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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Critical Medicines Act)
N° Cion doc.:	ST 6872 2025 INIT
Subject:	Critical Medicines Act - Comments from the delegations

Delegations will find enclosed comments on the chapter III and VII of the Critical Medicines Act (ST 6872/25).

Critical Medicines Act – Chapter III and VII Deadline: ***18 July 2025***

From: AT, BE, CZ, EE, FI, FR, HU, IE, LT, MT, NL, RO, SE, SI **Updated: 23/07/2025 11:26**

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Guidelines to be followed

Please add your contributions in the table below, only in the columns **'Drafting' and/or 'Comments'**

Name of document: please rename the MS Word document by adding the **two initials** of your delegation's Country followed by a space.

Only then you may add any text to the file name, for example, for Austria: **AT comments on … .docx .**

Thank you for your cooperation!

Commission proposal	Drafting suggestions and Comments
General comments	CZ (Comments): In relation to the medicinal products of common interest, CZ considers it important to define what is the market failure stated in its definition and to clarify the process of determining a medicinal product of common interest and where their list will be published at the EU level. This item should be clarified. SE (Comments): SE maintains its scrutiny reservation on the entire CMA proposal SI (Comments): SI expresses its support in principle for the possibility to recognise strategic projects and emphasize that in addition to promoting innovation, special attention should be paid to the EU's strategic independence from third markets and to ensuring that existing production within EU is maintained.

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Commission proposal	Drafting suggestions and Comments
	SI also highlights the need to ensure improved coordination at EU level in determining strategic projects, as it is necessary to strive for a harmonized approach at EU level. SI considers that the procedure for recognising the status of a strategic project, and roles of the competent authorities are not well defined. SI would also call on the European Commission to consider developing guidelines that would lead to improved coordination on strategic projects on EU level. Regarding the financial incentives, SI believes that it is necessary to rely both on state aid as well as on the EU financial mechanisms. We believe that we must not only have to check existing EU instruments (*Multiannual Financial Framework 2021-20271 strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme, Horizon Europe, and the Digital Europe Programme*), but also look beyond the current Multiannual Financial Framework, beyond 2027.
Chapter III **Enabling conditions for investment**	
SECTION I	

[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)

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Commission proposal	Drafting suggestions and Comments
CRITERIA AND PROCEDURE FOR THE RECOGNITION OF STRATEGIC PROJECTS	CZ (Comments): To ensure the clarity of the text and its consequent applicability, CZ is in general of the opinion that the manufacture of medicines in the EU and its significant part should be defined in relation to strategic projects, financial incentives and public procurement. This item should be clarified.
Article 5	FR (Comments): The definition of Strategic Projects fit perfectly with the need identified. if there was a need for a more restrictive definition of 'key inputs', it could be linked to the 'key inputs' identified in the 'vulnerability assessment' exercise. RO (Comments): RO supports the provisions of Article 5, considering important CAPEX and OPEX investments in production, environmental upgrades for a level playing field and digitalization so that production can adapt more easily to variations in demand in order to support the critical medicines industry. In this respect, in addition to strengthening the European pharmaceutical supply chain by facilitating the production of modernized active pharmaceutical ingredients (APIs), finished dosage forms, essential raw materials and key intermediate products within the EU, investments in innovative production processes, relocation of key chemical processes, water and energy efficiency and better batch quality control should be the focus of investment.

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Commission proposal	Drafting suggestions and Comments
Strategic Projects	CZ (Comments): For CZ it is crucial to establish a system that supports the medicine manufacture in the EU through the strategic projects, financial incentives and public procurement. Moreover, it should be ensured that medicines supported through strategic projects and related financial incentives will be bought and used in EU Member States as the aim is to ensure long lasting and safe supply chains for these medicines in the EU. FI (Comments): In general, FI supports the general concept. However, more guidance to Member States on the criteria could be useful. We support the DE proposal of derogation for application that poses national security.
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:	AT (Drafting suggestions): A project located in the Union and related to creating**,** ~~or~~ increasing **or preserving** manufacturing capacity shall be considered as a strategic project if it meets at least one of the following criteria: AT (Comments):

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Commission proposal	Drafting suggestions and Comments
	AT: Not only the expansion of capacities should be considered, but also the preservation of production capacities in the EU should be explicitly mentioned. Therefore, we suggest the wording "… creating, increasing or preserving manufacturing capacity …" to ensure complete clarity. LT (Comments): LT: We think that it would be appropriate to entitle the Commission to develop EU guidelines on the application of the criteria and the assessment of the compliance of projects with strategic projects. A harmonized approach is needed to what extent the manufacturing capacity of critical medicines, their active substances be increased, modernized, sustainability and efficiency must be increased in order for the project to be classified as a strategic project.
a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances;	AT (Drafting suggestions): AT: it creates or increases manufacturing capacity for one or more critical medicinal products, ~~**or**~~ for ~~**collecting or manufacturing**~~ their active substances **or for the synthesis of their raw materials;** AT (Comments):

Commission proposal	Drafting suggestions and Comments
	AT: We suggest to add the term "or for the synthesis of their raw materials" as some companies may be specialised in the synthesis of raw materials that are then needed in the further production process. This should not per se be excluded from the considerations for a strategic project.
b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency;	
c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances;	
d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.	
	CZ (Drafting suggestions): 2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from support for a strategic project in accordance with this Section shall prioritise supply to the Union market and use its very best efforts to ensure

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Commission proposal	Drafting suggestions and Comments
	that the critical medicinal product remains available in the Member State where it is being marketed. CZ (Comments): CZ believes that the Critical Medicines Act should state that critical medicines manufactured under strategic projects should primarily cover the needs of the EU market. Please see the proposed text. EE (Drafting suggestions): The Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article 24 may issue guidance to further specify the criteria. EE (Comments): Further guidance from the coordination group or the Commission on the criteria could be useful in order to facilitate implementation.
Article 6	
Recognition of Strategic Projects	FI (Comments): More clarity for the processes would be useful. To avoid duplication of work and harmonization of implementation, the coordination and information change between Member States should be ensured

