

Guarantee public return on public investment

Recitals 21 and 30d

Public funding must deliver concrete added public value. When financial incentives support strategic projects, binding access obligations should ensure not only availability but also affordability through equitable pricing, stockholding obligations in public procurement, and meaningful transparency. This way, the EU can ensure public return on public investment. This principle is already well established in EU legislation, for example in Articles 114 and 125 of [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#). These articles require recipients of EU research funding to ensure that the results of their activities are affordable, available and accessible to the public under fair and reasonable conditions.

The two following amendments should be therefore supported.

	Commission Proposal	EP Mandate	Council Mandate	Comments
	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	(21) Given the capital-intensive nature of pharmaceutical production, including the establishment or expansion of manufacturing sites for critical medicinal products, active substances, and key inputs, targeted financial support can play a crucial role in incentivising production within the Union. To strengthen the security of supply of critical medicinal products, and where private investment alone is not sufficient, financial support of investments in manufacturing capacity within the Union may be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with	(21) Given the capital-intensive nature of pharmaceutical production, including the establishment of , 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,	

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	<p>investments in manufacturing capacity within the Union may be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary.</p>	<p>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. <u>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.</u></p>	<p>financial support of investments in manufacturing capacity within the Union may be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary.</p>	
Recital 30d				
42d		<p><u>(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</u></p>		

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		<u>markets for medicines, vaccines, and other health products.</u>		

Articles 15 and 16

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

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	<p>strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary.</p>	<p><u>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.</u></p>	<p>financial support for strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary.</p>	
Article 15(1)				
143	<p>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).</p>	<p>1. Without prejudice to Articles 107 and 108 TFEU, Member States may<u>shall</u> prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products, <u>and, where applicable, medicinal products of common interest,</u> 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). <u>Financial support shall be proportionate to the financing needs of the strategic project and shall be subject to transparency requirements.</u></p>	<p>1. Without prejudice to <i>Union state aid rules as set out in</i> Articles 107 and 108 <i>Treaty of the Functioning of the European Union (TFEU)</i>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</p>	<p>A more robust EU transparency framework is indispensable to achieving equitable access and strengthened democratic accountability. The CMA should ensure that public financial support is subject to clear conditionalities, including comprehensive transparency requirements covering R&D costs, production costs, public contributions, commercial terms, and other key information and data.</p>

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			the Critical Medicines <i>Coordination</i> Group (<i>CMCG</i>) referred to in Article 26(2) point (a).	We therefore support the European Parliament's addition to subject financial support to binding transparency requirements, as a necessary safeguard to ensure public value for public investment and informed public oversight. The CMCG should develop guidelines detailing the transparency requirements.
Article 15(1a)				
143 a		<u><i>1a. Member States may, at the request of the Critical Medicines Group, establish contractual arrangements with economic operators on strategic projects to dedicate a portion of their manufacturing capacity to produce specific medicinal products, their pharmaceutical forms, their active substances and key inputs or technologies, or categories thereof, in order to address current, emerging or potential shortages within a fixed timeframe, determined by the Critical Medicines Group.</i></u>		
Article 15(1b)				
143 b		<u><i>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</i></u>		

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		<p><u>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.</u></p>		
Article 15(2)				
144	<p>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.</p>	<p>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 <u>by a Member State</u> for a strategic project shall prioritise <u>appropriate and continued</u> supply to the Union market <u>so that the needs of patients in the Member State in question are covered</u> and use its very best efforts to ensure that the critical medicinal product remains available in the Member States where it is being marketed. <u>This paragraph applies mutatis mutandis to medicinal products of common interest.</u></p>	<p>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 <i>all</i> the Member States where it is being marketed. <i>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.</i></p>	<p>In line with our calls for better articulated conditions on public funding, we support the EP's stronger wording on the obligations of producers benefiting from such funding to ensure a stable and reliable supply of products.</p>

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Article 15(2a)				
144 a		<u>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).</u>		As above, we support the dedicated wording obliging producers benefiting from public funding to take measures to ensure that end products are available and affordable. Such additions are aligned with the very purpose of the CMA.
Article 15(3), first subparagraph				
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 <u>project promoter to prioritise and</u> provide the necessary supplies of a critical medicinal product, <u>or, where applicable, medicinal product of common interest</u> , active substance or key inputs, as applicable, to the Union market <u>as a priority</u> to avoid shortages in one or several Member States.	3. The Member State that provided financial support to a strategic project may request <u>require</u> such undertaking to <u>prioritise supply and</u> 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 <u>more</u> 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	Any Member State that encounters a threat of shortages of the critical medicinal product <u>or medicinal product of common interest</u> in question may demand the Member State that provided financial support to submit a request on its	Any Member State that encounters a threat of shortages of the critical medicinal product in question may demand <u>request</u> the	

