntary mechanisms provided for in Union legislation, and upon a justified and substantiated request of one or more Member States concerned and subject to the prior approval of the Critical Medicines Group, adopt a binding decision requiring redistribution from a national stockpile or a contingency stock.		
Article 20b(2)				
167r		***2. Any distribution decision as referred to in the first paragraph shall:***		
Article 20b(2), point (a)				
167s		***(a) be based on an objective risk assessment and regularly updated data establishing both the shortage or supply disruption resulting in serious harm or risk of serious harm to patients and the negative impact in the internal market;***		
Article 20b(2), point (b)				
167t		***(b) specify the quantities to be transferred, the timeframe for***		

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		delivery, and any other necessary logistical arrangements;		
Article 20b(2), point (c)				
167u		***(c) ensure that transferring Member States retain adequate minimum levels of the relevant medicinal product.***		
Article 20b(3)				
167v		***3. A distribution decision adopted pursuant to this Article shall specify the date at which it takes effect and shall be notified by the Commission to the Member States concerned without delay/within ... [and at least 20 days before its date of application].***		
Article 20c				
167w		***Article 20c Appeal mechanism***		
Article 20c(1)				
167x		***1. A Member State concerned by a redistribution decision adopted and notified pursuant to Article 20b may submit a reasoned request for a review of the decision referred to in that Article. Such a request shall be submitted to the Commission within 10 days of the notification referred to in that Article and shall***		

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		state in detail the reasons for which that Member State considers that the decision does not comply with the conditions laid down in that Article or that its application would pose a disproportionate risk to public health.		
Article 20c(2)				
167y		***2. Following consultation of the Critical Medicines Coordination Group, the Commission shall adopt a review decision within 10 days of receipt of the reasoned request referred to in paragraph 1. That decision shall confirm, amend or revoke the distribution decision adopted and notified pursuant to Article 20b and shall state the reasons on which it is based.***		
Article 20c(3)				
167z		***3. The submission of a request for review shall not suspend the application of the distribution decision adopted and notified pursuant to Article 20b, unless the Commission, on duly justified grounds, decides to grant a suspension pending the outcome of the review.***		

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Article 20d				
167aa		***Article 20d*** ***Stockpile information and reporting obligations***		
Article 20d(1)				
167ab		***1. The Commission shall establish and maintain a digital reporting system that enables real-time updates on the status of national stockpiles and contingency stocks where such national stockpiles or contingency stocks are established under national law. Each Member State shall report to the European Commission at least quarterly on the status of their national stockpiles and contingency stocks, and immediately upon any significant change in stock levels.***		
Article 20d(2)				
167ac		***2. The report referred to in paragraph 1 shall include the following information:***		
Article 20d(2), point (a)				
167ad		***(a) a list of critical medicinal products for which contingency stocks or a national stockpile are held;***		
Article 20d(2), point (b)				

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167ae		***(b) the quantities of such stocks;***		
Article 20d(2), point (c)				
167af		***(c) the measures in place to ensure proper stock management, including rotation and the prevention of expiry.***		
Article 20d(3)				
167ag		***3. For the purposes of this Article, the Commission shall make use of existing Union data infrastructures and reporting mechanisms, including but not limited to the Technical Regulation Information System (TRIS), the European Medicines Verification System (EMVS), the European Shortages Monitoring Platform (ESMP), EudraGMDP, the Industry Single Point of Contact (iSPOC) network, and relevant instruments established under the Union Civil Protection Mechanism. The Commission shall be granted timely access to data held by the Agency, and by the competent authorities of the Member States in accordance with national law, to the extent necessary to support its mandate in the areas of situational awareness and risk assessment, as***		

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		well as coordination under this Chapter.		
Article 20d(4)				
167ah		***4. Information reported under this Article that relates to national stockpiles and contingency stocks shall be treated as strictly confidential. Such information shall not be made publicly available and shall be used solely for the purposes of this Chapter. The Commission and the competent authorities of the Member States shall ensure that commercially sensitive information, including trade secrets within the meaning of Directive (EU) 2016/943, and information the disclosure of which may compromise national security is protected under the applicable Union and national rules on confidentiality and the handling of sensitive or classified information. The Commission shall not publish, disseminate or otherwise disclose such information to third parties.***		
Article 20d(5)				
167ai		***5. The Commission may adopt implementing acts specifying the format, structure and detailed content of the reports referred to in***		

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		paragraphs 2 and 3 of this Article and of the digital reporting system referred to paragraph 1 in order to ensure their consistency, completeness and comparability across Member States. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20e(2).		
Article 20e				
167aj		***Article 20e Committee procedure***		
Article 20e(1)				
167ak		***1. The Commission shall be assisted by the Standing Committee on medicinal products for human use established by Article 214 of Directive (EU) …/… of the European Parliament and of the Council [reference to be added after adoption cf. COM(2023) 192 final]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.***		
Article 20e(2)				
167al		***2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.***		

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Article 20f				
167am		***Article 20f*** ***Obligations of Member States***		
Article 20f(1)				
167an		***Where the Commission adopts a redistribution decision pursuant to Article 20b, Member States shall:***		
Article 20f(1), point (a)				
167ao		***(a) comply with that redistribution decision;***		
Article 20f(1), point (b)				
167ap		***(b) notify, without undue delay, the Commission and the Agency if they impose contingency stocks requirements on economic operators;***		
Article 20f(1), point (c)				
167aq		***(c) cooperate fully and without delay and, where necessary, provide mutual support to any other Member State that has requested assistance pursuant to Article 20b(1), with a view to preventing or mitigating shortages of critical medicinal products.***		
Article 20g				
167ar		***Article 20g***		

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		Reimbursement and replacement		
Article 20g(1)				
167as		***1. Where a Member State or economic operator transfers critical medicinal products in accordance with a binding decision adopted pursuant to Article 20b, it shall be entitled to full reimbursement from the receiving Member State for the value of the critical medicinal products transferred and the costs of transport and a reasonable mark-up.***		
Article 20g(2)				
167at		***2. The value of the medicinal products shall be determined on the basis of their wholesale acquisition cost or an equivalent fair market value, as agreed between the Member States concerned.*** ***The transferring Member State or economic operator shall be entitled to reimbursement of the determined value as soon as possible, but not later than 30 day from the date of receipt of concerned medicinal product by receiving Member State.*** ***The Commission is empowered to adopt delegated acts in accordance***		

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		with Article 30a, to supplement this Regulation by laying down procedures for reimbursement or replacement, and for cost-sharing mechanisms between Member States where appropriate.		
Article 20h				
167au		***Article 20h Union Stockpile***		
Article 20h(1)				
167av		***1. In order to ensure the timely and effective availability of critical medicinal products with identified vulnerabilities in their supply chains, a Union Stockpile may be established as a last-resort mechanism to be activated in situations where the Union coordination mechanism for critical medicinal products indicates the existence of a recurrent or persistent shortage in national stockpiles and contingency stocks.***		
Article 20h(2)				
167aw		***2. The Commission is empowered to adopt delegated acts in accordance with Article 30a to supplement this Regulation by establishing:***		

