The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Proposed amendments to the Commission's Proposal for a Regulation on a Critical Medicines Act

The CPME statement on the Critical Medicines Act may be accessed here.

Amendment 1	
Article 4	
Text Proposed by the Commission	**CPME Proposed Amendment**
Strategic objective of the Union 1. The security of supply and availability of critical medicinal products for patients is a strategic objective of the Union. 2. The Member States and the Commission shall work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. 3. The Commission shall support the coordinated efforts of the Members States.	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. **1a. The Union shall pursue the objective of ensuring that medicinal products are available in all Member States to ensure equitable access of patients.** 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.
Justification	
Medicines should be available in all Member States once they are marked and this needs to be reflected as a strategic objective of the Union as a way to promote equitable access of medicines to all patients in the EU.	
Amendment 2	
Article 7	
Text Proposed by the Commission	**CPME Proposed Amendment**

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.	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. **Where such accelerated procedures or public funding is allocated, Member States shall ensure that they are conditional to clear and binding commitments by the beneficiary regarding security of supply, affordability of the end products and transparency in the use of public funds.** **To achieve the objective of contributing to the security of supply of critical medicinal products, Member States through their National Competent Authorities shall ensure that marketing authorization holders shall make the medicines that result from strategic projects available in all Member States. Marketing authorization holders who fail to fulfill their obligation shall face sanctions, through the repayment of direct or indirect aid received.**
Justification	
We stress the need to ensure that any public funding granted to pharmaceutical companies should go hand in hand with strong obligations regarding security of supply, affordability and transparency on the public money granted to companies. Any form of accelerated procedures applied by Member States' authorities (article 7) should follow this principle. Also, Member States through their national competent authorities should make sure that marketing authorisation holders that marketing authorisation holders shall make the medicines that result from strategic projects available in all Member States, Under penalty of having to return the public funding received for the development of this medicine and this should also be integrated in this provision.	

Amendment 3	
Article 15(2)	
Text Proposed by the Commission	**CPME Proposed Amendment**
Financial support by Member States 1. Without prejudice to Articles 107 and 108 TFEU, Member States may prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines Group referred to in Article 26(2) point (a). 2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from financial support for a strategic project shall prioritise supply to the Union market and use its very best efforts to ensure that the critical medicinal product remains available in the Member States where it is being marketed. 3. The Member State that provided financial support to a strategic project may request such undertaking to provide the necessary supplies of a critical medicinal product, active substance or key inputs, as applicable, to the Union market to avoid shortages in one or several Member States. 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.	Financial support by Member States 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). 2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from financial support for a strategic project shall prioritise supply to the Union market and use its very best efforts to ensure that the critical medicinal product remains available in the Member States where it is being marketed. 3. The Member State that provided financial support to a strategic project may request such undertaking to provide the necessary supplies of a critical medicinal product, active substance or key inputs, as applicable, to the Union market to avoid shortages in one or several Member States. 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. **The Member State must require the undertaking to submit a shortage prevention and mitigation plan as compensation for the financial support.** **4. Beneficiaries of strategic projects that fail to fulfill their obligation to prioritise supplying EU Member States and guaranteeing security of supply shall face sanctions, through the repayment of direct or indirect aid received.**
Justification	
We support the broad definition of strategic projects to increase production capacities for medicinal products, active substances and the modernisation of manufacturing infrastructures in the EU (article 5) which includes	

raw materials. In this context, the obligation set out in article 15(2) for priorisation of supply of critical medicines to EU Member States, should consider that manufacturers who do not fulfill their obligation to prioritise supplying EU Member States and guaranteeing security of supply face sanctions (CPME position to the general pharmaceutical legislation revision), including mandatory repayment of aid received. In paragraph 1, "Shall" is necessary to ensure resources address actual supply chain vulnerabilities.
The addition in paragraph 3 links the Critical Medicines Act with the EU's General Pharmaceutical Legislation revision. MAHs should submit Shortages Prevention and Mitigation Plans when granted funding to increase transparency and address vulnerabilities efficiently.

Amendment 4

Article 18(5)

Text Proposed by the Commission	CPME Proposed Amendment
Incentivising resilience, sustainability and positive social impacts in public procurement procedures 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. 2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments. 3. With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities may apply procurement requirements that favour suppliers	Incentivising resilience, sustainability and positive social impacts in public procurement procedures 1. For award procedures of critical medicinal products falling within the scope of Directive 2014/24/EU of the European Parliament and of the Council, contracting authorities in the Member States shall apply procurement requirements other than price-only award criteria such as procurement requirements that promote the resilience of supply in the Union. Those procurement requirements shall be defined in accordance with Directive 2014/24/EU and may relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority and contract performance clauses on timely delivery. 2. With regard to critical medicinal products for which a vulnerability in the supply chains has been confirmed through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of third countries, the contracting authorities shall, where justified, apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments. 3. With regard to other medicinal products of common interest, where justified by market analysis and public health considerations, the contracting authorities may apply procurement requirements that favour suppliers