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Commission proposal	Drafting suggestions and Comments
1. Each Member State shall designate an authority ('the designated authority') that shall assess and verify whether or not a project meets at least one of the criteria set out in Article 5 and therefore constitutes a strategic project.	BE (Drafting suggestions): Each Member State shall designate an authority ('the designated authority') that shall assess and verify whether or not a project meets at least one of the criteria set out in Article 5 and therefore constitutes a strategic project. **A Member State may designate more than one designated authority, at national or regional level.** BE (Comments): The appointment of the designated authority should take into account the constitutional realities of MS and the division of competences on both regional and national level. Therefore, it may be the case that one MS has more than one designated authority. LT (Comments): LT: We consider it appropriate to provide for the possibility for Member States to cooperate in the approval of strategic projects. Furthermore, it would be advisable to allow other interested Member States — for instance, those willing to provide financial or other forms of support — to participate in the process of evaluating and designating projects as strategic.

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Commission proposal	Drafting suggestions and Comments
A promoter may request the designated authority to assess whether a project is a strategic project.	CZ (Drafting suggestions): A promoter ~~may~~ shall request the designated authority to assess whether a project is a strategic project. CZ (Comments): Please see the CZ comment related to para 4 of this Article.
Any Member State authority may request the designated authority to verify its determination of whether a project is a strategic project.	CZ (Drafting suggestions): ~~Any Member State authority may request the designated authority to verify its determination of whether a project is a strategic project.~~ CZ (Comments): Please see the CZ comment related to para 4 of this Article. Therefore, this part is proposed to be deleted. EE (Drafting suggestions): ~~Any Member State authority may request the designated authority to verify its determination of whether a project is a strategic project.~~ EE (Comments):

Commission proposal	Drafting suggestions and Comments
	We propose that it should always be the promoter who will request determination as strategic project by the designated authority. A single entry-point at the national level would be more efficient. LT (Comments): LT: paragraph 1, subparagraphs 2-3 and paragraph 4 provide that the project promoter may apply for recognition of the project as strategic both to the designated authority and to any other Member State's authority. We think that such a procedure will potentially create an additional administrative burden for the authorities and creates uncertainty for stakeholders. It would be more rational to provide the task of project assessment only to the designated Member Sate's authority and, accordingly, to establish the obligation of the project promoter to apply only to it. RO (Comments): we would like to request clarifications on para. 3(1); In our understanding, since in para. 1(1) states that each MS shall designate an authority ("designated authority") to assess and verify whether or not a project fulfils at least one of the criteria set out in Article 5, we do not understand how and on what basis another institution of the same MS can request whether a project falls into this category, once it has been declared strategic. We also similarly wish to seek clarification on para. 4 for which we have the same comment.

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Commission proposal	Drafting suggestions and Comments
	We consider that the flow would be as follows: the initiator forwards the request to the designated authority in the MS; the other authorities should recognize and apply the conclusions of the designated authority, with the particularities that accompany such projects.
2. Member States shall communicate to the Commission what is the designated authority for the purposes of paragraph 1.	
3. The Commission shall provide a simple, accessible webpage on which the contact details and other relevant information on the Member States' designated authorities shall be clearly listed.	AT (Comments): AT: "other relevant information" needs to be further elaborated.
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.	CZ (Drafting suggestions): ~~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.~~ CZ (Comments):

Commission proposal	Drafting suggestions and Comments
	CZ considers it important to allow Member States to set the system of verification of the strategic projects so that the designated authority makes the decision, and not any other Member States authority, or, where appropriate, a binding opinion is issued by the designated authority. Therefore, this part is proposed to be deleted. EE (Drafting suggestions): ~~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.~~ EE (Comments): The request from the promoter should always be submitted to the designated authority as a first step. Although it might be considered as an additional administrative step, it would ensure an overview of strategic projects at the national level, also for better strategic planning. Moreover, other permit granting authorities may not be well-placed to decide on whether the project meets the criteria for strategic projects. FR (Comments): The French authorities have reservations about this mechanism, as we believe it would be more effective to have a centralised national mechanism with one or more Designated Authorities. This would (i) give these authorities a better overall view of strategic projects and enable them to take coherent action (ii) speed up the awarding of 'Strategic

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Commission proposal	Drafting suggestions and Comments
	Project' status thanks to one or more 'Designated Authorities' who would have a full grasp of the associated definitions and the issues relating to critical medicinal products. RO (Comments): See comments above.
	BE (Drafting suggestions): **The Member State authority shall assess whether at least the criteria are fulfilled within one month of the receipt of the request. Where the authority request the verification of the designated authority, the deadline shall be prolonged by an additional month.** **Where an authority decides that a project meets at least on of the criteria, it shall without undue delay inform the designated authority.** BE (Comments): There should be clear and predictable deadlines within which the decision should be taken. Additionally, it is essential that the designated authority is promptly informed by other relevant authorities whenever a project is granted "Strategic Project" status (for the cases where it is not involved). This notification is crucial given the SPOC's role in ensuring seamless coordination and communication..

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Commission proposal	Drafting suggestions and Comments
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.	CZ (Drafting suggestions): ~~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.~~ CZ (Comments): Please see the CZ comment related to para 4 of this Article. Therefore, this part is proposed to be deleted. MT (Comments): This could be interpreted that if a MS' designated authority refutes the Project and concluded it is not strategic, it cannot be initiated somewhere else. To introduce clarity, MT suggests rewording to "any other authority shall rely on that verification if the project was deemed strategic," If it was NOT deemed strategic by one MS, it might be more relevant to other MS', so it might be categorized as strategic to them but not the initial one(s) that did not initially deem the project as strategic.
	LT (Comments): LT: We think it would be beneficial for Member States if information were published about all strategic projects, not only those that have received financial support (as currently provided for in Article 17).