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Article 20h(2), point (a)				
167ax		***(a) the categories and specific types of critical medicinal products to be included in the Union Stockpile;***		
Article 20h(2), point (b)				
167ay		***(b) the minimum quantities to be stocked for each product, taking into account Union-level risk assessments, supply vulnerabilities, and public health needs;***		
Article 20h(2), point (c)				
167az		***(c) the logistical, technical and operational arrangements for storage and maintenance of the Union stockpile;***		
Article 20h(2), point (d)				
167ba		***(d) the criteria and procedures for the deployment of the stockpiled products in coordination with Member States.***		
Article 20h(3)				
167bb		***3. In the event that the Commission decides to establish a Union Stockpile for critical medicinal products with identified vulnerabilities in accordance with paragraphs 1 and 2, it shall:***		

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Article 20h(3), point (a)				
167bc		***(a) coordinate with national competent authorities to ensure alignment and ensure that the Union stockpile does not duplicate national contingency stock arrangements:***		
Article 20h(3), point (b)				
167bd		***(b) design and implement the measures to be taken in a way that does not result in any negative impact on availability of medicinal products in other Member States;***		
Article 20h(3), point (c)				
167be		***(c) in accordance with applicable law, ensure that packaging, labelling, and storage conditions are such as to enable the rapid and safe distribution and use of the products across the Union.***		
Article 20h(4)				
167bf		***4. The establishment, maintenance, and deployment of the Union Stockpile shall be supported by the Union budget. Expenditures under this article shall be subject to annual reporting to the European Parliament and***		

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		the Council, and to audits by the European Court of Auditors.		
Section II				
168	Section II Collaborative procurements	Section II Collaborative procurements	Section II ***Voluntary*** collaborative procurements	
Article 21				
169	Article 21 Commission facilitated Member States' cross-border procurement	Article 21 Commission facilitated Member States' cross-border procurement	Article 21 Commission facilitated Member States' cross-border procurement	
Article 21(1)				
170	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[1] for medicinal products of common interest. _____ 1. 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).	1. Upon a reasoned request of three or more Member States ('the request'), the Commission ~~*may*~~***shall*** act as facilitator for the requesting Member States' cross-border procurement as laid down in Article 39 of Directive ***2014/24/EC*** of the European Parliament and of the Council ~~*2014/24/EC*[1]~~ for medicinal products of common interest. _____ ~~*1. 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).*~~	1. Upon a reasoned request ~~*of*~~***from*** 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[1] for*~~***2014/24/EU[1] where the procurement concerns*** medicinal products of common interest. _____ 1. 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).	
Article 21(2)				

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171	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.	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.	2. Having received the request, the Commission shall inform all other Member States of the ~~*initiative*~~***request*** and set ~~*an appropriate*~~***a*** deadline ***of 20 working days for Member States*** ~~*for them*~~ to declare ***their*** interest ***in participating in the procedure. Participation in the procedure*** ~~*. Such a deadline*~~ shall ~~*not exceed three weeks*~~***be voluntary for Member States***.	
Article 21(3)				
172	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.	3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall communicate to the ~~*interested*~~***requesting*** Member States its decision on whether it agrees, or not, to facilitate the proposed initiative within three weeks of receiving the request. ***It shall inform the European Parliament thereof***	3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall ~~*communicate to*~~***inform*** the interested Member States ***of*** its decision on whether it agrees ~~*, or not,*~~ to facilitate the proposed ~~*initiative*~~***request*** within ~~*three weeks*~~ ***15 working days*** of receiving the request.	
Article 21(4)				
173	4. If the Commission declines the request, it shall provide reasons for the refusal.	4. If the Commission declines the request, it shall provide reasons for the refusal.	4. If the Commission declines the request, it shall ~~*provide*~~***state its*** reasons for the refusal.	
Article 21(5)				

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174	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.	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~~***interested*** Member States and provide advice on applicable Union public procurement rules***, including on the use of award criteria as set out in Article 18*** and on regulatory matters related to medicinal products.	5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the ~~interested~~***participating*** 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.	
Article 21(6)				
175	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.	6. The facilitation offered by the Commission shall be limited in time and end***, unless otherwise requested by the requesting Member States,*** ~~at the latest~~ upon signature of the procurement contract by the participating contracting authorities. ***Where requested by requesting Member States, the facilitation offered by the Commission shall end upon delivery of the medicinal products of common interest.***	6. The facilitation offered by the Commission shall be limited in time and ***shall*** end at the latest upon signature of the procurement contract by the participating contracting authorities. ***Member states participating in the cross-border procurement shall procure at their cost only.***	
Article 21(6a)				
175a		***6a. The Commission shall act as a facilitator under this Article***		

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		subject to the acceptance of the following conditions by the requesting Member States:		
Article 21(6a), point (a)				
175b		***(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patients needs in their territory;***		
Article 21(6a), point (b)				
175c		***(b) commercially sensitive information is treated in accordance with Directive (EU) 2016/943 and with applicable Union and national law on the protection of trade secrets, and is protected as such;***		
Article 21(6a), point (c)				
175d		***(c) participating Member States, for the duration of the contract, refrain from unilateral renegotiation of the agreed commercial terms, except where this is explicitly provided for in the contract;***		

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Article 21(6a), point (d)				
175e		***(d) regulatory flexibilities available under applicable Union law are applied to facilitate the process, including but not limited to the use of electronic packaging information (ePI), the harmonisation of pack sizes, and labelling flexibilities;***		
Article 21(6a), point (e)				
175f		***(e) participating Member States refrain, for the duration of the joint procurement procedure and resulting contract, from conducting separate negotiations or procurements for the same product.***		
Article 21(7)				
176	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.	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.	7. ***The Commission can be held liable in accordance with Article 340 TFEU.*** 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*~~ ***bear no*** liability associated with the conduct of the procurement procedure by ~~*interested*~~	

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			participating Member States ~~***and or for the***~~ implementation of the contract resulting from the procedure.	
Article 21(7a)				
176a		***7a. The provisions of this Article shall apply, mutatis mutandis, to candidate countries that choose to participate in the procedures established herein and with which the Union has entered into a bilateral agreement governing the facilitation of cross-border procurement, without prejudice to their accession negotiations or to the rights and obligations reserved to Member States under Union law. The participation of candidate countries shall not affect the need for three or more Member States to initiate the procedure.***		
Article 22				
177	Article 22 Commission procurement on behalf of or in the name of Member States	Article 22 Commission procurement on behalf of or in the name of Member States	Article 22 Commission procurement on behalf of or in the name of Member States	
Article 22(1)				
178	1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where nine or	1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where ~~*nine*~~***five***	1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where ~~*nine*~~ ***six***	

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	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;	or more Member States jointly request the Commission to procure on their behalf, or in their name, the Commission ~~*may*~~***shall*** initiate a procurement procedure under the conditions set out in this Article when the procurement relates to medicinal products belonging to one of the following categories below~~;~~**:**	or more Member States jointly request the Commission to procure on their behalf, or in their name ***and at their costs (`the joint request`)***, the Commission may initiate a procurement procedure under the conditions ~~*set out*~~***laid down*** in this Article when the procurement ~~*relates to*~~ ***concerns*** medicinal products belonging to one of the following categories below;	
Article 22(1), point (a)				
179	(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;	(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;	(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;	
Article 22(1), point (b)				
180	(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 [1], 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.	(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 [1], 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.	(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*~~ ***2021/2282/EU*** [18], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States ~~*as per*~~***pursuant to***	