that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments. 4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights. 5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2 and 3 where justified by market analysis or considerations related to the financing of health services.	that manufacture at least a significant proportion of these medicinal products in the Union. These requirements shall be applied in compliance with the Union's international commitments. 4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social rights. 5. Contracting authorities may exceptionally decide not to apply paragraphs 1, 2 and 3 where justified by market analysis or considerations related to the financing of health services. **6. The exemptions referred in paragraph 5 shall be limited to specific cases where the application of security of supply criteria would lead to disproportionate price.**
Justification	
CPME supports articles 18 and 19 of the proposed regulation and procurement of medicines should go beyond price and follow non-price criteria, such as security of supply, transparency throughout the supply chain and environmental criteria. Tenders who only have the lowest price as a rule could lead to shortages in the long-term, since there is dependency on only one or few suppliers who could either leave the market or increase the price. However, **article 18(5)** should not allow Member States to generally deviate from applying security of supply criteria. Exceptions should be limited to specific cases where the application of security of supply criteria would lead to disproportionate prices.	
Amendment 5	
Article 20	
Text Proposed by the Commission	**CPME Proposed Amendment**
Safeguards related to Member States' contingency stocks requirements and other security of supply measures Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. Member States shall ensure that any requirements	Safeguards related to Member States' contingency stocks requirements and other security of supply measures Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks. Member States shall ensure that any requirements

they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity.	they impose on companies in the supply chain to hold contingency stocks are proportionate and respect the principles of transparency and solidarity. **Member States shall ensure that companies have minimal safety stocks of critical medicinal products sufficient to meet the two-month demand for that critical medicinal product in Member States where the medicinal product has been placed on the market.** **Member States shall ensure that companies have in place dynamic stocks that can improve medicines availability and prevent waste.**
Justification	
We consider that the provision of article 20 on Member States' contingency stocks is insufficient. Minimal safety stocks of critical medicinal products shall be sufficient to meet the two-month demand for that critical medicinal product in Member States where the medicinal product has been placed on the market. Also, dynamic stocks could improve medicines availability and prevent waste, and this should be reflected in this provision.	
Amendment 6	
Article 20 (1) NEW	
Text Proposed by the Commission	**CPME Proposed Amendment**
–	**1. Member States shall notify any national stockpiling legislation in advance to the Commission and to the Critical Medicines Coordination Group, to not adversely affect other Member States, regions or healthcare facilities.** **2. In case a Member State fail to notify any national stockpiling legislation to the Commission and to the Critical Medicines Coordination Group, it shall face financial sanctions.** **3. The Critical Medicines Coordination Group shall assess the cases referred to in point 2.** **4. Assessments conducted by the Critical Medicines Coordination Group take the form of recommendations to the Commission, which shall result in a binding decision by the Commission.**
Justification	

We stress that stockpiling should not endanger other Member States, regions or healthcare facilities. Therefore, Member States should be obliged to notify any national stockpiling legislation in advance to the Commission and/or the Critical Medicines Coordination Group.

Also, the effective coordination and transparency of national stockpiling measures are essential to ensure the Union's preparedness and response capacity regarding critical medicines. Therefore, it's essential to establish clear obligations for Member States to notify national legislation to both the Commission and the Critical Medicines Coordination Group.

Amendment 7

Article 20 (2) NEW

Text Proposed by the Commission	CPME Proposed Amendment
–	**2. Member States may require manufacturers to establish and maintain appropriate dynamic stockpiles of essential raw materials necessary for the production of medicines. Such obligation shall be proportionate, take into account supply chain vulnerabilities, and be coordinated with the Critical Medicines Coordination Group.**

Since medicine shortages can be caused by shortage of raw materials needed later in the process of pharmaceutical manufacturing, it could be worth asking manufacturers to stockpile raw materials. This could help mitigate logistical issues and ultimately prevent shortages of medicines.
Also, the proposed stocks of raw materials should be dynamic to improve medicines availability and prevent waste, and this should be reflected in the text.

Amendment 8

Article 20 (3) NEW

Text Proposed by the Commission	CPME Proposed Amendment
–	**In addition to Member States' contingency stocks, the Commission Health Emergency and Response Authority (HERA) shall, in close collaboration with Member States, establish and maintain strategic EU-level stockpiles of critical medicines. These stockpiles shall be discussed and defined at the Critical Medicines Coordination Group, to address vulnerabilities identified at the EU Union list of Critical Medicines to tackle supply disruptions affecting multiple Member States.**

The COVID-19 pandemic has shown the limited capacity of national-level approach to preparedness. Article 20 of the proposed regulation address Member States' contingency stocks, but it doesn't provide a clear legal basis for a coordinated Union-level stockpile of critical medicines. HERA has already taken valuable steps to improve the EU's health security framework, including through the creation of the resEU medical stockpile (including personal protective equipment and emergency medical supplies), support for joint procurement and

advanced purchase agreements for vaccines and therapeutics. The future EU stockpile strategy has being developed in close collaboration with HERA and will aim precisely to foster crisis preparedness at the EU level.

We argue that, when needed, medicine stockpiling should take place at EU level and this should be reflected in the text. A new provision on EU-level stockpiling, in coordination with HERA and the Member States would address not only risks identified in the Union list of critical medicines, but also complement national contingency reserves and promote solidarity and equitable distribution across Member States. Finally, it will prove economies of scale and strengthen the EU's ability to respond effectively to future health emergencies and large-scale supply disruptions,

Amendment 9

Article 25 (2a) (NEW)

Text Proposed by the Commission	CPME Proposed Amendment
Establishment of Critical Medicines Coordination Group 2. The Member States and the Commission are Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status.	Establishment of Critical Medicines Coordination Group 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 public health expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status. **2a. The European Commission shall appoint representatives from doctors, pharmacists and other healthcare professionals as permanent members of the Critical Medicines Coordination Group.**

Justification

Healthcare professionals are key partners in mitigating the negative impact of shortages on patient safety and health. Hence, there is an utmost need to ensure that doctors, pharmacists and other healthcare professionals have are adequately and permanently represented at the Critical Medicines Coordination Group.
Also, the two high-level permanent representatives appointed by Member States should have public health expertise to provide appropriate inputs for the discussions and this needs to be reflected in this provision.