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Commission proposal	Drafting suggestions and Comments
Section II	
Facilitating administrative and permit-granting processes	EE (Drafting suggestions): **Facilitating administrative and permit-granting processes to strategic projects determined by the designated authority** EE (Comments): The concept of a strategic project as defined in Article 3 (10) covers only the identification of a project as strategic but does not entail its determination as such by the designated authority. For clarity, we suggest adding that the accelerated processes are enabled to those projects that have been determined by the designated authority in accordance with Article 6. Not all projects that may, by their nature, meet the criteria of Article 5 can be treated as projects to which accelerated procedures apply. This would make it very difficult for the Member States' authorities to plan and organise their work effectively. Alternatively, respective amendment in the definition of "strategic project" could be considered.
Article 7	

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Commission proposal	Drafting suggestions and Comments
Priority status of strategic projects	
Strategic projects shall be considered as contributing to the security of supply of critical medicinal products in the Union and, therefore, to be in the public interest.	
The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects are carried out in the fastest way possible, making available, in particular, any form of accelerated procedures that exists in applicable Union and national law.	
Article 8	
Administrative support	FI (Comments): The administrative support can mean a large administrative burden to the Member States.
1. Upon request of a project promoter, a Member State shall provide to a strategic project located on its territory all the administrative support	IE (Drafting suggestions):

Commission proposal	Drafting suggestions and Comments
necessary to facilitate its timely and effective implementation, including assistance:	Suggest removal of the words 'all the' and 'necessary', text to now read: Upon request of a project promoter, a Member State shall provide to a strategic project located on its territory administrative support to facilitate its timely and effective implementation, including assistance:
a) with regard to compliance with applicable administrative and reporting obligations;	
b) with regard to informing the public, with the aim of increasing public acceptance of the strategic project;	
c) along the permit-granting process.	
2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs) and, where appropriate, establish a dedicated channel for communication with SMEs to provide guidance and respond to queries related to the implementation of this Regulation.	AT (Comments): AT: It should be precisely defined when a dedicated channel is to be set up.

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Commission proposal	Drafting suggestions and Comments
Article 9	
Request for granting the status of highest national significance	NL (Comments): NL has one clarifying question regarding this article: We request clarification from the European Commission on the coherence of this proposal with European pharmaceutical legislation, and clarification on how this priority principle for strategic projects would affect the working methods of the EMA and what this means in practice.
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.	IE (Comments): In IE, Planning and Development Act currently provides for development to be designated as Strategic Infrastructural Development. Preference is for this to remain a competence of the Member State and for the text to reflect this. RO (Comments): In order to ensure a uniform and consistent application of the provisions, we consider it necessary to introduce a clear definition of the concept of "status of the highest national significance" in the text of the Regulation. In its current form, Article 9 allows this status to be granted " when such a status exists in national law ", but the lack of a common definition may lead to diverging interpretations between Member States, affecting the transparency, fairness and predictability of the authorization process for projects of strategic interest.

Commission proposal	Drafting suggestions and Comments
	While it is natural for each Member State to have its own methodology for setting national priorities, a common reference framework at European level would contribute to creating a harmonized minimum standard for the identification of projects of national importance and a common understanding of the eligibility criteria.
2. National authorities shall grant the status of the highest national significance to an application for a permit without prejudice to obligations provided for in Union law.	
Article 10	
Procedures relating to dispute resolution	
A project promoter may request that any dispute resolution procedure, litigation, appeal and proceedings on judicial remedies related to the permit-granting process and the issuance of permits for a strategic project in the Union before any national courts, tribunals or panels, including with regard to mediation or arbitration, where they exist in national law, is treated as urgent if and to the extent to which national law provides for such an urgency procedure. The applicable rights of defence of	BE (Drafting suggestions): ~~A project promoter may request that~~ **A**ny dispute resolution procedure, litigation, appeal and proceedings on judicial remedies related to the permit-granting process and the issuance of permits for a strategic project in the Union before any national courts, tribunals or panels, including with regard to mediation or arbitration, where they exist in national law, ~~is~~ **shall be** treated as urgent if and to the extent to which national law provides for such an urgency procedure. The applicable rights of defence

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Commission proposal	Drafting suggestions and Comments
individuals or of local communities shall be respected during such urgency procedure.	of individuals or of local communities shall be respected during such urgency procedure. BE (Comments): In line with the Net Zero Industry Act, it should be mandatory to treat all dispute resolution procedure or other proceedings as urgent. It should not be written as a mere option as it currently is. LT (Drafting suggestions): A project promoter may request that any dispute resolution procedure, litigation, appeal and proceedings on judicial remedies related to the permit-granting process and the issuance of permits for a strategic project in the Union before any national courts, tribunals or panels, including with regard to mediation or arbitration, where they exist in national law **and where national law provides for the possibility of applying mediation or arbitration in disputes of this type**, 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. LT (Comments): LT: the mere formal existence of mediation or arbitration institutions in national law does not determine their applicability to a specific type of

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Commission proposal	Drafting suggestions and Comments
	dispute. Therefore, in order to achieve legal clarity regarding the application of mediation and arbitration in disputes relating to the permit-granting process for strategic projects in the Union, and to ensure the compatibility of the provisions of the Proposal with the specificities of national legal systems, we suggest amending this provision.
	LT (Comments): LT: It follows from the provisions of Article 10 ar Article 7 of the Proposal that urgency procedures apply only when they are provided for in national law. Nevertheless, Recital 18 provides that strategic projects should benefit from streamlined procedures and given priority status but does not refer to national law. In the interests of legal clarity, it is appropriate to amend Recital 18 by clearly indicating that this is left to the discretion of the Member States and regulated by national law.
The project promoter shall participate in such urgency procedures, where applicable.	
Article 11	

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Commission proposal	Drafting suggestions and Comments
Regulatory and scientific support from medicines agencies and pharmaceutical inspectorates	CZ (Comments): CZ would like to point out that timelines for granting manufacturing authorization are set by Directive 2001/83/EC (90 days), but there are no defined criteria for the priority inspections or processing of the application. Internal procedures can be used to prioritise GMP inspections, specifically in the context of strategic projects, however, we are of the opinion that compliance with GMP requirements shall not be compromised. This part should be clarified. FI (Comments): The regulatory support by the National Medicines Agencies need to be ensured in strategic projects dealing with critical medicines. FR (Comments): Generally speaking, the French authorities are in favour of regulatory fast track that can enable faster market access for strategic projects. One of the weakest links in the value chain is API production (which has been documented by the alliance). CEP approval, although not required, helps API producers penetrate the EU market. For strategic projects it would be relevant to also gain a deeper understanding of how this regulatory process can be fast tracked for strategic projects. As such, the French authorities would like the Commission to present the various mechanisms for fast-tracking (in the pharma legislation for example) including an EDQM presentation for the CEP part.