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	_____ 1. 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)	1. 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)	Article 23(1) point (e) of that Regulation. _____ ~~*1. 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)*~~	
Article 22(2)				
181	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.	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 ***and affordability*** of critical medicinal products in the Union or ***to*** ensure the availability ~~*and*~~, accessibility ***and affordability*** of medicinal products of common interest, as applicable.	2. The joint request referred to in paragraph 1 shall only be ~~*made*~~ ***submitted*** where the medicinal product concerned fulfils one of the criteria ~~*set out*~~ ***laid down*** in that paragraph and ~~*if*~~ ***where*** the requested procurement procedure ~~*will help*~~ ***is expected*** to improve the security of supply and availability of critical medicinal products in the Union or ***to*** ensure the availability and accessibility of medicinal products of common interest, as applicable.	
Article 22(3)				
182	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	3. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the ***joint*** request ***referred to in paragraph 1***, through	3. The participation in the procurement procedure shall be open to all Member States. ***Having received the joint request,*** the Commission shall inform all ***other*** Member States of the ***joint*** request, through the ~~*Critical Medicines*~~	

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	Group, and invite them to join the procedure.	the Critical Medicines Group, and invite them to join the procedure.	~~*Group, and invite them to join*~~ ***CMCG, and set a deadline of 20 working days for Member States to declare their interest in participating in*** the procedure. ***Participation in the procurement procedure shall be voluntary for Member States.***	
Article 22(4)				
183	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.	4. The Commission shall assess the utility, necessity and proportionality of the ***joint*** request ***referred to in paragraph 1*** and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	4. The Commission shall assess ~~*the utility, necessity and proportionality of the request and*~~ whether the ***joint*** request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could ~~*constitute*~~ ***result in*** discrimination or restriction ~~*to*~~***on*** trade or a distortion ~~*to*~~ ***of*** competition ***taking into account the utility, necessity and proportionality of the joint request***.	
Article 22(5)				
184	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.	5. The Commission shall ~~*inform the interested*~~***communicate to the requesting*** Member States ***its decision*** within one month of the request of its decision and state its reasons in case of a refusal. ***It shall inform the European Parliament thereof***	5. ***Within 20 working days of receiving the joint request,*** 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.	

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Article 22(5a)				
184a		***5a. The Commission shall ensure that any procurement procedure under this Article applies to the award criteria and requirements referred to in Article 18(1) to (4), including those on supply chain resilience, diversification and innovation.***		
Article 22(5b)				
184b		***5b. The Commission shall conduct a procurement on behalf or in the name of Member States under this Article subject to the acceptance of the following conditions by the requesting Member States:***		
Article 22(5b), point (a)				
184c		***(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patient needs in their territory;***		
Article 22(5b), point (b)				

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184d		***(b) commercially sensitive information is treated in accordance with Directive (EU) 2016/943 and with applicable Union and national law on the protection of trade secrets, and is protected as such;***		
Article 22(5b), point (c)				
184e		***(c) participating Member States, for the duration of the contract, refrain from unilateral renegotiation of the agreed commercial terms, except where this is explicitly provided for in the contract;***		
Article 22(5b), point (d)				
184f		***(d) regulatory flexibilities available under applicable Union law are applied to facilitate the process, including but not limited to the use of electronic packaging information (ePI), the harmonisation of pack sizes, and labelling flexibilities;***		
Article 22(5b), point (e)				
184g		***(e) participating Member States refrain, for the duration of the joint procurement procedure and resulting contract, from***		

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		conducting separate negotiations or procurements for the same product.		
Article 22(5c)				
184h		***5c. The provisions of this Article shall apply, mutatis mutandis, to candidate countries that choose to participate in the procurement procedure established herein and with which the Union has concluded a bilateral agreement providing for such a participation, without prejudice to their accession negotiations or to the rights and obligations reserved to Member States under Union law. The participation of candidate countries shall not affect the requirement of a minimum of five participating Member States in accordance with paragraph 1.***		
Article 22(6)				
185	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	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*~~	6. ~~*If in light of*~~***Where based on its assessment,*** the Commission ~~*assessment, it is*~~***may, if*** necessary~~*, in order*~~ to achieve the objectives of this Regulation, ~~*to conduct*~~***make the initiation of*** the procurement ~~*as exclusive for the*~~***procedure conditional upon the interested*** Member States ~~*or to agree to*~~***accepting binding*** minimum	

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	acceptance of these conditions by interested Member States.	~~*upon acceptance of these conditions by interested Member States.*~~	~~*binding*~~ quantities, ~~*the Commission agreement to pursue the*~~***in accordance with their national need, or refraining from participating in competing subsequent procurement processes. Such a procurement*** procedure may ***only be initiated once***~~*be conditioned upon acceptance of*~~ these conditions ***have been accepted by the***~~*by*~~ interested Member States.	
Article 22(7)				
186	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[1]. _____ 1. 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).	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[1]. _____ 1. 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).	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[1]. _____ 1. 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).	
Article 23				
187	Article 23 Joint Procurement	Article 23 Joint Procurement	~~*Article 23*~~ ~~*Joint Procurement*~~	
Article 23(1)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
188	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.	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~~***five*** Member States may engage, as contracting parties, in a joint procurement procedure.	~~*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.*~~	
Article 23(2)				
189	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:	2. A joint procurement procedure ~~*may*~~***shall*** be organised following a request by the Member States or ***may be organised*** at the Commission's initiative when the procurement relates to medicinal products belonging to one of the categories below:	~~*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:*~~	
Article 23(2), point (a)				
190	(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;	(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;	~~*(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;*~~	
Article 23(2), point (b)				

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191	(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 [1], 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. _____ 1. 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)	(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 [1], 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. _____ 1. 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)	~~*(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 [1], 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.*~~ _____ ~~*1. 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)*~~	
Article 23(3)				
192	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.	3. The Commission may decide to conduct the joint procurement procedure if the procurement procedure helps to improve the security of supply ~~*and*~~, availability ***and affordability*** of critical medicinal products in the Union or ***to*** ensure the availability ~~*and*~~, accessibility ***and affordability*** of medicinal products of common interest, as applicable.	~~*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.*~~	
Article 23(4)				

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193	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.	4. The participation in the procurement procedure shall be open to all Member States. The Commission shall inform all Member States of the request through the Critical Medicines Group and invite them to join the procedure. ***It shall inform the European Parliament thereof***	~~*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.*~~	
Article 23(5)				
194	5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	5. The Commission shall assess the necessity of a joint action and whether the request ***referred in paragraph 2*** is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.	~~*5. The Commission shall assess the necessity of a joint action and whether the request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.*~~	
Article 23(5a)				
194a		***5a. The Commission shall ensure that any procurement procedure under this Article applies to the award criteria and requirements referred to in Article 18(1) to (4), including those on supply chain resilience, diversification and innovation.***		
Article 23(5b)				