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	financial support to submit a request on its behalf.	behalf. <u><i>The project promoter shall undertake its very best efforts to supply such products in the requesting Member State.</i></u>	Member State that provided financial support to submit a request on its behalf.	
Article 15(3a)				
146 a		<u><i>3a. Where a project promoter that receives financial support fails to comply with the obligations in paragraphs 2 and 3, the financial support granted to the strategic project may be suspended, revoked or recovered, in whole or in part, by the Member State concerned. In addition, the project promoter may be subject to an effective, proportionate and dissuasive financial penalty in accordance with national law of the Member State concerned or an exclusion from funding proportionate to the impact and severity of non-compliance.</i></u>		Along with the explicit obligations, we support the inclusion of dissuasive penalties to increase compliance by funding beneficiaries and to ensure that the public interest objectives of the legislation are met. Effective penalties are essential to guarantee that obligations attached to public funding are enforceable.
Article 15(3b)				
146 b		<u><i>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-</i></u>		

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		<u>limited and targeted to safeguard public health within the Union.</u>		
Article 15(3c)				
146 c		<u>3c. Where financial support has been granted, the project promoter shall demonstrate that the funds have been used within the territory of the Union.</u>		
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(1)				
148	<p>1. For the duration of the Multiannual Financial Framework 2021-2027¹ strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme², Horizon Europe³, and the Digital Europe Programme⁴ provided that such support is in line with the objectives set out in the regulations establishing those programmes.</p> <p>¹ Council Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial</p>	<p>1. For the duration of the<u>All the Union funding under the current and future</u> Multiannual Financial Framework 2021-2027¹ <u>Frameworks, including regional policy funding programmes, may support</u> strategic projects may be supported by Union funding, including but not limited to such Union <u>unless explicitly excluded by the legal basis or the scope of relevant</u> programmes as the EU4Health Programme², Horizon Europe³, and the Digital Europe Programme⁴ <u>and</u> provided that such support is in line with the objectives set out in the regulations establishing those programmes.</p> <p>1. Council Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for years 2021 to 2027, as amended (OJ L1 433,</p>	<p>1. Financial support for strategic projects underFor the duration of the Multiannual Financial Framework 2021-2027¹ 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 Programme², established by Regulation (EU) 2021/522, Horizon Europe³ established by Regulation (EU) 2021/695, and the Digital Europe Programme⁴ established by Regulation (EU) 2021/694,</p>	

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	<p>framework for years 2021 to 2027, as amended (OJ L1 433, 22.12.2020, p.11, ELI: http://data.europa.eu/eli/reg/2020/2093/oj)</p> <p>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)</p> <p>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)</p> <p>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)</p>	<p>22.12.2020, p.11, ELI: http://data.europa.eu/eli/reg/2020/2093/oj)</p> <p>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)</p> <p>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)</p> <p>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)</p>	<p>provided that such support is in line with the objectives set out in the respective regulations establishing those programmes.</p> <p>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.</p> <p>1. Council Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for years 2021 to 2027, as amended (OJ L1 433, 22.12.2020, p.11, ELI: http://data.europa.eu/eli/reg/2020/2093/oj)</p> <p>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)</p> <p>3. Regulation (EU) 2021/695 of the European Parliament and of</p>	

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			<p><i>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)</i></p> <p><i>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)</i></p>	
Article 16(1), second subparagraph				
148 a		<p><u><i>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</i></u></p>		

	Commission Proposal	EP Mandate	Council Mandate	Comments
		<u><i>instruments, to support the achievement of the objectives of this Regulation.</i></u>		
Article 16(1), third subparagraph				
148 b		<u><i>If a project promoter has received financial support for a strategic project from Union funding, it shall prioritise supply to the Union market and shall ensure that the critical medicinal product or, where applicable, medicinal product of common interest, remains available in the Member States where it is being marketed.</i></u>		
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	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	

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	strategic projects identified as addressing an existing vulnerability in the supply chains without delay.		<p>shall inform the Commission about the strategic projects identified as addressing an existing vulnerability in the supply chains without delay.</p> <p><i>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.</i></p>	
Article 16(2a)				
149 a		<u>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</u>		As mentioned in our comment on line 146a, we support the establishment of proportionate and dissuasive penalties to

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		<u><i>57 of Directive (EU) .../... of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final]. Where a project promoter fails to comply with those obligations, the Commission may suspend, revoke or recover the funding, in whole or in part, in accordance with the applicable rules. In addition, the Commission may impose a financial penalty or exclusion from future funding that is proportionate to the impact of the non-compliance, time-limited, and targeted to safeguard public health within the Union.</i></u>		support the achievement of the objectives of this legislation.
Article 16(2b)				
149 b		<u><i>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.</i></u>		
Article 16(2c)				
149 c		<u><i>2c. The Commission shall establish a 'one-stop-shop' to coordinate the award of Union funds pursuant to this</i></u>		

	Commission Proposal	EP Mandate	Council Mandate	Comments
		<u>Article and to support Member States' authorities with the prioritisation of financial support to strategic projects pursuant to Article 15.</u>		
Article 16(2d)				
149 d		<u>2d. Where financial support has been granted, the project promoter shall demonstrate that the funds have been used within the territory of the Union.</u>		