

HERA should serve patients and promote public health

A shared vision for the EU's new Authority

We welcome and applaud the initiative of the European Commission to set up an operational Health Emergency Preparedness and Response Authority (HERA). We agree that HERA is essential to ensure better EU preparedness and response in terms of medical countermeasures to serious cross border health threats. HERA is a great opportunity to build on the excellent European science, to learn the lessons from the ongoing crisis and ensure that the public acts as a wise investor which steers meaningful, needs-driven, patient-centric innovation. For the new Authority to serve patients and public health, it should:

- **Be an independent public authority with a clear mandate** driven by the public interest, a transparent and accountable decision-making process, a strong degree of autonomy with respect to the EU, national governments and the private sector, and the ability to take risks by following a portfolio management approach;
- **Possess a transparent and balanced governance structure** that includes patient organisations as well as other public health organisations, representatives of public research bodies; healthcare and medical professionals; structured and systematic involvement of stakeholders should be supported with appropriate resources;
- **Make long-term, sustained, and balanced research and development (R&D) investments** between the public and private sectors, not-for-profit entities and partnerships;
- **Foresee clauses guaranteeing downstream access and affordability**, as well as the transfer of manufacturing know-how to third parties to achieve greater scale and faster delivery of products. To accomplish this, it must take into consideration the multi-layered public investment through funding of early-stage research, and de-risking of investments through advance purchasing agreements (APAs), which was identified as a challenge during the COVID-19 pandemic;
- **Seek to achieve broad public rights** in both foreground and background intellectual property through its licensing agreements;
- **Have its R&D priority settings be aligned with the WHO Priority Pathogen List**, to anticipate and fund R&D to address emerging resistance threats, and address priority populations such as neonates and children;
- **Ensure R&D programmes reach the most vulnerable and disadvantaged communities** (children, elderly, migrants, refugees, community sex workers, homeless) in the EU;
- **Prioritise the development and access to medical countermeasures** to tackle emerging and pandemic infectious diseases, including AMR. To this end, it should

introduce subsidies and incentives for the development of new antibiotics that ensure private and not-for-profit developers will not require sales revenues linked to volume to ensure a return on investment;

- **Establish public sector, end-to-end, research infrastructure** and guarantee better coordination amongst existing R&D efforts;
- **Honour the specific transparency norms** including transparency of net prices, patent landscapes, units sold, sales revenues, subsidies and incentives, registration status in countries, the costs of clinical trials and the outcomes from trials, in accordance with the WHO transparency resolution (WHA 72.8);
- **Ensure that a large budget is made available in the form of transfers** from various EU budget lines, co-funding from Member States, or through public-private cooperation and partnerships. If HERA's budget remains too small to effectively define and implement its mission, the EU's ability to coordinate both preparedness and response will be inevitably jeopardized.

The European Public Health Alliance (EPHA) and the European Patients' Forum (EPF) would like to express our commitment to work with the European Commission, Parliament and Member States towards achieving this vision for the new HERA. Our organisations look forward to building a continuing collaboration with the new Authority.

#HERAforPatients #HERAforPublicHealth

The European Public Health Alliance (EPHA) is a member-led organisation made up of public health NGOs, patient groups, health professionals and disease groups working to improve health and strengthen the voice of public health in Europe. www.eph.org

The European Patients' Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease-areas. Our 77 members include disease-specific patient groups active at EU level and national coalitions of patients. Our Mission is to advance the interests of patients and patients' communities by strengthening their collective impact across Europe through effective advocacy, education, empowerment, and partnership. <http://www.eu-patient.eu>