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On 20 March 2021, the CPME Board adopted the 'CPME Position on the Commission's Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices' (CPME 2021/021 FINAL).

CPME Position Paper on the European Commission's

Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

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 institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.[1]

CPME welcomes the opportunity to comment on the European Commission's Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. We wish to highlight the following key aspects:

General remarks

European doctors have a positive view of the European Commission's proposal for extending the mandate of the European Medicines Agency (EMA). All the exceptional measures introduced by the EMA to increase transparency and explain its regulatory activities, ensure continuous communication with and among Member States and developers, and provide scientific advice and recommendations have certainly contributed to building confidence in safety and efficacy of the medical countermeasures against COVID-19 and to the EU's overall approach to tackling the crisis. The ad hoc processes and resources currently put in place for the Agency should be reinforced and formalised so that the EMA is not forced to operate in an emergency mode and has better infrastructure and sufficient capacity in the future.

CPME would like to highlight the need to ensure the division of tasks between the different agencies (European Medicines Agency, European Centre for Disease Prevention and Control, and the future Health Emergency Response Authority (HERA) is coordinated to avoid competing competences and overlap.

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41.

Healthcare professional engagement in the EMA's crisis preparedness and management framework (Recitals 13 and 18)

- The Commission notes the importance of the EMA's close cooperation with Member States and the pharmaceutical industry to e.g., monitor and mitigate shortages of medicines and medical devices considered as critical in order to address a given public health emergency or, for medicines, major event. However, the proposal limits the involvement of healthcare professionals representatives to the possibility of inviting them to attend the meetings of the Steering Groups and the Emergency Task Force.
- European doctors emphasise the value of including health professionals' views in various aspects of the proposed framework, such as reporting on medicine shortages, defining criteria for identifying medicines as critical or making recommendations on the use of medicines which may have the potential to address public health emergencies.
- Accordingly, the Regulation should ensure a greater involvement of relevant stakeholders in these instances.

Competences given to the Emergency Task Force (Recital 21 – new)

- The Commission proposes to give the Emergency Task Force competences to review clinical trial protocols and advice developers on clinical trials which are conducted in the Union.
- As of now, the EMA and other regulatory authorities are not empowered to require developers to comply with specific criteria or characteristics of medical countermeasures to become effective public health interventions. The WHO published a Target Product Profile for that purpose in April 2020, however this remained aspirational. Regulators cannot impose public health imperatives on developers.
- In the current R&D model, it is left at the discretion of developers to define vaccine and treatment efficacy targets they will measure in clinical trials. In the context of the COVID-19 pandemic, the WHO proposed a collaborative efficacy trial "Solidarity" to directly compare the performance of different vaccines. However, developers of the COVID-19 vaccine candidates preferred to compare their candidates to placebos and measure efficacy in different ways, making the results impossible to compare.
  The Emergency Task Force could therefore use these new competences to influence the definition of the clinically most relevant performance targets for medical countermeasures to be measured in clinical trials.

Obligations on marketing authorisation holders (Article 10)

- The Commission proposes to establish a framework for the monitoring and reporting on shortages of medicines and medical devices during health emergencies, and to enhance the reporting obligations on Member States and marketing authorization holders (MAHs).
- European doctors support these initiatives. However, in the context of reporting obligations on MAHs, the Commission should avoid repeating the mistake in Article 81 of the Community Code Directive 2001/83/EC, which lacks imposing sanctions for non-compliance. The imposition of sanctions must be included in the Regulation to hold MAHs accountable.

Communication on the Medicines Steering Group (Article 13)

- The Commission proposes to inform the public and interest groups with regard to the work of the Medicines Steering Group.
- European doctors support this measure but notes that it is insufficient in regard to informing the relevant stakeholders of problems related to the supply of medicines.
- Communication is crucial in preventing and managing shortages. Doctors must be warned about the supply problems and have access to up-to-date information to be able to adequately respond to arising and existing shortages. Early awareness of a supply problem and early identification of potential therapeutic alternatives may mitigate the possibility for adverse reactions endangering patient safety.
- Therefore, besides the measure proposed by the Commission in Article 13, a dedicated early warning system should be established to inform the relevant stakeholders, including doctors and community and hospital pharmacists of any problems related to the supply of medicines included by the Medicines Steering Group on the critical medicines lists.