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Commission proposal	Drafting suggestions and Comments
	It will also be interesting to understand thanks to EMA how this fast-track mechanism would be organized in the context of centralised procedures. IE (Drafting suggestions): *Regulatory support from medicines agencies and pharmaceutical inspectorates*
1. Upon request of a project promoter, a Member State shall provide regulatory support to a strategic project located on its territory, including by prioritising Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project.	BE (Drafting suggestions): 1. **Project promoter shall inform the national competent authority in advance of their intention to submit a request at the time of the first application pursuant to Article 6.** Upon request of a project promoter, a Member State shall provide regulatory support to a strategic project located on its territory, including by prioritising Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project. BE (Comments): In the proposal for the Critical Medicines Act, promoters of strategic projects are to receive regulatory support from Member State authorities, including, for example, prioritised inspections of Good Manufacturing Practices (GMP) for new or expanded manufacturing sites. While we

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Commission proposal	Drafting suggestions and Comments
	endorse the intentions of these provisions, a prior notification by the project promoter to the designated authority would be a crucial element for the feasibility of such prioritisation as, for example, the legally mandated timeframe in the case of GMP inspections is very short (90 days). To ensure the shortest possible timeline, it is essential that projects are submitted in a clear and structured manner within a reasonable timeframe, accompanied by a detailed retroplanning. This will help identify potential issues early and allow for inspections to be scheduled as efficiently as possible. HU (Drafting suggestions): (1) Upon request of a project promoter, a Member State shall provide regulatory and **scientific support** to a strategic project located on its territory, including by prioritising Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project. HU (Comments): HU believes that the pharmaceutical authorities should be the key players in the authorisation processes for strategic projects. We therefore believe that, in addition to regulatory support, Member States should be allowed to provide scientific support to project sponsors through their pharmaceutical authorities. IE

Commission proposal	Drafting suggestions and Comments
	(Comments): During WP meeting on 16th July, MS raised issue with the text of the article and the text of the title not matching. In relation to the addition of the words 'and scientific' to subsection 1 of Article 11, broadly IE could support this concept. However, we would have potential concerns around the implications of this addition in the absence of further specification of what is envisaged to constitute such 'scientific support'. For example, subsection 2 specifies the type of scientific support that is envisaged to be provided by the EMA. This is of particular importance in light of the fact that subsection 1 of Article 11 is a 'shall' provision, and as such the MS will be obligated to provide 'scientific support' if requested by a project promoter. For this reason, IE supports a change to the title of Article 11, as suggested above. RO (Drafting suggestions): Upon request of a project promoter, a Member State shall provide regulatory support **and single point of contact** to a strategic project located on its territory, including by prioritising Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project. RO (Comments): We ask a clarification of the term 'regulatory support'. Does this refer to prioritizing inspections, simplifying/prioritizing the issuing of marketing authorizations, informing health professionals and patient associations? We also believe that this scientific and regulatory support should be granted according to a degree of vulnerability resulting from the

Commission proposal	Drafting suggestions and Comments
	assessment, not for all medicinal products assessed as having a vulnerability - in which sense the assessment criteria and the methodology applied will be particularly important, as will the frequency with which the conclusions of this assessment are published.
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.	FR (Drafting suggestions): Upon request of a project promoter, the European Medicines Agency ('the Agency') shall provide, within the scope of its mandate and expertise, dedicated advice to assist project promoters expertise ~~developing projects relying on innovative manufacturing processes.~~ FR (Comments): The French authorities are in favour of not limiting the nature of advice provided by the EMA to manufacturing processes and have a case-by-case approach to advisory (within the EMA's expertise). IE (Drafting suggestions): 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. The relevant national inspectorate should be involved in this process in line with national member state processes. IE (Comments):

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Commission proposal	Drafting suggestions and Comments
	We would note that where the EMA is providing advice to project promoters on innovative manufacturing process and such advice includes aspects related to Good Manufacturing Practices, which would be subject to review during manufacturing site inspections, the relevant national inspectorate should also be involved. If this text is to remain in the final version, our preference would be that there is mention of the role of the national inspectorate. RO (Drafting suggestions): Upon request of a project promoter, the European Medicines Agency ('the Agency') shall provide dedicated advice **a single point of contact and accelerated review process** to assist project promoters developing projects relying on innovative manufacturing processes.
Article 12	SE (Comments): General comments on articles 12 and 13: As mentioned during the last meeting, SE fully supports the overall objective of this proposal, however we have some concerns about the scope and proportionality of the proposal. This concerns spatial planning, environmental assessment & authorisation, as well as issues related to national preparedness and national stocks of medicinal products which was discussed during last week. In general, the measures proposed should be proportionate and not go beyond what is necessary to achieve their objectives.