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194b		***5b. The Commission shall conduct a joint procurement under this Article subject to the acceptance of the following conditions by requesting Member States:***		
Article 23(5b), point (a)				
194c		***(a) contracting authorities from the participating Member States agree to procure minimum binding quantities based on individual Member States needs and to take the necessary steps to ensure that a product is promptly made available to cover patient needs in their territory;***		
Article 23(5b), point (b)				
194d		***(b) commercially sensitive information is treated in accordance with Directive (EU) 2016/943 and with applicable Union and national law on the protection of trade secrets, and is protected as such;***		
Article 23(5b), point (c)				
194e		***(c) participating Member States, for the duration of the contract, refrain from unilateral renegotiation of the agreed commercial terms, except where***		

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		this is explicitly provided for in the contract;		
Article 23(5b), point (d)				
194f		***(d) regulatory flexibilities available under applicable Union law are applied to facilitate the process, including but not limited to the use of electronic packaging information (ePI), the harmonisation of pack sizes, and labelling flexibilities;***		
Article 23(5b), point (e)				
194g		***(e) participating Member States refrain, for the duration of the joint procurement procedure and resulting contract, from conducting separate negotiations or procurements for the same product.***		
Article 23(5c)				
194h		***5c. The provisions of this Article shall apply, mutatis mutandis, to candidate countries that choose to participate in the procedures established herein and with which the Union has entered into a bilateral agreement governing the procurement activities referenced in this Article, without prejudice to their accession negotiations or to the rights and***		

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		obligations reserved to Member States under Union law. The participation of candidate countries shall not affect the need for five Member States to engage in the procedure.		
Article 23(6)				
195	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.	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.*~~	~~*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.*~~	
Article 23(7)				
196	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.	7. The Commission shall ~~*inform the interested*~~***communicate to the requesting*** Member States ***its decision*** within one month of the request ~~*of its decision*~~, and state its reasons in case of a refusal.	~~*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.*~~	
Article 23(8)				
197	8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall	8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall be	~~*8. Except for the derogations provided for in this Regulation, the joint procurement procedure shall*~~	

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	be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.	carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.	~~*be carried out by the Commission in accordance with Article 168 (2) of Regulation (EU, Euratom) 2024/2509.*~~	
Article 24				
198	Article 24 Agreement concerning procedures under Articles 22 and 23	Article 24 Agreement concerning procedures under Articles 22 and 23	Article 24 Agreement concerning procedures under ~~*Articles 22 and 23*~~***Article 22***	
Article 24(1)				
199	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.	1. Member States participating in the procurement procedures covered by Articles 22 and 23 shall share with the Commission any information relevant for the procurement procedure. Member States shall provide resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge. ***Procurement procedures shall ensure that smaller Member States and SMEs can participate effectively, avoiding market distortion and ensuring equitable access to critical medicinal products.***	1. Member States participating in the procurement procedures covered by ~~*Articles 22 and 23*~~***Article 22,*** shall share with the Commission any information relevant for the procurement procedure. ***The participating*** Member States shall provide ***the*** resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge.	
Article 24(2)				
200	2. An agreement between the Member States and the Commission	2. An agreement between the Member States and the Commission	2. An agreement between the Member States and the Commission	

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	shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process.	shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. ***Those practical arrangements shall also cover, where appropriate, the designation of the contracting authority, the distribution of procured stocks, and the identification of storage locations. Regulatory flexibilities may be granted with regard to packaging and labelling requirements, including the use of electronic package leaflets, while ensuring that patients retain the right to request paper leaflet.***	shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. ***The procedure shall be carried out in accordance with the mandate given to the Commission by the Member States.***	
Article 24(2a)				
200a		***2a. The Commission shall, following a consultation with relevant stakeholders, including patient and consumer organisations, healthcare professional organisations, public healthcare payers, and marketing authorisation holders, issue Union guidelines recommending common standards for procurement activities under Articles 22 and 23 of this Regulation, ensuring predictability for companies.***		

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Chapter V				
201	Chapter V Critical Medicines Coordination Group	Chapter V Critical Medicines Coordination Group	Chapter V Critical Medicines Coordination Group	
Article 25				
202	Article 25 Establishment of Critical Medicines Coordination Group	Article 25 Establishment of Critical Medicines Coordination Group	Article 25 Establishment of Critical Medicines Coordination Group	
Article 25(1)				
203	1. A Critical Medicines Coordination Group ('Critical Medicines Group') is hereby established.	1. A Critical Medicines Coordination Group ('Critical Medicines Group') is hereby established.	1. A Critical Medicines Coordination Group ('~~*Critical Medicines Group*~~***CMCG***') is hereby established.	
Article 25(2)				
204	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	2. The Member States***, the Agency,*** ~~*and*~~ the Commission ~~*are*~~***and representatives from patient organisations and healthcare professional organisations shall be*** Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level 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	2. The Member States and the Commission are Members of the ~~*Critical Medicines Group*~~***CMCG*** . Each Member State shall appoint ~~*a maximum of two high-level*~~ ***one*** permanent ~~*representatives, with the*~~ ***representative, with strategic*** expertise relevant for implementing ~~*all*~~ the different measures set out in this Regulation. ~~*Where relevant as regards the function and expertise*~~***As necessary*** , Member States may appoint ~~*different*~~***an alternate permanent representative and additional expert***	

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	ensure the necessary coordination within their respective Member State. The Agency shall have an observer status.	representatives in relation to different tasks of the Critical Medicines Group. Appointed ~~*permanent*~~***national*** representatives shall ensure the necessary coordination within their respective Member State. The Agency shall ***appoint two members of the MSSG as representatives. The Critical Medicines Group shall appoint two representatives from patient organisations and two permanent representatives from healthcare professional organisations.*** ***The European Parliament shall*** have ~~*an*~~ observer status ***and shall be represented by two Members of the European Parliament. The European Parliament shall be entitled to receive meeting agendas, documents, reports, and any other materials circulated to members of the Critical Medicines Group, and to participate in debates. The European Parliament shall not have voting rights and shall not be counted for the purpose of determining the quorum.***	representatives ***to accompany the permanent Member State representative in order to support the*** ~~*in relation to*~~ different tasks of the ~~*Critical Medicines Group*~~***CMCG***~~*. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State.*~~ The Agency shall have an observer status.	
Article 25(2a)				

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204a		***2a. The representatives appointed to the Critical Medicines Group and its working group or working groups shall make a declaration of their financial and other interests and update it annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve, or give rise to, a conflict of interest.***		
Article 25(3)				
205	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.	3. The Critical Medicines Group shall work closely with the MSSG, the Agency, ***the Commission*** and national authorities responsible for medicinal products. For discussions where input from the ~~*medicines*~~***national*** regulatory authorities' ***responsible for medicinal products'*** perspective is necessary, the Critical Medicines Group ~~*may*~~***and the MSSG shall*** organise joint meetings. ***The Group shall also cooperate closely with patient and consumer organisations, healthcare professional organisations, and relevant marketing authorisation holders to fulfil its tasks, consulting***	3. The ~~*Critical Medicines Group*~~ ***CMCG*** shall work closely with the MSSG, the Agency, and national ***competent*** authorities ~~*responsible*~~ for medicinal products. For discussions where input from the medicines regulatory authorities' perspective is necessary, the ~~*Critical Medicines Group*~~ ***CMCG*** may organise joint meetings with the MSSG.	