The Emergency Task Force (Article 14)

- In paragraph 9 of Article 14, the Commission proposes that the EMA will publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.
- European doctors support this initiative but suggest including in the Regulation a provision that all clinical trials data on which the Agency authorises medicines or vaccines should be published, as should clinical trials protocols on which the Agency advises, in line with the Clinical Trial Regulation.
- During the COVID-19 pandemic EMA proactively shared data on approved vaccines and medicines and information on the conduct of the Agency's activities. EMA also explained the regulatory processes to the public. These approaches taken are considered highly beneficial. The same level of transparency should be ensured in the future.

Monitoring and mitigating shortages of critical medical devices and support for expert panels (Chapter IV)

- The Commission proposes to empower EMA to monitor and advise on the supply of medical devices in the context of health emergencies.
- Given that health crises affect the development and supply of medicine and medical devices to a similar extent, it is logical to not duplicate efforts but to allow the Agency to address both areas.
- The establishment of parallel Executive Steering Groups for medicines and for medical devices, and the inclusion of expert panels on medical devices within the Agency structure should streamline communication and cooperation that are crucial during crises and beyond.
- European doctors fully support this solution and call on the EU co-legislators to recognize its added value in bringing the two areas closer together.

Proposed amendments

Proposal for a regulation – Recital 13

Commission proposal	*CPME amendments*
In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.	*In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.* ***The Agency should also establish a similar system for the exchange of information on the availability of medicines and medical devices with relevant stakeholders such as medical doctors or community and hospital pharmacists****.*
Justification Health care professionals face medicine and medical device shortages firsthand in their practices and can often be the first ones that could alert the Agency regarding supply problems.	

Proposal for a regulation – Recital 18

Commission proposal	*CPME amendments*
The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight against the disease that is responsible for the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.	*The Emergency Task Force should provide recommendations* ***– developed with the input from relevant stakeholders such as medical doctors and pharmacists –*** *with regard to the use of medicinal products in the fight against the disease that is responsible for the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.*
Justification In developing its recommendations, the Emergency Task Force should draw on the expertise of health care professionals who have direct experience with the use of various medications in the context of a given emergency.	

Proposal for a regulation – Recital 21

Commission proposal	*CPME amendments*
new	***The Emergency Task Force should review clinical trial protocols and advice developers on clinical trials which are conducted in the Union. The Emergency Task Force should define the most clinically relevant performance targets for vaccines and treatments to be measured in clinical trials, so that they can meet the criteria for effective public health interventions.***
Justification The Emergency Task Force, with proposed competences to review clinical trial protocols and advise developers on conducting trials in the EU, could influence the definition of the clinically most relevant performance targets for medical countermeasures to be measured in clinical trials.	

Proposal for a regulation – Article 10 – paragraph 4

Commission proposal	CPME amendments
new	***4. Marketing authorisation holders failing to comply with their reporting obligations shall be subject to sanctions.***
Justification The Commission should avoid repeating the mistake in Article 81 of the Community Code Directive 2001/83/EC, which lacks imposing sanctions for non-compliance. The imposition of sanctions must be included in the Regulation to hold MAHs accountable.	

Proposal for a regulation – Article 13

Commission proposal	CPME amendments
The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.	***1. The Agency shall establish an early warning system to inform relevant stakeholders, including medical doctors and community and hospital pharmacists of any supply problems and potential or actual shortages of medicines included on the critical medicines lists.*** 2. The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and

	interest groups with regard to the work of the Medicines Steering Group.
Justification Besides the measure proposed by the Commission in Article 13, a dedicated early warning system should be established to inform the relevant stakeholders, including doctors and community and hospital pharmacists of any problems related to the supply of medicines included by the Medicines Steering Group on the critical medicines lists.	

Proposal for a regulation – Article 14 – paragraph 9

Commission proposal	CPME amendments
9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.	9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal. ***The Agency shall also publish clinical trials data on medicines and vaccines reviewed by the Emergency Task Force and clinical trials protocols on which the Emergency Task Force provided advise to developers, in line with the provisions of the Regulation (EU) No 536/2014.***
Justification The EMA should in the future maintain the level of transparency it established during the COVID-19 pandemic. The Regulation should also include a provision that all clinical trials data on which the Agency authorises medicines or vaccines should be published, as should clinical trials protocols on which the Agency advises, in line with the Clinical Trial Regulation.	