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Commission proposal	Drafting suggestions and Comments
	We should also strive towards simplification in terms of regulatory frameworks to reduce unnecessary burdens. Against this background, we are wondering whether the opportunities described in articles 12 and 13 are not too broad and whether they should be granted to all strategic projects or limited to specifically designated projects with a clear public interest, e g through contributing significantly to addressing acute shortages of important medicines. The size and scope of a project will also have an impact and should be taken into consideration.
Environmental assessments and authorisation	FI (Comments): The obligations need to be proportionate and decrease the administrative burden of Member States. We have no information about the content of the strategic projects. The deadlines are too tight giving extra burden to authorities and challenges to follow them. RO (Comments): in view of the competence and implications on this article, as further discussions with the competent authority at national level are needed, we indicate a scrutiny reservation. SE (Comments):

Commission proposal	Drafting suggestions and Comments
	We are concerned that the proposal in this article (12) is not compatible with current national administrative legislation and risks causing additional work for the authorities. Also, the proposed deadline (45 days with possibility to extend one time with 15 days at the most) is also too tight as well as more time for adaptations. The proposal seems to assume that Member States have a separate environmental assessment, while in Sweden we integrate the environmental assessment into the permit examination.
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/EEC2, Directive 2000/60/EC of the European Parliament and of the Council3, Directive 2001/42/EC of the European Parliament and of the Council4, Directive 2008/98/EC of the European Parliament and of the Council5, Directive 2009/147/EC of the European	LT (Comments): LT: we suggest to delete the reference to Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment in paragraph 1, since the assessment of the effects of a plan or programme on the environment is not identical to the assessment of a

[2] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj).

[3] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

[4] Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj).

[5] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj).

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Commission proposal	Drafting suggestions and Comments
Parliament and of the Council6, Directive 2010/75/EU of the European Parliament and of the Council[7], Directive 2011/92/EU of the European Parliament and of the Council[8] or Directive 2012/18/EU of the European Parliament and of the Council[9], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied.	specific project, which is carried out under Directive 2010/75/EU on industrial emissions and Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment. It should be noted that the assessment under Directive 2001/42/EC is referred to in Article 13(2) of the Proposal, indicating the obligation of an integrated assessment with other directives (Directive 92/43/EEC, Directive 2000/60/EC, Directive 2014/89/EU).
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.	IE (Drafting suggestions): Under the coordinated procedure referred to in the first subparagraph, a competent authority **may** coordinate the various individual assessments of the environmental impact of a particular project required by the relevant Directive.
Under the joint procedure referred to in the first subparagraph, a competent authority shall provide for a single assessment of the	

6 Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj).

7 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

8 Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj).

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

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environmental impact of a particular project required by the relevant Directive.	
2. Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information.	AT (Drafting suggestions): AT: 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 **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**. AT (Comments): AT: Based on national experience, we suggest extending the time limit to 90 days as 45 days seem rather short and, therefore, unrealistic. Additionally, we recommend clarifying that the time limit begins from the time the documents are complete and the public participation and any cross-border consultations have been carried out. For comparison, please see Art. 12, para. 3, of Regulation (EU) 2024/1252 and Art. 10, para. 3, of Regulation (EU) 2024/1735: “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 of a Strategic Project within 90 days of receiving all necessary information pursuant to

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	Articles 5, 6 and 7 of that Directive and after completing the consultations referred to in Articles 6 and 7 of that Directive." IE (Comments): A 45 or 60 day timeline for reasoned conclusions would be challenging if not impossible in most instances of the EPA's licensing process as currently set out in national legislation and IE would not be able to support this article. IE is currently considering what timeline would be suitable and will revert. RO (Comments): Negative scrutiny reservation. As already mentioned during the WP, several MS emphasized the administrative burden on national competent authorities as well as the short timeline.
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.	

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4. The deadlines for consulting the public concerned as referred to in Article 1(2), point (e), of Directive 2011/92/EU and the authorities referred to in Article 6(1) of that Directive on the environmental impact assessment report referred to in Article 5(1) of that Directive shall not be longer than 85 days and not shorter than the 30 day period referred to in Article 6(7) of that Directive.	
5. With regard to the environmental impacts or obligations referred to in Article 4(7) of Directive 2000/60/EC, Article 9(1), point (a), of Directive 2009/147/EC, Articles 6(4) and 16(1) of Directive 92/43/EEC and for the purposes of Article 4(14) and (15) and Article 5(11) and (12) of Regulation (EU) 2024/1991 strategic projects in the Union may be considered to have an overriding public interest and to serve the interests of public health and safety provided that all the conditions set out in those acts are fulfilled.	IE (Drafting suggestions): Removal of this point. IE (Comments): It is not clear how the concept of "overriding public interest" would affect a decision to be made by the EPA in IE on a licence application. This is because the last part of that sentence requires nonetheless that "all the conditions set out in those acts are fulfilled", those acts including the Water Framework Directive, the EIA Directive and the Habitats Directive. Meeting the requirements of "those acts" is not a new expectation. For the EPA to grant a licence it must be satisfied that all relevant aspects of "those acts" are complied with and this assessment is a key part of our consideration of a licence application. How we would overlay "overriding public interest" onto our process is not at this time clear and guidance would be required were the provision to survive the legislative drafting process.

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Article 13	RO (Comments): in view of the competence and implications on this article, as further discussions with the competent authority at national level are needed, we indicate a scrutiny reservation. SE (Comments): See comments under Article 12
Planning	
1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant spatial planning data is available.	
2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of	

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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 Council10, the combined assessment shall also cover those impacts.	
Article 14	IE (Comments): IE would vote to move point 1 to the recital and eliminate point 2 from the regulation.
Applicability of UNECE Conventions	
1. This Regulation is without prejudice to the obligations under the United Nations Economic Commission for Europe (UNECE) Convention	IE (Comments):

[10] Directive 2014/89/EU of the European Parliament and of the Council of 23 ELI: http://data.europa.eu/eli/dir/2014/89/oj July 2014 establishing a framework for maritime spatial planning (OJ L 257, 28.8.2014, p. 135, ELI: http://data.europa.eu/eli/dir/2014/89/oj).