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		them and other stakeholders as needed, including through structured joint meetings ~~*with the MSSG*~~.		
Article 25(4)				
206	4. The Commission shall organise and coordinate the work of the Critical Medicines Group by means of the Secretariat.	4. The Commission***, acting as the Secretariat of the Critical Medicines Group,*** shall organise ***regular meetings*** and coordinate the work of the Critical Medicines Group ~~*by means of the Secretariat*~~.	4. The Commission shall organise and coordinate the work of the ~~*Critical Medicines Group*~~ ***CMCG*** by means of the Secretariat. ***The CMCG shall establish its rules of procedure, including procedures relating to the working group referred to in paragraph 6.***	
Article 25(5)				
207	5. A representative of the Commission shall chair the meetings of the Critical Medicines Group.	5. A representative of the Commission shall chair the meetings of the Critical Medicines Group.	5. ***The CMCG shall be co-chaired by*** a representative of the Commission ~~*shall chair the meetings*~~***and by a representative*** of the ~~*Critical Medicines Group*~~***Member States, who shall be elected by and from among the representatives of the Member States***.	
Article 25(6)				
208	6. The Critical Medicines Group, at the proposal of the Chair or any its members, may decide to establish a working group.	6. The Critical Medicines Group, at the proposal of the Chair or any ***of*** its members, may***, on a case-by-case basis,*** decide to establish ~~*a*~~***one or more*** working ~~*group*~~***groups***.	6. The ~~*Critical Medicines Group*~~***CMCG*** , at the proposal of the ~~*Chair*~~***co-chair*** or any ***of*** its members, may decide to establish a working group.	

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Article 25(6a)				
208a		***6a. The Critical Medicines Group shall have biannual meetings, and additional meetings when needed, to consult with the Critical Medicines Alliance on vulnerabilities in supply chains and on mitigation measures to address structural risks and reinforce supply. The Critical Medicines Group shall take into account the findings from the Critical Medicines Alliance, where relevant. The Commission, as the Group's secretariat, shall ensure regular and transparent communication with the Alliance.***		
Article 25(7)				
209	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.	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.	7. The ~~*Critical Medicines Group*~~ ***CMCG*** shall use its best endeavours to reach consensus, where possible***, when providing advice as referred to in Article 26(2) points (d) and (db) and providing an opinion as referred to in Article 26 (2) point (a) and (3). If such consensus cannot be reached, the CMCG shall issue its position by a majority of two-thirds of its members. Each Member State shall have one vote***. Members with	

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			diverging positions may request that their positions and the grounds on which they are based be recorded in the ~~*Critical Medicines Group*~~***CMCG***'s position.	
Article 26				
210	Article 26 Tasks of the Critical Medicines Coordination Group	Article 26 Tasks of the Critical Medicines Coordination Group	Article 26 Tasks of the Critical Medicines Coordination Group	
Article 26(1)				
211	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.	1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission~~,~~ so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market ***or on national healthcare systems***.	1. The ~~*Critical Medicines Group*~~ ***CMCG*** shall facilitate coordination in the implementation of this Regulation ~~*and*~~, ***including,*** where appropriate~~,~~ advise ***to*** the Commission ***or Member States at their request***, so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market ***or on national healthcare systems***.	
Article 26(1a)				
211a		***1a. The Critical Medicines Group shall include in its rules of procedure provisions for the systematic consultation of Union and national patient organisations and other relevant stakeholder to encourage the exchange of***		

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		information about the working group's activities and promote transparency. It shall ensure alignment and data coherence with the EMA's MSSG.		
Article 26(2)				
212	2. In order to attain the objectives referred to in paragraph 1, the Critical Medicines Group shall perform the following tasks:	2. In order to attain the objectives referred to in paragraph 1, the Critical Medicines Group shall perform the following tasks ***in compliance with the necessary guarantees of protection of commercial confidential information***:	2. In order to attain the objectives referred to in paragraph 1, the ~~*Critical Medicines Group*~~ ***CMCG*** shall perform the following tasks:	
Article 26(2), point (a)				
213	(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;	(a) facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States***, as well as critical distribution infrastructure capacity*** and facilitate discussion on the capacity needed in the Union to strengthen its supply security ~~*and*~~***,*** availability ***and affordability*** of critical medicinal products***, active substances and key inputs*** within the Union***, as well as***	(a) facilitate coordination ***and, on its own initiative or upon a request from the Commission, provide an opinion*** on strategic orientation of the financial support for strategic projects, including by exchanging information***, where available,*** 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***, their***	

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		to ensure that the public health and patient safety implications are explicitly assessed and taken into account in all related decisions;	***active substances and key inputs*** within the Union;	
Article 26(2), point (aa)				
213a			***(-a) engage in dialogue with the industry and other relevant stakeholders in order to promote synergies towards strategic projects.***	
Article 26(2), point (ab)				
213b	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. Moved reference text		~~*3.*~~***(aa)*** ~~*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*~~***facilitate*** coordination of respective actions aiming to attain the objectives of this Regulation. Moved from row 217 [217 - 213b]	
Article 26(2), point (b)				
214	(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;	(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;	(b) facilitate exchanges on the national programmes referred to in Article 19 and ~~*enable*~~ ***promote best practice and, where appropriate, voluntary*** cooperation on ~~*and coordination of*~~ Member States	

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			public procurement policies with regard to critical medicinal products;	
Article 26(2), point (ba)				
214a			***(ba) facilitate exchanges of information and guiding principles on contingency stocks requirements as referred to in Article 20(3a).***	
Article 26(2), point (c)				
215	(c) facilitate discussion of the need for a collaborative procurement initiative for a given medicinal product;	(c) facilitate discussion of the need for a collaborative procurement initiative for a given medicinal product;	(c) facilitate ***strategic*** discussion ~~*of the need for a*~~ ***on*** collaborative procurement ~~*initiative for a given medicinal product*~~***initiatives*** ;	
Article 26(2), point (ca)				
215a		***(ca) issue guidelines on measures to support availability and affordability in the Union market of critical medicinal products in the context of strategic projects that have received financial support;***		
Article 26(2), point (d)				
216	(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.	(d) ~~*advise*~~***provide recommendations to*** the MSSG ~~*to provide the*~~***on*** order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of	(d) advise the MSSG to provide the order of priority of critical medicinal products for vulnerability evaluation ***as set out in Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]***, and propose a review or an	

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		existing evaluations where necessary~~.~~**;**	update of existing evaluations where necessary.	
Article 26(2), point (da)				
216a		***(da) facilitate discussion and exchange among members of the Critical Medicines Group and, where appropriate, coordinate and exchange with the EU stockpiling network, as established by the Commission with Member States, in relation to Article 20, specifically sharing best practices in stock management, including real-time tracking, condition monitoring, expiry alerts, stock rotation, shelf-life and waste management, including waste reduction facilities, and evaluations where necessary;***		
Article 26(2), point (da)				
216b	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.		~~*4.*~~***(da)*** ~~*The Critical Medicines Group shall periodically*~~***regularly*** 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.	

