The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME response to the review of the Health Emergency Preparedness and Response Authority (HERA)

CPME welcomes the opportunity to comment on the extent to which the Health Emergency Preparedness and Response Authority (HERA) contributed to strengthening the EU's ability to respond to health threats. Two years after its creation is a good moment to reflect on whether HERA has complemented the work of other EU health-related bodies, HERA's mandate vis-à-vis current health challenges, as well as determine if changes to HERA's structure and mandate are necessary.

1. Performance analysis

With the creation of HERA, the European Commission has rightly recognised a need for a new mechanism responsible for improving emergency preparedness and response. HERA's added value has so far been proven by many important activities, such as European Union preparedness reports, support to Ukraine, purchase of monkeypox virus vaccines and therapeutics distributed across the EU. In terms of preparedness, HERA has made first steps to prioritise medical countermeasures, identify ways to bring novel antimicrobials to the market, and develop an innovation financing mechanism that has the potential to accelerate and de-risk research and development activities. More and more work is being done on joint procurement and on stockpiling and a dedicated strategy is expected soon. This is also a definite added value of HERA.

2. Structure and governance

Transparent governance of public funding and of cooperation with public and private partners is essential to build trust and confidence in managing health emergencies. To this end, HERA meets the transparency criteria to the limited extent e.g., through cooperation and regular exchange of information between civil society and the publication of important documents in the public domain. The governance structure remains unclear with no composition of the HERA Advisory Forum published and no detailed information on HERA Board. One major limitation in the governance of HERA is a lack of parliamentary oversight due to the refraining from using the ordinary legislative procedure through Article 168 TFEU in setting up HERA. HERA does not benefit from the same scrutiny requirements as other EU agencies, such as the EMA and the ECDC. This is a major shortcoming in ensuring transparency and necessary accountability for public spending and decision-making in the area of public health.

3. Scope of HERA's mandate

Choosing a rather narrow mandate for HERA in the first stages of operation was a feasible decision, but it should not remain as the final scope of activities for this authority. There should be detailed reflection on several elements. First, one of the main weaknesses for the future is the very narrow definition of medical countermeasures, which places particular emphasis on medicines, medical devices and personal protective equipment.[i] Other measures can be equally important in preventing and managing health emergencies. Health threats need a comprehensive public health approach, and options such as recommendations on human resources for health, training, supporting national capacity building are of crucial importance. Second, HERA does not dedicate sufficient attention to affordability and equitable distribution of medical countermeasures (as per current definition). HERA should be explicitly mandated to determine from the outset the fair sharing of risks and rewards of future innovations between the public and private sectors. Such a mandate must ensure that end products are accessible to all EU citizens and that technologies and know-how can be shared globally. Third, Europe currently lacks a true R&D coordinator to fill the gaps in research and production of health technologies necessary to address current and future health threats. HERA could play a role, as some preliminary steps have already been taken such as incentives for new antimicrobials. There is a need to further reflect whether HERA should be tasked with boosting the Union's strategic autonomy in medicine and medical devices production beyond health emergencies. Last, there is a need to clarify the scope and competences assigned to HERA with regard to training programmes as foreseen in the provisions of the SCBTH regulation.[ii]

4. Tools and resources

Currently, HERA needs to follow the relevant programme committees in charge of the funding allocated to the activities (EU4Health, Horizon, rescEU). Its creation in the middle of the current Multiannual Financial Framework (MFF) limits its capacity to manage more directly and in sufficient quantity the resources that are needed to fulfil its goals. Looking ahead, HERA should receive a larger and more flexible allocation from MFF, that allows for more risk-taking in funding relevant health technologies and can accommodate obsolescence. A dedicated equal access plan and IP sharing will be necessary going forward to ensure resources are spent in public interest.

5. Complementarity and overlaps

The system of preparedness and response at EU level is complex, and there is a need for better cooperation and coordination with other institutions, EU agencies, Member States and partners. For example, while ECDC's mandate was expanded with antimicrobial resistance, and EMA's one with medicine shortages, it is essential to clarify in a binding way the respective competences. HERA's activities fall under a significant number of comitology procedures. The SCBTH establishes a Health Security Committee, while the emergency framework regulation[iii] sets up a Health Crisis Board. No matter the future status of HERA, its place should be better described.

6. Status of HERA

The EU needs to take responsibility to ensure health innovation follows the public interest and addresses the current shortcomings of the biopharmaceutical R&D system. Preparing or responding to an emerging health threat requires evidence-based decision-making beyond political influence. HERA should be able to budget, plan and implement its decisions in an independent way allowing for an “end to end” approach to medical countermeasures and other health technologies addressing market challenges along the translational value chain. At the same time, there is a need for coherence with other policies and institutional actors. Similarly, to the effective work done by EMA and ECDC, it should be considered if HERA could operate as an independent agency in close cooperation with all Member States and stakeholders, under the necessary scrutiny of the European Parliament to evaluate options for future functioning. Having an ambitious budget at its disposal, HERA would be able to invest adequately in preparedness and response.

[i] Article 3, point (10), of Regulation (EU) 2022/2371
[ii] Article 11, of Regulation (EU) 2022/2371
[iii] Council Regulation (EU) 2022/2372