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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.	We would remove this point in its entirety as we belief it is better placed in the recital.
2. All decisions adopted pursuant to the Articles in this section shall be made publicly available.	IE (Drafting suggestions): We would remove this point in its entirety.
Section III	
Financial incentives	
Article 15	LT (Comments):

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	LT: We have a general scrutiny reservation on Article 15. We are of the view (especially in light of the explanations provided by the Commission during the last meeting) that the proposed provision on financial support does not sufficiently address one of the key challenges related to critical medicines — namely, how to ensure a balanced supply of critical medicines, active substances, and key inputs when production volumes do not fulfil the needs of the entire EU market. We are confident that the supply of critical medicinal products must be ensured also to those Member States, where critical medicinal products have not been supplied before. The supply should be ensured without the additional administrative procedures, such as submitting a request to the Member State that provided financial support for the strategic project. RO (Comments): We would like to draw attention to the fact that in terms of establishing support measures at national level, the only options at the moment are: regional State aid (for investments, with significant own contribution, depending on the size of the enterprise and the geographical area, according to Regulation (EU) No. 651/2014), State aid for research (only for certain eligible costs and within the intensities allowed by the EU Regulation) or State aid for compensation granted for the provision of services of general economic interest (only if it can be demonstrated that there are no undertakings on the market that can provide the service under the conditions desired by the public authority), within the conditions set out in the State aid legislation.

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	Under these circumstances, the EU should give MS the possibility to apply for more flexible regional aid by increasing the share of aid allocated to the production of critical medicines, especially in regions with an industrial tradition. This approach would allow companies to consolidate and expand their existing production capacities, capitalizing on the availability of skilled and unskilled workforce and existing industrial infrastructure. Consequently, in order to achieve the objectives of this proposal, we consider it necessary to introduce more relaxed or targeted state aid rules (e.g. the introduction of a new article dedicated to critical medicines in EC Regulation 651/2014 or in the Commission Decision of 20.12.2011 on the application of Article 106(2) of the EC Treaty in the case of State aid in the form of public service compensation granted to certain undertakings entrusted with the provision of a service of general economic interest, so as to make the applicable procedure simpler and/or faster. Also, similar to the observation mentioned in Article 11, we consider it necessary to prioritize funding according to a degree of vulnerability resulting from the assessment, not for all medicines assessed with a vulnerability - in this sense we reiterate the importance of the assessment criteria and methodology applied, as well as the periodicity of publication of the conclusions of this assessment.
Financial support by Member States	BE (Comments): It must also be ensured that all the appropriate demand-side measures, such as MEAT procurement criteria, are activated, to favour the effective use of

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	the investments on the long-run and avoid the loss of the investment due to market failure, outside a crisis situation. CZ (Comments): CZ is of the opinion that at the level of Member States, the granting of public aid is limited by the applicable public aid rules, which, however, do not include a block exemption for the pharmaceutical manufacture sector, and restrict the possibility of aid to large enterprises and economically strong regions. These conditions need to be adjusted beyond the Critical Medicines Act so that investments in developed regions and for large enterprises can be effectively supported through Member States incentives, e.g., by introducing a block exemption for strategic projects in the pharmaceutical sector in line with the General Block Exemption Regulation.
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).	BE (Drafting suggestions): 1. Without prejudice to Articles 107 and 108 TFEU, Member States **shall** 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).

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	BE (Comments): These projects should focus on products for which the supply chain has been demonstrated to be vulnerable. EE (Comments): The text might benefit from more clarity that it refers to the vulnerability evaluation performed by the MSSG as foreseen in the pharmaceutical legislation (Art 132 Regulation). The EU level vulnerability evaluation should also reflect the regional aspects in order to ensure geographical balance and diversification of production capacity within the EU. IE (Comments): We would suggest that additional assurances may be needed to address scenarios where the entity who receives the financial support is no longer involved in the supply of the critical medicinal product (e.g. due to a transfer of ownership) to secure the long-term benefits for MSs for the financial support offered. We would also suggest that undertakings that receive financial support should be required to use their very best endeavours to make the critical medicinal product available in additional EU MSs and not just those where it is currently marketed, as additional manufacturing capacity may provide opportunities to supply additional MSs.
2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from	AT (Drafting suggestions):

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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 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. **If an undertaking has benefitted from financial support according to Art. 16 for a strategic project, it shall make the critical medicinal product available and supply on the market of the Union in sufficient quantities and in the presentations necessary to cover the needs of patients in the Union and prioritise supply to the Union market.** **For the purpose of safeguarding sufficient supply of critical medicinal products, the European Commission following a request by at least one Member State may decide to:** **(a) introduce measures/provisions ensuring that such an undertaking shall not export, re-export, transfer, or otherwise make available the respective critical medicinal product to any natural or legal person, entity, or country subject outside the EU; and/or** **(b) introduce provisions requiring an export authorisation prior to any transfer of the critical medicinal product outside the EU.**

Commission proposal	Drafting suggestions and Comments
	Any breach of this clause shall entitle the respective Member State to terminate the financial support for a strategic project with immediate effect, without prejudice to any other rights or remedies available. **(new 2a.) An undertaking that has benefitted from financial support for a strategic project shall make sure the marketing authorisation application is first submitted to the competent authority in the Union or is submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the Union.** AT (Comments): AT: welcomes that financial support is linked to prioritising supply to the Union market. Therefore, priority supply to the Union market and launch in Europe should be obligatory. Additionally, measures to limit exports in cases of shortages need to be established. CZ (Drafting suggestions): 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 based on this Article 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. CZ (Comments):

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	CZ is of the opinion, that it is important to clarify that *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* in case of Member State financial support as well as Union financial support. Please see the changes in wording proposed. Please see also the proposed text for Article 16 para 1a (there is also a possibility to state this obligation in a separate Article for both types of financial support). EE (Drafting suggestions): 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.~~ EE (Comments): We request the deletion of "where it is being marketed". There might be situation where the product is not marketed at a certain point of time but there still is a need in a particular Member State to have the product on the market. It would not be prudent to narrow it down to availability in those MS where the product is on the market at a certain point in time. Alternatively, it should be rephrased to "where it has a valid marketing authorisation"