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	Moved reference text		Moved from row 218 [218 - 216a]	
Article 26(2), point (da)				
216c				
Article 26(2), point (db)				
216d		***(db) assess national stockpiling strategies, their proportionality, compatibility with the internal market, and feasibility for implementation by industry, and, where appropriate, issue recommendations on Union-wide minimum standards;***		
Article 26(2), point (db)				
216e			***(db) where appropriate, advise the Commission or Member States, at their request, on matters relating to the implementation of this Regulation.***	
Article 26(2), point (dc)				
216f		***(dc) decide on whether to give to the Commission its prior approval to requests for the redistribution of critical medicinal products submitted by one or more Member States pursuant to Article 20b in the event of a shortage or supply disruption;***		
Article 26(2), point (dd)				

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216g		***(dd) assess Union needs to determine whether specific projects concerning medicinal products of common interest should qualify as strategic projects;***		
Article 26(2), point (de)				
216h		***(de) assess Union needs to reserve a defined portion of manufacturing capacity, within a fixed timeframe, for the production of specific medicinal products, including their pharmaceutical forms, active substances, key inputs, or enabling technologies;***		
Article 26(2), point (df)				
216i		***(df) assess, in accordance with Article 6, whether a proposed strategic project would result in a significant duplication of existing or planned manufacturing capacities within the Union;***		
Article 26(2), point (dg)				
216j		***(dg) recommend minimum common indicators for monitoring the environmental and supply-resilience performance of national programmes referred to in Article 19, ensuring proportionality and avoiding duplication;***		

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Article 26(2), point (dh)				
216k		***(dh) based on relevant financial expertise, examine the bottlenecks and Union wide financial needs of strategic projects, advise on ways of coordinating Union and national financing with regard to those financial needs, and share best practices;***		
Article 26(2), point (di)				
216l		***(di) establish the process for the strategic foresight report and prepare the annual strategic foresight report on strategic projects in accordance with Article 26a;***		
Article 26(2), point (dj)				
216m		***(dj) issue a recommendation concerning the applicability of any of the provisions referred to in Article 2(2a) to medicinal products of common interest.***		
Article 26(2a)				
216n		***2a. In carrying out the task referred to in paragraph 2(dc) of this Article, only the representatives of the Member States within the Critical Medicines Group shall have the right to vote. The decision***		

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		shall be adopted by a two-thirds majority of the Member States present and voting.		
Article 26(3)				
217	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.	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.	Moved to row 213b [217 - 213b]	
Article 26(4)				
218	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.	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.	Moved to row 216a [218 - 216a]	
Article 26(5)				
219	5. The Critical Medicines Group, at the Commission's request, may provide an opinion on matters related to the application of	5. The Critical Medicines Group, at the Commission's request, may provide an opinion on matters related to the application of this	~~*53*~~. The ~~*Critical Medicines Group*~~***CMCG*** , at the Commission's ***or Member States*`** request, may provide an opinion ~~*on matters*~~	

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	this Regulation in the context of performing tasks as referred to in this Article.	Regulation in the context of performing tasks as referred to in this Article.	~~*related to the application of this Regulation in the context of performing tasks*~~ ***where providing advice*** as referred to in ~~*this Article*~~***paragraph 2, points (d) and (db) and may, on its own initiative or at the Commission's request, provide an opinion as referred to in point (a)***.	
Article 26(5a)				
219a		***5a. The Critical Medicines Group shall assess the Union-wide financial needs of strategic projects and issue recommendations on how to ensure adequate financing, including through the Union budget, in order to support the achievement of the objectives of this Regulation; and advise on the coordination of financing by the Union, Member States, the European Investment Bank and the private sector.***		
Article 26a				
219b		***Article 26a Strategic Foresight on Critical Medicinal Products***		
Article 26a(1)				
219c		***1. In order to strengthen the Union's preparedness and ensure a***		

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		coordinated approach to future challenges in the supply of critical medicinal products, the Critical Medicines Group shall establish a strategic foresight process.		
Article 26a(2)				
219d		***2. The strategic foresight process shall be established after consultation with the Commission, the Agency, and the Critical Medicines Alliance.***		
Article 26a(3)				
219e		***3. The strategic foresight process shall identify medicinal products of common interest that would advance the objectives of this Regulation if included in Chapter III.***		
Article 26a(4)				
219f		***4. The strategic foresight process shall identify and assess potential strategic projects, taking into account long-term trends, vulnerabilities, opportunities for enhancing the resilience and sustainability of supply chains within the Union, and patients' unmet medical needs.***		
Article 26a(5)				

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219g		***5. The Critical Medicines Group shall prepare the report and communicate it to the Commission, the Agency and the European Parliament.***		
Article 26a(6)				
219h		***6. Following the preparation of the foresight report, the Critical Medicines Group shall make recommendations to the Commission and Member States on actions to be taken, including the identification and support of projects. Where there is a need to strategically reserve manufacturing capacity, recommendations shall specifically include proposals for strategic projects pursuant to Article 5(2), for the production of specific pharmaceutical forms, active substances, key inputs, or technologies within a defined timeframe.***		
Chapter VI				
220	Chapter VI International cooperation	Chapter VI International cooperation	Chapter VI International cooperation	
Article 27				
221	Article 27 Strategic partnerships	Article 27 ***International cooperation and*** strategic partnerships	Article 27 Strategic partnerships	

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Article 27, first paragraph				
222	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.	Without prejudice to the prerogatives of the Council, the Commission, shall ~~*explore possibilities of concluding*~~***seek to conclude*** strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also ~~*explore the possibility of building*~~***aim to build*** on existing forms of cooperation, when possible, to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union.	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*~~***where appropriate*** , to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. ***The Commission shall regularly inform the CMCG about their ongoing considerations and assessments.***	
Article 27, first paragraph a				
222a		***The Commission shall endeavour to incorporate health security aspects into strategic partnerships. Such aspects may include measures to promote open and resilient supply chains, including through crisis response mechanisms and collaboration to prevent export***		

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		restrictions during public health emergencies and to foster regulatory convergence and cooperation in the pharmaceutical sector. The Commission shall endeavour to include access to active substances and API starting materials within strategic partnerships, in order to ensure timely availability of critical medicinal products under this mechanism.		
Article 27, first paragraph b				
222b		***The Commission shall establish and regularly update a list of countries that meet Union regulatory standards for the quality and safety of medicinal products, including key inputs and active substances. It shall make that list available to contracting authorities and healthcare professionals involved in the selection, procurement, prescribing, management, dispensing, and monitoring of such products.***		
Article 27, first paragraph c				
222c		***In the context of accession negotiations, the Commission shall support the progressive alignment of candidate countries with the***		

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		Union acquis in the field of pharmaceuticals, with a view to facilitating their gradual integration into the Union's internal market and strengthening the resilience of the Union's supply chains for critical medicinal products.		
Article 27, first paragraph d				
222d		***The Commission shall inform the Critical Medicines Group about possible strategic partnerships on an annual basis.***		
Article 27, first paragraph e				
222e		***The Commission shall, within the framework of strategic partnerships, promote the harmonisation of Union quality, safety and environmental standards for pharmaceutical production between the Union and third countries.***		
Article 27, first paragraph f				
222f		***By ... [two years from the entry into force of this Regulation], the Commission shall develop a structured methodology when identifying and prioritising such partnerships, distinguishing between: (a) partnerships designed***		

