

## Non-paper

### Addressing public health threats in line with public health needs – Success factors for the future HERA

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The Covid-crisis has demonstrated beyond doubt that Europe needs to be much better prepared for the next crisis, especially for the provision of medical countermeasures like PPE and vaccines. In this regard, Belgium [to add others as appropriate] fully supports the Commission's announcement to set up a Health Emergency Response Authority (HERA) to *'enable adequate EU preparedness via an EU level countermeasure management system that would allow rapid and equal access, availability, development and deployment of the most advanced medical countermeasures in the event of a health emergency'*.

Learning the important lessons of recent experiences with the provision of medical countermeasures will be central to making the HERA viable and successful.

First, the Covid-crisis has demonstrated that the production and development of medical countermeasures should be considered a **(global) public good**. They cannot and should not be considered as 'normal' commodities subject to 'normal' market dynamics. As a matter of principle, governments worldwide need to be able to guarantee fair, affordable and needs-based access to medical countermeasures, as fast as possible while respecting high quality standards. In health care, market dynamics do not meet all public health needs, even in normal circumstances let alone in crisis.

Second, this crisis showed that public authorities are capable of organising access to medical countermeasures. Public authorities exercised leadership in securing access to PPE; in funding and coordinating R&D; and in providing the conditions and cooperation to facilitate private sector vaccine production. The European experience with the provision of medical countermeasures has been **an innovative public private experience on which we should build**.

Therefore, HERA needs to bring a shift in our mindset on how to approach crises collectively. It needs to integrate and provide strategic steering to our value chain, in particularly at times of crises. It is an opportunity to create an alternative publicly managed pathway for the research, development and supply of countermeasures for public health emergencies. Rather than leaving the development of innovative solutions to market actors only, HERA should align development and innovation with public needs. HERA should ensure essential supplies and actively manage and steer all stages of the innovation process, including bringing public goods to market. This will mean HERA taking on additional risk at early stages of development and needs to be balanced by compensating mechanisms if the consumer is not to pay twice.

Based on these experiences, we see following four success factors for the future HERA:

#### 1. Safeguarding a fair balance between public and private investment

HERA should create a route for innovation to meet public health needs and protect public investment. Instead of becoming a producer itself, HERA should develop a framework that prioritizes, rewards, and pays for preparedness while guaranteeing a fair balance between financing and gains of HERA supported products. Investment in preparedness when there is no guarantee of success is a considerable risk that needs fair returns. Moreover, on principle citizens 'should only pay once' so where the R&D of a product is by public

investment through HERA, this needs to be reflected in the establishment of public ownership or other rights. In this regard, HERA led public investments should include provisions on access, pricing, licensing and intellectual property.

## **2. Putting public health at the centre of an agile structure**

HERA should focus at all times on clearly identified public health needs and be very clear about its priorities. It must guard against 'pan-hysteria' taking over the agenda and causing suboptimal use of scarce public resources. The starting point should therefore be a focused mandate on major risks to public health, identified with the involvement of relevant authorities and experts. The scope has to go broader than medical countermeasures for pandemic preparedness and even beyond non-medical pandemic countermeasures. It needs to address wider public health emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks; and emerging infectious diseases (EID).

This requires a governance structure that puts public health at its centre. In order for HERA to succeed it will need continuous access to expertise from research, development, manufacturing and supply, including from the private sector. In order to fully play its pivotal role at the strategic heart of public health crisis management, HERA must be embedded within Commission structures and closely aligned with the strategic orientations provided by Member States. This is also critical to ensure consistency of action with other bodies such as EMA and ECDC.

Individual steps of the development process will involve collaboration with a wide range of stakeholders, in particular in academia and private sector. However, these structures of advice and collaboration should be kept separate from HERA's core governance – through for example a multidisciplinary expert advisory committee – which must ensure accountability to public authorities for setting overall directions and ongoing oversight.

In emergency periods, HERA will also need the legal authority and operational autonomy to act quickly and take decisions with policy and financial consequences. This requires a lean and agile governance structure with emergency powers defined in advance. It should also comprise a process for public authorities to declare a state of emergency which allows HERA to activate its emergency authority.

## **3. Preparing for the unexpected through European collaboration and solidarity**

While preparing for the next health crisis is inherently difficult, the pandemic has shown is that a European approach based on collaboration and solidarity is the most effective way forward. It has indisputably shown that no single European country has all the expertise and capacity to manage such a crisis alone. Ensuring our common health security and strategic autonomy can only be guaranteed when we work together. In this regard, HERA should be an authority that brings together the brightest minds in Europe under the same roof, with the intellectual and operational power to develop necessary programmes and collaborations. By identifying clear and specific missions, HERA can create a strong vision around which the wider European community of researchers, innovators and producers can align.

## **4. Global collective responsibility**

Strengthening the global governance for health-related R&D as well as solidarity with developing countries should be inherent in the genetics of the HERA. Solidarity should be organized along the full spectrum of the HERA's activities and be linked to public financing. There should also be purposive efforts to coordinate with regional blocs outside the EU to avoid duplication and waste.