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	FI (Comments): How would this be monitored? How will the Members States get information on undertakings and their possible prioritizing of supply to the EU market? FR (Drafting suggestions): ~~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. FR (Comments): Although the French authorities consider that it is perfectly natural for new State aid arrangements for critical medicinal products to be associated with compensatory measures (supply of the European market), these could be specified in a dedicated guideline or in the associated aid scheme. The counterparties should be specified with more precise guidelines, as at this stage the nature of the quid pro quos is very vague and does not provide either the beneficiaries or the Member States with any security. The French authorities will be making proposals for clarification. IE (Drafting suggestions): **Once** a critical medicinal product **has been placed** on the Union List of Critical Medicinal Products, an undertaking that has benefitted from

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	financial support for a strategic project shall prioritise supply to the Union market and use its very best efforts to ensure that the critical medicinal product remains available in the Member States where it is being marketed.
3. The Member State that provided financial support to a strategic project may request such undertaking to provide the necessary supplies of a critical medicinal product, active substance or key inputs, as applicable, to the Union market to avoid shortages in one or several Member States.	BE (Drafting suggestions): 3. The Member State that provided financial support to a strategic project may **require** 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. BE (Comments): Financial support, be it national or European, should only be granted on the condition that the European market receives priority in the delivery of medicines. EE (Comments): We would like to see more explicit wording on the obligation of the MAH to supply the Union market as a condition of receiving public funding and we are open to consider AT drafting proposals in his regard. At the same time, it would be important to maintain as far as possible an

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	EU approach to meeting the demand on the single market, not limited to self-sufficiency of individual Member States. FI (Comments): A safeguard relating to the functioning of the internal market should be added FR (Comments): As it stands, paragraph 3 is too vague to be applicable or reassuring for companies. The counterparties should be specified with more precise guidelines, as at this stage the nature of the quid pro quos is very vague and does not provide either the beneficiaries or the Member States with any security.
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.	
	AT (Drafting suggestions): AT: **(new 4.) For the purposes of paragraph 2, a Member State may require the undertaking that may benefit from financial support for a strategic project, to submit a roll-out plan which shall include information about the supply of the critical medicinal product (including quantities and presentations) by the undertaking over a**

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	given period in the Member State concerned. The roll-out plan shall be prepared by the undertaking and be agreed by the Member State concerned. The Member State may require the undertaking to update the roll-out plan upon request by the Member State. AT (Comments): AT: supports the inclusion of a roll-out plan to see if a strategic project can realistically cover demand.
	AT (Drafting suggestions): AT: **(new 5.) In the context of financial support according to Art. 15 or Art. 16, the sponsoring authority shall have the possibility to set up a list of requirements to be fulfilled for an agreed period concerning the framework conditions for the undertaking e.g. the supply, the pricing, export restrictions. These requirements will have to be agreed upon between the sponsoring authority and the undertaking. If the undertaking does not meet these requirements, the sponsoring authorities have the possibility of introducing appropriate sanctions, e.g. in the form of repayment of the financial support.** AT (Comments): AT: We suggest considering the possibility of introducing appropriate sanctions, for example in the form of repayment of the financial support,

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	if pre-agreed obligations concerning the supply in the Union are not fulfilled.
Article 16	CZ (Comments): CZ is of the opinion that it is necessary to secure EU funding for financing strategic projects beyond 2027.
Financial support from the Union	BE (Comments): We advocate for adequate European financing to cover the needs of the market. Ensuring access to critical medicines requires a realistic and flexible funding strategy that balances national and European contributions effectively. It is important the the EU provides sufficient incentives and resources to provide support for production capacity and strategic stockpiling. EE (Comments): Funding of strategic projects should focus primarily on products and supply chain segments where the EU faces the highest dependencies on third countries and the most severe risks of supply disruptions. It needs to be considered what would be the most effective way to set priorities for Union funding but also to coordinate national investment strategies. For example, to avoid that multiple Member States are investing in the same product or API in the same region, while also ensuring geographical balance. Currently this task is given to the Coordination

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	Group but we would be open to consider how to strengthen EU coordination even further. We note that there are no corresponding provisions as regards obligation to supply the Union market as a condition for receiving Union funding. Similar provisions should be included for both Articles 15 and 16. RO (Comments): We would like to reiterate that the proposal lacks a funding line dedicated to the large-scale production of critical medicines, the main funding instruments being those already approved in the current Multiannual Financial Framework 2021-2027, thus highlighting the primary role of national funding, limited funding as mentioned above in art. 15. As a result, in line with the recommendations set out in the report of the Critical Medicines Alliance, which clearly highlights the lack of a specific instrument and the need for such a coordinated EU funding program, it is an obvious need to create a fund dedicated to the objectives set out in the proposed AMC, as well as through the defence and competitiveness funds.
1. For the duration of the Multiannual Financial Framework 2021-202711 strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health	AT (Comments): AT: We see it of utmost importance that sufficient financial resources are also made available at the EU level. The support should not be left solely to the Member States as this would likely lead to significant discrepancies and be particularly problematic for small Member States. Promoting

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

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Programme12, Horizon Europe13, and the Digital Europe Programme14 provided that such support is in line with the objectives set out in the regulations establishing those programmes.	pharmaceutical production is cost-intensive and complex; funds from the EU defence budget should be accessible for CMA funding. FR (Drafting suggestions): For the duration of the Multiannual Financial Framework 2021-202715 strategic projects may be supported by Union funding, including but not limited to such Union programmes as the EU4Health Programme16, Horizon Europe17, and the Digital Europe Programme18. FR (Comments): As outlined by the Critical Medicines Alliance, current EU funding programmes are not fit for typical critical medicines projects (CAPEX, infrastructure modernisation, additional production lines…)

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12 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)

13 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)

14 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)

15 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)

16 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)

17 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)

18 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)

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	Without adapting these funds (in the current MFF) to the characteristics of the critical medicine's capacity building projects, the impact of this article will be limited.
	CZ (Drafting suggestions): 1a. 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 based on this Article 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. CZ (Comments): CZ would like to point out that while the financial incentives from the Member States require the subsequent supply of such critical medicines manufactured under such support to the EU market, the Union financial incentives are not linked to such an obligation. It should be stated in the Article 16 (or separate Article) similarly to the Article 15 para 2. Please see the changes in wording proposed.
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	AT (Comments): AT: As the methodology for the vulnerability evaluation is not yet established (which indicators?, what are the data requirements?, reasonable thresholds?, which data sources?, access to data? responsibilities?,…); the proposed time frame of 15 working days cannot yet be specified/fixed and is considered too tight.