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		to leverage and strengthen existing cooperation frameworks and trade relations that contribute to security of supply and supply chain stability; and (b) partnerships designed to develop new or intensified cooperation to reduce strategic dependencies and ensure geographical diversification of supply chains.		
Article 27, first paragraph g				
222g		***Strategic partnerships shall also seek to address trade and regulatory barriers that impede supply chain resilience, promote regulatory cooperation to facilitate faster and more predictable market access, and support the smooth cross-border movement of medicinal products and critical components, while remaining fully consistent with the Union's international obligations.***		
Article 27, first paragraph h				
222h		***The Commission shall also build on existing forms of cooperation, where relevant, to reinforce efforts to strengthen the production and supply resilience of critical medicinal products, their active***		

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		substances and key inputs in the Union and globally.		
Chapter VII				
223	Chapter VII Amendments to Regulation (EU) 2024/795	Chapter VII Amendments to Regulation (EU) 2024/795	Chapter VII Amendments to Regulation (EU) 2024/795	
Article 28				
224	Article 28	Article 28	Article 28	
Article 28, first paragraph				
225	Regulation (EU) 2024/795 is amended as follows:	Regulation (EU) 2024/795 is amended as follows:	Regulation (EU) 2024/795 is amended as follows:	
Article 28, first paragraph, point (a)				
226	(a) in Article 2, (1) point (a), subparagraph (iii) is replaced by the following:	(a) in Article 2, (1) point (a), subparagraph (iii) is replaced by the following:	(a) in Article 2, (1) point (a), subparagraph (iii) is replaced by the following:	
Article 28, first paragraph, point (a), amending provision, numbered paragraph (iii), first subparagraph				
227	‘ (iii) biotechnologies, and any other technologies relevant for manufacturing of critical medicinal products as defined in Critical Medicines Act *;	‘ (iii) biotechnologies, and ~~*any other*~~***directly related enabling*** technologies ~~*relevant for*~~***necessary for the development or*** manufacturing of critical medicinal products***, including their active substances and key inputs,*** as defined in Critical Medicines Act*;	‘ (iii) biotechnologies, and any other technologies relevant for manufacturing of critical medicinal products as defined in Critical Medicines Act *;	
Article 28, first paragraph, point (a), amending provision, numbered paragraph (iii), second subparagraph				

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228	_____	_____	_____	
Article 28, first paragraph, point (a), amending provision, numbered paragraph (iii), third subparagraph				
229	* 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]; ,	* 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]; ,	* 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]; ,	
Article 28, first paragraph, point (b)				
230	(b) in Article 2, the following subparagraph is added in paragraph 3:	(b) in Article 2, the following subparagraph is added in paragraph 3:	(b) in Article 2, the following subparagraph is added in paragraph 3:	
Article 28, first paragraph, point (b), amending provision, first paragraph				
231	' 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	' 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	' 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	

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	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.; ,	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.; ,	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.; ,	
Article 28, first paragraph, point (c)				
232	(c) in article 2, paragraph 8 is added:	(c) in article 2, paragraph 8 is added:	(c) in article 2, paragraph 8 is added:	
Article 28, first paragraph, point (c), amending provision, numbered paragraph (8)				
233	‘ 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).; ,	‘ 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).; ,	‘ 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).; ,	
Article 28, first paragraph, point (d)				

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234	(d) in Article 4, paragraph 7 is replaced by the following:	(d) in Article 4, paragraph 7 is replaced by the following:	(d) in Article 4, paragraph 7 is replaced by the following:	
Article 28, first paragraph, point (d), amending provision, numbered paragraph (7)				
235	‘ 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.;	‘ 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.; ’	‘ 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.; ’	

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	’			
Article 28, first paragraph, point (e)				
236	(e) in Article 6, paragraph 1, point c is replaced by the following:	(e) in Article 6, paragraph 1, point c is replaced by the following:	(e) in Article 6, paragraph 1, point c is replaced by the following:	
Article 28, first paragraph, point (e), amending provision, numbered paragraph (c)				
237	‘ (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. ’	‘ (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. ’	‘ (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				
238	Chapter VIII Final provisions	Chapter VIII Final provisions	Chapter VIII Final provisions	
Article 29				
239	Article 29 Obligation of the market actors to provide information	Article 29 Obligation of the market actors to provide information	Article 29 Obligation of the market actors to provide information	
Article 29(1)				
240	1. Marketing authorisation holders and other economic operators in the supply and	1. Marketing authorisation holders and other economic operators in the supply and	1. ***For the purposes of Articles 6, 8, 11(1), 12, 15, 16(2) and 26(2) point (a) the national***	

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	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.	distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission***, the Agency*** or national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation.	***competent authorities concerned may request information from promoters of industrial projects, project promoters,*** marketing authorisation holders and other ~~*economic operators*~~ ***actors*** in the supply and distribution chains of critical medicinal products ~~*including*~~***,*** their ~~*key inputs and*~~ active substances or ***key inputs, including from importers and manufacturers of medicinal products, active substances or key inputs and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply*** medicinal products ~~*of common interest shall upon request provide the Commission or*~~***to the public.*** ***For the purposes of Article 30 the*** national ***competent*** authorities~~*, as relevant, the requested*~~ ***may request*** information ~~*necessary*~~ ***from the market actors referred to in paragraph 1, contracting authorities and other stakeholders.***	

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			For the ~~*purpose of application of this Regulation*~~***purposes of Article 11(2) the Agency may request information from project promoters, marketing authorisation holders, manufacturers of medicinal products and manufacturers or suppliers of active substances or key inputs***.	
Article 29(2)				
241	2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.	2. The Commission***, the Agency*** and national authorities of the Member States shall ~~*aim*~~***take all appropriate measures*** to avoid duplication of the information requested and submitted***, making full use of information already available to them under Union pharmaceutical legislation, including data submitted in the context of marketing authorisation procedures, variations, inspections, and other regulatory filings, so as to minimise additional administrative burden on economic operators. Requests for supplementary information shall be limited to what is necessary to ensure effective monitoring, analysis and assessment.***	2. ~~*The Commission and*~~***Where information is requested by*** national ***competent*** authorities ~~*of the Member States shall aim to avoid duplication of*~~***or the Agency, as relevant, pursuant to paragraph 1, an actor may indicate that*** the information requested ***has already been provided to the national competent authority concerned or the Agency pursuant to other relevant Union legal acts. In such cases the national competent authority concerned or the Agency shall take due account of the information already provided in so far as this information has been provided and may be used also for the purposes of this Regulation*** ~~*and submitted*~~.	
Article 29(3)				

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242	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.	3. The Commission***, the Agency and the competent*** ~~*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***, and shall restrict access to such information strictly to staff responsible for applying this Regulation. The Commission and the national authorities, their officials, employees and other persons working under the supervision of those authorities shall ensure the confidentiality of information obtained in carrying out their tasks and activities in accordance with relevant Union and national law. This paragraph shall also apply to all representatives of Member States, observers, experts and other participants attending meetings of the Critical Medicines Group. In addition, they shall also ensure that digital systems used for data collection and analysis include***	3. ***Where a market actor submits information pursuant to paragraph 1, the actor shall indicate whether the information provided contains any commercially confidential information, identify the relevant parts of that information having a commercially confidential nature and explain why that information is of such nature. The*** ~~*The Commission and*~~ national ~~*authorities of the Member States*~~***competent authority or the Agency, as relevant,*** shall assess the merits of ~~*duly substantiated*~~***each*** confidentiality ~~*claims*~~***claim*** made by ~~*marketing authorisation holders and other economic operators, requested to provide information per paragraph 1,*~~ ***the actors*** and shall protect any information that is commercially confidential against unjustified disclosure ***in accordance with Article 29a***.	

