.B.A.H
Bundesverband der
Arzneimittel-Hersteller e.V.

Position paper

of the German Medicines Manufacturers‘ Association (BAH) on

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

What should be considered when implementing the regulation?

Introduction

The new regulation aims to help the European Medicines Agency (EMA) prevent future shortages of critical medicines and medical devices, anticipate, coordinate, and manage the impact of public health emergencies on medicines and medical devices and major events at Union level, and develop medicines against diseases such as COVID-19 more quickly.
In principle, BAH welcomes the transfer of coordinating, advisory and supporting tasks to the EMA in certain defined (crisis) situations, especially in connection with combating shortages. At this point, however, BAH would also like to point out some aspects that should be considered in the concrete implementation.

New committees and structures

According to the regulation, various bodies such as the executive steering groups on shortages and safety of medicinal products and medical devices, respective working groups and an emergency task force are to be set up at the EMA within a defined institutional framework. When composing the committees, care should be taken to ensure that interfaces, tasks and responsibilities are precisely defined so that regulation is practicable, information chains function effectively and excessive bureaucracy on national authorities and medicine manufacturers is avoided. Committees should be staffed in a way that national peculiarities can also be considered in the committee discussions. When selecting experts and staff, care should also be taken to ensure that they have the relevant practical experience, so that the committees are well positioned to discuss pragmatic solutions and always make decisions

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considering feasibility for the stakeholders. It is also indispensable that interfaces between the steering groups resp. working groups of the EMA and the bodies of the European Centre for Disease Prevention and Control (ECDC) and the Health Emergency Preparedness and Response Authority (HERA), whose tasks also include crisis preparedness and response, are observed.

Lists of critical medicinal products and medical devices

According to Article 9 and Article 25 of the Regulation, the Agency shall specify the procedures and criteria for establishing and reviewing the lists of critical medicinal products and medical devices, respectively. This should always be accompanied by a risk assessment from a patient access perspective to ensure effective and proportionate use of the resources of authorities and companies. This applies, for example, to non-prescription medicines, as substitution is possible – also with the help of a pharmacist – and in most cases there are alternatives (with the same or a different active ingredient for the same indication). In these cases, a shortage usually has no impact on patients' security of supply. Due to the low risk of supply shortages for non-prescription medicines, these are only proactively monitored in a few European countries. Accordingly, OTC medicines should not be considered when establishing the lists.

European shortages monitoring platform

To ensure that prevention, monitoring and reporting of drug supply shortages are truly improved and made more efficient through a European database, the EMA should set up the planned platform in such a way that the information in the database has a real added value to the information already existing at national and European level. Thus, it should not only reflect the status on medicinal product supply shortages, but should assist national competent authorities, marketing authorisation holders, wholesalers and other persons or entities authorised or empowered to supply medicinal products to the public to counteract medicinal product shortages at an early stage (predictive approach). This is the only way to fulfil the database's task of obtaining information about supply difficulties at an early stage so that meaningful supply shortage management can be initiated promptly to either avert or cushion a delivery bottleneck or even supply shortage.

In addition, already existing structures and databases should be used for data collection. Duplicate reporting obligations and parallel database structures should be avoided by all means. Additional administrative effort on the part of the companies should be rewarded with the fact that the companies themselves also receive important information from the database (e.g., to support their own demand planning). Any duplication of work and unnecessary effort must be prevented for all parties involved.

To facilitate the coordination function of the Agency, interoperability of data with Member States' existing IT platforms for supply shortage monitoring and, where appropriate, with other systems is crucial. This is the only way to enable the transmission of relevant information to the European database in an efficient and structured manner.

No database can tackle causes of shortages per se. Shortages often have complex causes that need to be recorded, analysed and finally tackled in more detail on a case-by-case basis together with all stakeholders involved.

Electronic monitoring and reporting systems in the medical devices sector

Regarding the Executive Steering Group on Medical Devices, it is indicated that the Agency will "develop streamlined IT monitoring and reporting systems" (Article 25(1)(b)). In addition, the Steering Group may “make use of data from device registries and databases where such data is available to the Agency” (Article 23(2)). Such data will already be included in the Eudamed database. As already mentioned in the medicinal products sector, duplicate reporting obligations and duplicate database structures must also be avoided at all costs in the medical devices sector. It should be mandatory for the Steering Group to make use of data already available.

The regulation clarifies that interoperability with existing IT tools and Eudamed, once fully functional, should be enabled.

Support of the expert panels for medical devices

Pursuant to Article 30 of the Regulation, since 1 March 2022, the Agency shall provide on behalf of the Commission the secretariat of the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 and shall provide the support necessary to ensure that those expert panels can efficiently perform their tasks set out in Article 106(9) and (10) of

that Regulation. According to Article 30 of the Regulation, the necessary support by the Agency shall be purely administrative, which is understandable. However, it should be imperative to ensure that this support is not provided in a substantive way, as the Agency has – undoubtedly – a high level of expertise in the field of medicinal products, but less so in the field of medical devices.

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