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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 Swedish delegation

Delegations will find enclosed additional comments from the Swedish delegation on the Chapter I, II, V, VI and VIII of the Critical Medicines Act (ST 6872/25).

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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!

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General comments		**SE General comments:** SE is positive to the intended goals of this proposed regulation, to mitigate and provide remedies to shortages of important medicinal products, in the EU. SE has at present a general scrutiny reservation with regard to the CMA, and reserves itself to further comments after an impact assessment has been presented and discussed. A general concern is that there may be differences in national legal instruments between MS that may distribute/drive allocation of strategic projects and their financing in a non-equitable way between MS. There are also concerns on legal interference with national competence. As an example, there is a need to clarify if a national authority in one

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		MS may to verify strategic projects on behalf of a national authority in another MS that may have financial consequences for concerned MS. Why is Article 6(4) (see also recital 18) necessary? What weight does a MS' assessment carry for another MS? Furthermore, we question the necessity and adequacy of regulating national building permit and planning procedures in a legal act concerning pharmaceuticals. National building permit and planning procedures should remain a national concern. The increased sectoral approach only risks increasing the overall incoherence in the national system, as well as the administrative burden for permit and planning authorities. There is a need for harmonised criteria for a project to be strategic to allocate state funding. There is a need to be clearer on expectations of delivery of critical medicines from MAHs that have received financial support. There is a need to determine relevant criteria for lack of availability (Articles 5, 15(2)) and when a MS may to act on joint procurement. There is a need of alignment, connecting points and avoiding duplication of relevant structures,

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		tasks and coordinating processes, with Chapter X in the proposed Pharmaceutical Regulation.
Chapter I **General provisions**		
Article 1		
Objectives and subject matter		
1. The objective of this Regulation is to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to		General question: What platform, control mechanism and legal instruments are there for an MS to contest or question support to strategic projects by other MS, if it risks distortion of an already functioning market?

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patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.		
2. To achieve the objectives referred to in paragraph 1, the Regulation sets out a framework to:		
(a) facilitate investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union;		
(b) lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures of critical medicinal products and other medicinal products of common interest;		

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(c) leverage the aggregated demand of participating Member States through collaborative procurement procedures, and		
(d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.		
Article 2		
Scope		
1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products referred to in Article 131 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final].		
2. Chapter IV and Article 26(2) point (c) also apply to medicinal products of common		

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interest. Chapter III does not apply to medicinal products of common interest.		
Article 3		
Definitions	(x) 'contingency stock' means a buffer stock of medicinal products to mitigate the risk of supply disruption;	There is a need to add a definition of "contingency stock". This concept occurs in the recitals and in Article 20. Our proposed definition is shorter, but in line with, the definition presented by the Commission at the WP-meeting 8th of April ("an obligation imposed on supply chain actors to establish buffer stocks of certain medicines to mitigate the risk of supply disruption). The definition should also work for the Pharma package, (see e.g. recital 138a in the regulation Council's mandate of June 4)
For the purpose of this Regulation, the following definitions shall apply:		
(1) 'medicinal product' means a medicinal product as defined in Article 4 point (1) of		

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Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];		
(2) 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including primary packaging materials, excipients, solvents and reagents;		Is this list exhaustive? There may be other necessary manufacturing components not mentioned here to be included. Specified elsewhere in a guideline?
(3) 'active substance' means an active substance as defined in Article 4 point (3) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];		
(4) 'critical medicinal product' means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients as defined in Article 4 point (13) of		

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Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final];		
(5) 'medicinal product of common interest' means a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States;		There is a need to determine the precise criteria for MS to draw the conclusion that the market supply is insufficient. This is important as if forms the basis for what products that will be on the list of procurement, as proposed by this regulation. This could done be by an implementing Act.
(6) 'vulnerability in the supply chains' means risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level, taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation, that compromise the continuous supply of such medicinal products to patients in the Union;		

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(7) ‘vulnerability evaluation’ means the evaluation of the supply chains of critical medicinal products to identify their vulnerabilities performed by the MSSG in accordance with Regulation (EU) …/… of the European Parliament and of the Council1 [reference to be added after adoption cf. COM(2023) 193 final];		
(8) ‘common name’ means a common name as defined in Article 4 point (48) of Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];		

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[1] Regulation (EU) …. of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ …) *[D.G.: Title according to COM(2023) 193 final. Please check against latest version of this draft Regulation]*.