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		appropriate cybersecurity measures.		
Article 29a				
242a		***Article 29a*** ***Obligation of the Commission to collect information on medicinal products with no adequate Union substitute***		
Article 29a(1)				
242b		***1. The Commission shall collect the necessary information from the Agency and national authorities of the Member States and establish, taking as a basis the list of critical shortages of medicinal products referred to in Chapter X of Regulation (EU) No …/… [reference to be added after adoption cf. COM(2023) 193 final], a list of critical medicinal products originating from third countries for which no adequate substitute produced within the Union is available. The Commission shall maintain and keep that list regularly updated.***		
Article 29a(2)				
242c		***2. The list referred to in paragraph 1 shall serve to identify***		

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		and monitor strategic dependencies and to support the adoption of appropriate measures under this Regulation aimed at ensuring the continuous supply and availability of such medicinal products within the Union.		
Article 29a(3)				
242d		***3. In developing and updating the list referred to in paragraph 1, the Commission shall take into account the public health relevance, therapeutic importance, and criticality of the medicinal products.***		
Article 29a				
242e			***Article 29a*** ***Handling of confidential information***	
Article 29a(1)				
242f			***1. Information acquired in the course of implementing this Regulation shall be used only for the purposes of this Regulation and shall be protected by the relevant Union and national law.***	
Article 29a(2)				
242g			***2. Member States, the Commission and the Agency shall***	

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			ensure the protection of trade and business secrets and other commercially confidential information obtained and processed in application of this Regulation, in accordance with Union and relevant national law.	
Article 29a(3)				
242h			***3. The Commission, the Agency and the national competent authorities, their officials, employees and other persons working under the supervision of those authorities shall ensure the confidentiality of information obtained in carrying out their tasks and activities in accordance with relevant Union or national law. This obligation also applies to all representatives of Member States, observers, experts and other participants attending meetings of the CMCG pursuant to Article 25.***	
Article 29a(4)				
242i			***4. Any obligations on sharing information pursuant to this Regulation shall not apply to data that concerns the essential interests of the Member States' security or defence.***	

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Article 30				
243	Article 30 Evaluation	Article 30 Evaluation	Article 30 Evaluation	
Article 30(1)				
244	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.	1. ***The Commission shall regularly monitor the implementation of this Regulation and its impact on the functioning of the internal market, competition, and the security of supply of medicinal products in the Union. In addition,*** by [OP please insert the date of:] five years after the date of application of this Regulation and every five years thereafter, the Commission shall ~~*evaluate*~~***within its evaluation assess the impact of other relevant Union legislation on*** this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.	1. By [OP please insert the date of:] ***at the latest*** five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.	
Article 30(2)				
245	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.	2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1	2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1 have been achieved. ***The evaluation***	

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		have been achieved. ***The evaluation shall in particular assess:***	***shall include an assessment of the scope, functioning and efficiency of Article 18 as well as coherence of this Regulation with developments within the field of public procurement.***	
Article 30(2), point (a)				
245a		***(a) data on the number of new manufacturing sites opened or modernised within the Union and the number of existing manufacturing lines extended;***		
Article 30(2), point (b)				
245b		***(b) the number and nature of projects confirmed, supported, or recommended by the Critical Medicines Group under this Regulation;***		
Article 30(2), point (c)				
245c		***(c) progress made in diversifying sources of active substances, starting materials, and other key inputs;***		
Article 30(2), point (d)				
245d		***(d) the effectiveness of measures adopted to mitigate structural risks and strengthen supply resilience;***		
Article 30(2), point (e)				

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245e		***(e) unintended effects on market concentration, competition including impact on SMEs, innovation incentives, or barriers to entry, and assess whether the Regulation remains proportionate and effective.***		
Article 30(3)				
246	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.	3. The national authorities and the economic operators***, patient and consumer organisations, as well as healthcare professional organisations*** 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.	3. The national authorities ~~*and the economic operators*~~ shall, upon request, provide the Commission with any relevant information they have and that ***is necessary for*** the Commission ~~*may need*~~ for its assessment ***and review*** pursuant to ~~*in paragraph 1*~~ ***paragraphs 1 and 2***.	
Article 30(3a)				
246a		***3a. Where the evaluation referred to in paragraph 1 identifies a potential risk to the availability or security of supply of a critical medicinal product in the Union, the Commission shall carry out a coordinated, evidence-based impact assessment and, where appropriate, propose proportionate and appropriate mitigating measures in consultation with the***		

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		Member States and relevant stakeholders.		
Article 30(3a)				
246b				
Article 30a				
246c		***Article 30a*** ***Exercise of the delegation***		
Article 30a, first paragraph				
246d		***1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.***		
Article 30a, second paragraph				
246e		***2. The power to adopt delegated acts referred to in Articles 20g(4) and 20h(2) shall be conferred on the Commission for an indeterminate period from … [date of application of this Regulation].***		
Article 30a, third paragraph				
246f		***3. The delegation of power referred to in Articles 20g(4) and 20h(2) may be revoked at any time by the European Parliament or the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It***		

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		shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 30a, fourth paragraph				
246g		***4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.***		
Article 30a, fifth paragraph				
246h		***5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.***		
Article 30a, sixth paragraph				
246i		***6. A delegated act adopted pursuant to Articles 20g(4) and 20h(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act. to the European Parliament***		

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		and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.		
Article 31				
247	Article 31 Entry into force and application	Article 31 Entry into force and application	Article 31 Entry into force and application	
Article 31, first paragraph				
248	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	***1.*** This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	
Article 31, second paragraph				
249	It shall apply from [….].	It shall apply from [….].	***2.*** It shall apply from [….].	
Article 31, second paragraph a				
249a			***3. Article 18 (1) and (2) shall apply from [12 months after the date of application in paragraph 2]. The requirements in Article 18 (1) and (2) shall apply to public procurement procedures launched after this date.***	
Article 31, third paragraph				

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250	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Formula				
251	Done at Strasbourg,	Done at Strasbourg,	Done at Strasbourg,	
Formula				
252	For the European Parliament	For the European Parliament	For the European Parliament	
Formula				
253	The President	The President	The President	
Formula				
254	For the Council	For the Council	For the Council	
Formula				
255	The President	The President	The President	

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