

Prescrire's response to the European Commission public consultation on the Inception Impact Assessment on a "European Health Emergency Preparedness and Response Authority"¹

Paris, 23rd February 2021

We welcome the opportunity to contribute to this first round of consultation on the establishment of a European Health Emergency Preparedness and Response Authority.

The Covid-19 pandemic has illustrated the need for enhanced EU action and coordination in response to cross-border health threats. It has exposed weaknesses in the current framework regarding health emergency preparedness and responses. Any new initiative should therefore be built on lessons learnt from and management of current and previous crises.

We would like to underline the following aspects which deserve particular attention:

A strong and independent Agency with public health missions

The Covid-19 pandemic illustrated the importance of **public leadership and capacities** to handle health emergency crises. A strong capable European Agency to prevent and to react to health emergencies should be of benefit for all Member states and their citizens. It would be helpful to state which missions related to health emergency preparedness and response are already tackled by existing agencies in particular ECDC and EMA. In case a European HERA would be established, this Agency should be agile, able to act quickly to deliver appropriate action to prevent, remove or limit damages. It should have a long-term vision supported by a predictable and **substantial budget** addressing the challenges. It should be **an independent public driven agency with clear public health missions, not a private-public partnership**. The Agency should act in the general public interest and respond to public health needs and act in full transparency.

Effective governance and transparency

The Inception Impact Assessment doesn't provide detailed information on the governance process and structure of the Authority. Yet an effective governance is a cornerstone of enhanced preparedness and speedy action.

The current crisis illustrated how a lack of transparency (for instance on vaccine contracts) undermines public trust. Effective governance, communication and transparency are key elements which should be integrated as building blocks of the new Authority or Agency to protect the general public interest.

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Independent organisation
continuing education
for health professionals

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¹ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA->



Public funding: transparency and conditionalities to safeguard the public interest

The pandemic illustrated the crucial role of public funding needed to share risks and scale up countermeasure responses.

However, there is currently no clear oversight on all public interventions (at the EU and national levels) related to the various R&D supports for health technologies and on production capacities (strategic point for vaccines). Member states and the European Institutions should be accountable on the use of public money. There should be full transparency on public support (at both national and EU level) and on R&D funding. In addition, public funding should come with conditionalities to guarantee affordability, accessibility and availability of health technologies, access to clinical data and research results and transparency on R&D costs. To ensure equitable access to essential health technologies, the European Commission and Member states should leverage the use of existing tools like TRIPS flexibilities and share of know-how.

Vulnerabilities in global supply chains

As stated in the Inception Impact Assessment, the pandemic unveiled existing vulnerabilities in global supply chains. We encourage the European Commission and Member states to launch an assessment of the organisation and functioning of the supply chains including an analysis of existing manufacturing capacities (private and public) in order to identify vulnerabilities and the bottlenecks that need to be overcome. This is not only important for health emergency preparedness and response but also to prevent and mitigate drug shortages which dramatically increased over the last years.

Shortages of medicines entail considerable risks for the health and safety of patients. To fight this global threat, full transparency on the supply chain is needed. Key information on the supply chain can't anymore be treated as "trade secrets" or "commercially confidential information": the public health risks at stake are too high. Option 2.2 refers to a dedicated "EU centralized, flexible and scalable manufacturing and innovation capacities", including establishing manufacturing and innovation infrastructure. The development of European non-profit undertakings, especially for essential medicines at high risk of shortage should be explored. Next to relocation of production, the diversification of sources of production of active pharmaceutical ingredients (API), raw materials and finished pharmaceutical products and technologies are key for a reliable and resilient supply chain.

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