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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.	As mentioned earlier, harmonisation with the General Pharmaceutical Legislation is essential as the provision for the vulnerability evaluation is embedded there. CZ (Comments): CZ would like to ask for clarification of Article 16 para 2 and would like to know what is meant by this provision and if it is useful. Moreover, the linkage between the assessment of the vulnerability in supply chains of medicines done by the designated authority and the vulnerability evaluation done by the MSSG which is mentioned in the Pharmaceutical Package should be clarified. CZ would also like to ask for clarification of the term "necessity to provide results". CZ cannot agree with the obligation of the designated authority to assess the vulnerability in supply chain of medicines in case of Union financial support. CZ will send the proposed text after the Working Party on July 23-24. EE (Comments): We are not certain about the role of the designated authority to provide the assessment in case of EU funding, it should be rather done at the EU level. The 15-days deadline would need to be reconsidered. IE (Comments):

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	We believe that vulnerability assessments to inform applications for Union funding should be performed at Union level with national input through MS membership of the group performing that evaluation.
	CZ (Drafting suggestions): **Article 16a** The European Commission shall in close collaboration with Member States create and update a Union investment strategy for critical medicines to ensure a diversified market and to avoid supporting similarly targeted strategic projects. CZ (Comments): CZ considers it appropriate not to support similarly targeted strategic projects across the Member States as we should avoid duplications, so that the EU market is diversified. A Union investment strategy for critical medicines should be developed and the coordination of those activities should be done at the Union level through the Coordination Group for Critical Medicines. Please see the proposed text. Additionally, changes to Chapter V shall be made. EE (Drafting suggestions): When providing Union funding, particular attention shall be paid to small and medium size enterprises (SMEs), including by offering administrative support to facilitate access to funding. EE

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	(Comments): A provision on special attention to SMEs should be included when it comes to access to Union funding.
Article 17	
Exchange of information on funded projects	
1. Member States shall inform the Critical Medicines Coordination Group ('the Critical Medicines Group') referred to in Article 24 of the intention to provide financial support to strategic projects sufficiently in advance to allow the group to carry out its coordination task as set out in Article 25.	
2. The Commission shall inform periodically the Critical Medicines Group of the strategic projects that benefited from financial support from the Union.	
The Commission may inform the Critical Medicines Group of the intention to propose the establishment of funding possibilities specifically designed to address vulnerabilities in the supply chains as well as inform	AT (Drafting suggestions):

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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 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. AT (Comments): AT: We suggest using the term "shall" instead of "may" in order to encourage a clear flow of information. CZ (Drafting suggestions): The Commission ~~may~~ shall 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. CZ (Comments): CZ is of the opinion that the Commission shall have an obligation to inform the Critical Medicines Coordination Group, not only a possibility. Please see the changes in wording proposed.

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Chapter VII **Amendments to Regulation (EU) 2024/795**	CZ (Comments): CZ agrees that strategic projects have the potential to fulfil the aim of the STEP. Therefore, CZ welcomes the possibility to priorities the strategic investments, or rather the support of these strategic projects through the financial instruments (InvestEU, Recovery and Resilience Plan, Horizon Europe, EU4Health, Digital Europe and cohesion policy programmes).
Article 28	
Regulation (EU) 2024/795 is amended as follows:	
(a) in Article 2, (1) point (a), subparagraph (iii) is replaced by the following:	
‘(iii) biotechnologies, and any other technologies relevant for manufacturing of critical medicinal products as defined in Critical Medicines Act *;	

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* Regulation (EU) … of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of critical medicinal products as well as for improving the availability of, and access to, medicinal products of common interest, and amending Regulation (EU) 2024/795.' [D.G.: reference to be completed with the definitive title of the 'Critical Medicines Act' and with its publications references once they are available];'	
(b) in Article 2, the following subparagraph is added in paragraph 3:	
'By way of derogation from the first subparagraph of this paragraph, the value chain for the development or manufacturing of medicinal products that fall within the scope of the [Critical Medicines Act] and that are referred to in paragraph 1, point (a)(iii) of this Article, relates to finished dosage forms, as well as to active pharmaceutical ingredients and other	

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key inputs necessary for the production of the finished dosage forms of critical medicinal products as defined in the Regulation.’;	
(c) in article 2, paragraph 8 is added:	
‘8. Strategic projects designated in accordance with the [Critical Medicines Act] that address a vulnerability in the supply chains of critical medicinal products shall be deemed to contribute to the STEP objective referred to in paragraph 1, point (a)(iii).’;	
(d) in Article 4, paragraph 7 is replaced by the following:	
‘7. Strategic projects recognised in accordance with the relevant provisions of the Net-Zero Industry Act, the Critical Raw Materials Act [and the Critical Medicines Act] that fall within the scope of Article 2 of this Regulation and that receive a contribution under the programmes referred to in Article 3 of this Regulation may also receive a contribution from any other Union programme, including funds under shared management, provided that those contributions do not cover the same	

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costs. The rules of the relevant Union programme shall apply to the corresponding contribution to the strategic project. The cumulative funding shall not exceed the total eligible costs of the strategic project. The support from the different Union programmes may be calculated on a pro rata basis in accordance with the documents setting out the conditions for support.’;	
(e) in Article 6, paragraph 1, point c is replaced by the following:	
(c) details of projects that have been recognized as strategic projects under the Net-Zero Industry Act, the Critical Raw Materials Act and the [Critical Medicines Act], to the extent that they fall within the scope of Article 2 of this Regulation.	

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