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(9) 'contracting authorities' means contracting authorities as defined in Article 2(1) point (1) of Directive 2014/24/EU;		
(10) 'strategic project' means an industrial project identified pursuant to the criteria set out in Article 5;		
(11) 'project promoter' means any undertaking or consortium of undertakings developing a strategic project;		
(12) 'permit granting process' means a process covering all relevant permits to build and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures;		

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(13) 'innovative manufacturing process' means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform techniques, 3D manufacturing;		
(15) 'Member States' cross-border procurement' means a procurement procedure initiated between the contracting authorities from different Member States on the basis of Article 39 of Directive 2014/24/EC;		
(16) 'procurement on behalf of or in the name of the Member States' means a procurement procedure initiated at the request of Member States and mandating the Commission to act as a central purchasing body on behalf of, or in the name of, the requesting Member States, as		

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provided for in Article 168(3) of Regulation (EU) 2024/2509;		
(17) 'joint procurement' means a procurement procedure carried out jointly by the Commission and Member States, as provided for in Article 168(2) of Regulation (EU) 2024/2509;		
(18) 'supplier' means the manufacturer or marketing authorisation holder of finished dosage forms, or manufacturer of key inputs or active substances;	Alt 1 ~~(18) 'supplier' means the manufacturer or marketing authorisation holder of finished dosage forms, or manufacturer of key inputs or active substances;~~ Alt 2 (18) 'supplier' means the **authorised** manufacturer or marketing authorisation holder of **medicinal products** ~~finished dosage forms~~, or manufacturer of key inputs or active substances;	Alt 1, as a preferred first alternative we propose the deletion of this definition since it is only used once in Article 18 (1). Instead, we propose to amend Article 18 (1) (not included in this template). As a second alternative we would adjust (18) as proposed: We are reluctant to introduce the new terms "supplier" and "finished dosage forms" and prefer "marketing authorisation holder", authorised manufacturer" and "medicinal product", respectively.
(19) 'strategic partnership' means a commitment between the Union and a third country, group of third countries or international		

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organisations to increase cooperation related to one or more critical medicinal products that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation.		
Chapter II **Strengthening the Union's security of supply**		
Article 4		
Strategic objective of the Union		
1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union.		

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2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market.		
3. The Commission shall support the coordinated efforts of the Members States.		
Chapter V **Critical Medicines Coordination Group**		
Article 25		See general comments in the beginning of the document. We think that the more operative EMA group MSSG and the Coordination Group proposed here, can co-exist as long as there is no overlap in functions.

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		However, we have a question on how the CMA aligns with Chapter X in the Pharma package, where COM has a coordinating function, take actions and can issue recommendations (e.g. Article 134). We would like to avoid duplication of structures and a coherent flow of information.
Establishment of Critical Medicines Coordination Group		
1. A Critical Medicines Coordination Group ('Critical Medicines Group') is hereby established.		
2. The Member States and the Commission are Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of		

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the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status.		
3. The Critical Medicines Group shall work closely with the MSSG, the Agency, and national authorities responsible for medicinal products. For discussions where input from the medicines regulatory authorities' perspective is necessary, the Critical Medicines Group may organise joint meetings with the MSSG.		
4. The Commission shall organise and coordinate the work of the Critical Medicines Group by means of the Secretariat.		
5. A representative of the Commission shall chair the meetings of the Critical Medicines Group.		

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6. The Critical Medicines Group, at the proposal of the Chair or any its members, may decide to establish a working group.		
7. The Critical Medicines Group shall use its best endeavours to reach consensus, where possible. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the Critical Medicines Group's position.		SE: The wording of 7. alludes to decision making. We would like to have a clarification on what grounds and what topics diverging positions need to be recorded at this level.
Article 26		
Tasks of the Critical Medicines Coordination Group		Note that the MSSG is not a legal body that can replace the MS' ministry/government level or all other national competences concerned. Hence, it is important that the operative tasks of the MSSG do not overlap or duplicated by the Coordination group. Question: the information to be disclosed and exchanged, to what degree may trade secrets or national confidential information be disclosed?

