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Medicines for Europe Position on the European Commission proposal for Regulation on a reinforced role for the **European Medicines Agency (EMA)** in crisis preparedness and management for medicinal products and medical devices

KEY MESSAGES

Medicines for Europe welcomes the two general objectives of the Regulation:

- strengthening the EU's ability to manage and respond to public health emergencies;
- ensuring the functioning of the internal market for medical products during public health emergencies.

Specific objective that the EMA regulation should achieve to ensure availability of essential medicines, during a health crisis:

- monitoring and mitigating shortages of medical products deemed as critical by a robust harmonised digital reporting system in Europe by all EU national competent authorities (NCAs)
- Establish a two-way communication between authorities, industry and supply chain actors to provide the transparency needed to take actions to prevent and mitigate cross border shortages and ensure access for patients

GENERAL CONSIDERATIONS

Medicines for Europe welcomes the European Commission's proposal on the Regulation on strengthening the European Medicines Agency (EMA) mandate. Drawing on the Covid-19 lessons learned, the proposal aims to codify the solutions to become efficient and predictable in the future. The proposal presents a step in the right direction, **giving the EMA a stronger mandate to coordinate solutions** for securing stable medicines supply in any future European-wide public health crisis. The proposal also keeps in mind the need for a framework for a **prompt and efficient approval process of medicines and vaccines** in the context of a serious public health emergency.

However, **the proposal could deliver more in terms of a coordinated approach to management and mitigation of medicines shortages**. The current shortage notification system brings more challenges than benefits as it is not designed to be interoperable with the National medicines agencies. In addition, data shared by the industry to each national regulatory authority are not harmonised, this makes it difficult for regulators to exchanges data and compare them. **To achieve the full potential of any digital solution, the proposal should include room for a robust harmonised and interoperable digital system for reporting and notification of shortages**.

During the first wave of the COVID-19 pandemic in Europe *ad hoc* solutions were employed to find ways to contain the risk of shortages of medicines and medical devices. This was made possible by agreements between all involved stakeholders. The proposal falls short by **omitting a stronger call for cooperation and two-way communication between authorities and medicines manufacturers** in times of crisis as they are the most informed stakeholder when it comes to the medicines supply chain. It is important to create direct cooperation between the industry representatives and regulatory authorities to prevent uncoordinated actions, which only slow down the response to any emergency.

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POSITIVE ASPECTS

* A call for the development of a streamlined electronic monitoring and reporting system for medicines and medical devices shortages (art. 9 c)
* Creation of an essential medicines list for public health emergencies (art. 6)
* Establishment of the Medicines Steering Group for monitoring any potential or actual shortages of medical products included on the critical medicines list (art. 3)

CHALLENGES

* Mentioning the **definition of a medicine shortage** as the inability of the supplier to meet the demand for a certain medicinal product or medical device, rather than focusing on meeting the real needs of patients and healthcare actors. This **might lead to** the creation of "**artificial shortages**" caused by a spike in demand that is not backed up by any data. (Art. 2, lett. d).
* The **proposal leaves the monitoring and reporting system** for medicines shortages **open to duplication of work,** which is detrimental in times of emergency when clear communication is essential and can lead to different interpretations of reported data.
* The proposed digital solution (art 9) of reporting shortages is not sufficiently clear in view of achieving various objectives of digitalisation of the system
* As the COVID-19 crisis clearly demonstrated, **coordination and two-way communication with the industry is key** to having a strong and prompt reaction to an emergency situation.

RECOMMENDATIONS

The EMA proposal for Regulation should include clear policies for building a **robust harmonized pan-European interoperable and digital reporting system to monitor and mitigate shortages**. To avoid duplications that slow down an efficient response and enable regulators to react adequately to any emergent large-scale crisis, such a system should be **in place and functional also under normal circumstances** and built on:

→ a **common definition of medicines shortage** in view of actual patient need to avoid the creation of artificial shortages;

→ **the implementation of existing digital infrastructure (telematics)** and on-going digital projects on data management system (*Substance, product, organisation and referential data* - SPOR and *Target Operating Model* – TOM) to achieve an EU centralised mechanism to monitor the entire value chain;

→ **common data fields**:

- a harmonised digital data format with the same information provided by the marketing authorisation holders to all Member States;

→ **the interoperability** between all EU National Competent Authorities (NCAs) as well as the European Medicines Agency to have agile communication and avoid duplication of reporting;

→ **A two-way communication system**, between industry and the Agency, to start early discussions about expected potential drug shortages and sharing expected supply constraints which authorities become aware of via the notification process.

→ **Allow triggering regulatory flexibilities** to enable supply from another market by alternative Marketing Authorisation Holders

Therefore, in order to deliver on patient access to medicines, the **Medicines Steering Group during crisis preparedness and major events should**:

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- Request supplementary information via the industry single point of contact (iSPOC), only if they have not already shared in the harmonised pan-European interoperable and digital system via National Competent Authorities;
- Consult and actively involve the industry in the determination of the list of critical products;
- Maintain two-way communication with the industry during the whole health emergency.
- Include the industry in the elaboration of solutions to adequately respond to a crisis.

USEFUL DOCUMENTATION

* Medicines for Europe FEEDBACKS to the EC public enquiry
* FACTSHEET
* INFOGRAPHIC