German Medicines Manufacturers' Association

Position Paper

of the German Medicines Manufacturers‘ Association (BAH)

on the Inception Impact Assessment of the European Commission on building a European Health Emergency Preparedness and Response Authority (HERA)

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About us

The German Medicines Manufacturers‘ Association (BAH) represents the interests of the pharmaceutical and medical device industry both nationally and internationally vis-à-vis politicians, authorities and institutions in the healthcare sector. With around 400 member companies, it is the association with the largest membership in the pharmaceutical and medical products sector in Germany. The political representation of interests and the support of members cover the field of prescription and non-prescription medicines as well as self-care and medical devices, including medical apps and digital health applications.

Introduction

The European Commission's impact assessment addresses the establishment of an EU Health Emergency Preparedness and Response Authority (HERA) similar to the U.S. Biomedical Advanced Research and Development Authority (BARDA). The authority is designed to ensure monitoring on the needs, swift development, manufacturing, procurement, and equitable distribution of key medical countermeasures such as personal protective equipment, medical devices and in vitro medical devices (including tests and testing materials), available therapies, vaccines and essential medicines.

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The BAH welcomes the European Commission's efforts to address the weaknesses in European health preparedness and crisis response to severe cross-border health threats revealed by the COVID-19 pandemic. We understand the intention to facilitate coordinating activities along the entire value chain and the monitoring of production capacities, raw material needs and availability through a European Health Emergency Response Authority (HERA). However, it is of utmost importance to shed light on the multifactorial causes of development, production, procurement and distribution problems in order to take appropriately targeted measures.

Regulatory Framework

In setting up a new authority, it is crucial for medicines manufacturers that the roles between the different European authorities are clearly defined – also against the background of the concrete proposals to extend the mandates of the European Medicines Agency (EMA) as well as the European Centre for Disease Prevention and Control (ECDC) – and that **no duplicate or even multiple structures** are established. In this context, coordination and cooperation with national authorities must ultimately also be clarified. The aim should be to **simplify the administrative and regulatory framework** in order to establish efficient decision-making structures.

In this context, the other strategic initiatives of the European Commission, such as the Pharmaceutical Strategy for Europe, as well as the ongoing efforts to create the necessary infrastructure for the success of the existing regulatory framework, such as the Regulation on Medical Devices, should also be considered. The principle must be to **avoid unnecessary duplication of work**, ensure a **proportionate and appropriate division of responsibilities**, and create the **necessary synergies** with other policies and stakeholders.

Among other things, the new EU authority should increase the production capacity and adaptability of medicines manufacturers. However, this does not necessarily require a new authority. Already a higher level of **regulatory flexibility** for medicines manufacturers might achieve the desired results to a certain extent. The **administrative burden** regarding approval and market access **must be reduced** to a reasonable level. For example, it should be easier for a medicines manufacturer to switch to another active ingredient manufacturer as part of the

production process, thus facilitating substitution, especially in the case of supply shortages. Particular attention should generally be paid to the too far-reaching **regulatory requirements for medicines with known substances** for which regulatory relief would increase the availability of products.

Evaluation

To generate real added value from HERA, it would be appropriate to first carefully **evaluate existing decision-making structures** and verify which (additional) roles might be taken over by the new authority. This includes urgent responses to health threats but also long-term planning for example in the context of the EU research programs. The new EU authority would have to complement and **create synergies** with the work of existing EU agencies, in particular the ECDC and EMA.

Furthermore, the causes of the weaknesses in European health preparedness and crisis response to severe cross-border health threats revealed by the COVID-19 pandemic are multifactorial. In order to support the response capacity of Member States and the availability of and access to countermeasures, **evaluation and promotion of various short-, medium-, and long-term solutions** are needed.