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1. The Critical Medicines Group shall facilitate coordination in the implementation of this Regulation and, where appropriate, advise the Commission, so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market.		
2. In order to attain the objectives referred to in paragraph 1, the Critical Medicines Group shall perform the following tasks:		
(a) facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security and availability of critical medicinal products within the Union;	(a) facilitate coordination on strategic orientation of the financial support for strategic projects, including by exchanging information on the manufacturing capacity and the EU market designated production for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security and availability of critical medicinal products within the Union;	SE proposes in (a) to underscore need for information on production directed to the EU market. This refers also to Article 15 (3) where the concerned Member State may request supplies.

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(b) facilitate exchanges on the national programmes referred to in Article 19 and enable cooperation on and coordination of Member States public procurement policies with regard to critical medicinal products;		
(c) facilitate discussion of the need for a collaborative procurement initiative for a given medicinal product;		
(d) advise the MSSG to provide the order of priority of critical medicinal products for vulnerability evaluation, and propose a review or an update of existing evaluations where necessary.		
	(e) coordinate relevant issues related to application of Article 134 in Regulation (Pharma Regulation)	Proposal to connect with the Pharma package, where COM has a coordinating role, can take actions and issue recommendations role (the Council mandate of June 4).

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3. The Critical Medicines Group shall enable the exchanges of information between the Member States and the Commission as referred to in Article 17 and shall enable, where necessary, a coordination of respective actions aiming to attain the objectives of this Regulation.		In Article 17 (not in this template) there is a mention of the the Critical Medicines Coordination Group by reference to Articles 24 and 25, but should rather be to Articles 25 and 26 instead.
4. The Critical Medicines Group shall periodically discuss the potential contribution of strategic partnerships to the objectives of this Regulation, prioritisation of third countries for this purpose, and the consistency and potential synergies between Member States' cooperation with relevant third countries and the actions carried out by the Union.		
5. The Critical Medicines Group, at the Commission's request, may provide an opinion on matters related to the application of this		

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Regulation in the context of performing tasks as referred to in this Article.		
Chapter VI **International cooperation**		
Article 27		
Strategic partnerships		
Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, when possible, to support security of supply and		

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reinforce efforts to strengthen the production of critical medicinal products in the Union.		
Chapter VIII **Final provisions**		
Article 29		SE would like to hear the explanation on how to implement Article 29 in practise. It is of vital importance that there is no increased burden of administration or duplication of information. Question: the information to be disclosed and exchanged, to what degree may trade secrets or national confidential information be disclosed?
Obligation of the market actors to provide information		
1. Marketing authorisation holders and other economic operators in the supply and distribution chains of critical medicinal products including their key inputs and active substances or medicinal products of common interest shall upon request provide the Commission or		

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national authorities, as relevant, the requested information necessary for the purpose of application of this Regulation.		
2. The Commission and national authorities of the Member States shall aim to avoid duplication of the information requested and submitted.		
3. The Commission and national authorities of the Member States shall assess the merits of duly substantiated confidentiality claims made by marketing authorisation holders and other economic operators, requested to provide information per paragraph 1, and shall protect any information that is commercially confidential against unjustified disclosure.		Question: What criteria will be used for assessment of confidentiality by the Commission and the MS' competent authorities, respectively?

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Article 30		
Evaluation		
1. By *[OP please insert the date of:]* five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.		
2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1 have been achieved.		
3. The national authorities and the economic operators shall, upon request, provide the Commission with any relevant information		

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they have and that the Commission may need for its assessment pursuant to in paragraph 1.		
Article 31		
Entry into force and application		
This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.		
It shall apply from [….].		
This Regulation shall be binding in its entirety and directly applicable in all Member States.		
Done at Strasbourg,		
For the European Parliament *For the Council*		
The President *The President*		

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