

Health Emergency Preparedness and Response Authority (HERA) – review

January 19th, 2024

The European Patients' Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 79 members include disease-specific patient groups active at EU level and national coalitions of patients.

EPF welcomes the opportunity to contribute to this consultation on HERA's mission, mandate, tasks, structure and resources.

Chronic diseases patients are particularly vulnerable to public health threats. The COVID-19 pandemic has showed the need for better coordination among member states to ensure equitable access to medical countermeasures, well-established information exchanges channels, and improved communication to the public. It further highlighted shared challenges among countries including shortages of critical medicines and health workforce as well as ill-equipped, under-resourced healthcare systems. We believe that HERA's role and mandate could be further strengthened by adopting a comprehensive approach to pandemic preparedness which includes continuity of care, supports member states' actions to improve access to critical medicines, and improved coordination at global level. As HERA's mandate develops, we call on the EU and member states to ensure that HERA has sufficient resources to fulfil its mission. We further encourage HERA to continue liaising with the Civil Society Forum, of which EPF is part, and closely involve civil society in its activities.

Healthcare systems' resilience

Chronic diseases patients faced significant obstacles in accessing their usual care during the COVID-19 pandemic. Not only did delays and discontinuation of care create worse health outcomes, but they also had a significant impact on patients' mental health, including <u>stress</u>, <u>anxiety and isolation</u>.

As a result, the emergency response must take into account the need to minimise these disruptions and maintain continuity of care for existing patients, including prevention, detection, treatment and follow-up interventions, alongside additional resources to ensure the health system's ability to address the direct impacts of the pandemic. In view of HERA's mandate, it is critical that HERA supports member states in developing national health crisis preparedness and response plans that include measures to improve the resilience of healthcare systems and their ability to ensure continuity of care. While the management of healthcare systems is a national competence, HERA can provide added value in developing blueprints, evidence, and promoting best practices and capacity building for member states in crisis preparedness and response.

Availability of critical countermeasures and medicines

All patients in the EU should have fair and equitable access to safe and effective countermeasures, such as vaccines, therapies, and personal protective equipment. We believe that HERA has a leading role in ensuring a coordinated approach to research and development of critical countermeasures

while integrating access considerations to ensure they reach all EU patients who need them. In that process, transparency is key along with close collaboration with other relevant agencies and institutions to ensure that e.g. appropriate scientific and regulatory guidance is available. EPF further supports HERA's work with the European Medicines Agency and others on facilitating clinical trials in times of crisis and as part of preparedness plans. In establishing these clinical trials networks, close coordination with patient organisations remains critical. Patient involvement in clinical research, including priority settings, supports participation and retention of patients and the development of products that meet patients' needs.

Beyond countermeasures in times of crisis, HERA also plays a role in addressing medicines shortages and availability issues in view of the urgency of the issue for patients. Shortages can have serious consequences for public health and patient safety. EPF welcomes HERA's role in the Critical Medicines Alliance, which will bring together all relevant stakeholders to identify priorities for action and propose solutions to strengthen the supply of critical medicines in the EU. EPF recalls the importance of involving patients and patient organisations in the development of the list of Critical Medicines to ensure that the criteria for "criticality" reflect patients' needs.

A broader mandate reflecting public health priorities

EFF strongly supports calls, despite the EU's limited competence in this area, for HERA's activities to be carried out more effectively by taking a comprehensive approach to public health, going beyond medical countermeasures, and more actively addressing issues such as shortages, allocation of human resources, environmental health and consistent communication to patients and health professionals about health threats. On the latter, ensuring consistent messaging and clear public communication strategies should be seen as an integral part of crisis preparedness and response. For example, HERA could support the development of educational and training materials as well as templates for communication campaigns, in collaboration with other agencies and institutions. In these efforts, involvement of civil society organisations will be critical as they act as multipliers in awareness raising campaigns and ensure that the content is relevant for the targeted audience.

More specifically, we also strongly encourage HERA to coordinate with other initiatives at international level to facilitate synergies and avoid duplications. A number of public health challenges are global, such as antimicrobial resistance and climate change, and require a coordinated approach, recognising the specific needs of each jurisdiction. As a result, it is important that HERA builds partnerships and communicates with the relevant stakeholders at global level to exchange best practices, compare research priorities and coordinate funding efforts to the extent needed.