The Consumer Voice in Europe

THE HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA): A CONSUMER PERSPECTIVE

BEUC position

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Why it matters to consumers

During the early stages of the COVID-19 pandemic there was a shortage of essential equipment for consumers such as masks, whilst intensive care units at hospitals sometimes ran out of medicines. Insufficient coordination of research efforts may well have delayed the development of new medicines to treat COVID-19. The European Health Emergency preparedness and Response Authority can help prevent these deficiencies from happening again.

Summary

The COVID-19 crisis is a reminder that our societies live under the threat of emerging pathogens that can cause serious illness and spread quickly, disrupting people's lives everywhere. With climate change, the risk of health outbreaks increases, making more urgent the need to be well prepared to respond to future crises.

For this reason, BEUC welcomes the creation of the European Health Emergency preparedness and Response Authority (HERA) and the proposed framework for addressing public health emergencies.[1] [2]

Whilst these are positive initiatives, there is room for improvement. For HERA to ensure that consumers have timely and affordable access to crisis-relevant medicines, medical devices and equipment:

1. **Research and Development (R&D) and production processes must be steered and aligned with the public interest**: this requires that EU research funding programmes prioritise public health needs, make use of mechanisms such as prizes for the most successful stimuli leading to medical innovation in areas where there is less commercial interest, and support non-profit Product Development Partnerships. The EU should set up a network of public and non-profit manufacturing entities to help boost product supplies.

2. **There must be a good public return on investment**: public funding to support research and production efforts should be made conditional on products being affordable and widely available. Sharing intellectual property rights and know-how with third parties is necessary to ensure large-scale production of medicines and equipment in crisis situations.

3. **HERA has to be transparent in its functioning:** for accountability purposes, the activities of HERA's governing and advisory bodies must be well-documented and be made public.

[1] European Commission, Commission Decision establishing the Health Emergency Preparedness and Response Authority, 16 September 2021.
[2] European Commission, Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, 16 September 20201.

4. **Consumer groups must be included in HERA's activities:** the HERA Board must set up an advisory group of civil society representatives and ensure adequate consultation processes.

5. **HERA must work in sync with international initiatives:** HERA's activities should contribute to boost global cooperation on R&D and procurement, promote IP pooling and open trade flows.

The EU institutions must ensure that HERA follows these measures and has enough resources to contribute effectively to crisis preparedness and response.

1. Introduction

1.1. What HERA is about

In September 2021, one year and a half into the COVID-19 pandemic, the European Commission published a decision to launch HERA. This initiative builds on a key lesson from the crisis: the need to strengthen the EU's capacity on crisis preparedness and response. HERA will bring the Commission and Member States together to work on these two fronts.

During the ''preparedness phase'', HERA will focus on detecting emerging health threats, promoting advanced research for the development of medical products, identifying bottlenecks in production chains, and mapping production sites. It will also work to increase stockpiling capacity and promote Member States' use of EU-level procurement.

As soon as the EU declares a public health emergency, HERA is meant to switch to the ''crisis phase''. At this point, the Council could activate a framework of emergency measures that is that is under discussion at EU level[3]. This could involve triggering emergency R&D plans and funding, monitoring the supply and demand of crisis-relevant medicines and equipment and activating 'ever-warm' production facilities for additional drug manufacturing capacity. As for COVID-19 vaccines, the Commission could negotiate joint advance purchases with companies on behalf of Member States.

HERA will be set-up as an internal Commission entity. It will be governed by a coordination committee, composed of high-level Commission representatives and the HERA Board. This board will bring together Member State representatives and the Commission's appointed head of HERA. In addition, the proposed regulation foresees that a specific Health Crisis Board is set up when the emergency framework is activated.

Regarding financing, HERA will have a budget of €6 billion that will come from the current Multiannual Financial Framework (2021-2027). HERA will rely on funding from existing programmes such as Horizon Europe for R&D activities.[4] During a public health emergency, there could be additional emergency funding.

BEUC welcomes that HERA will increase cooperation among Member States and that the focus is on supporting the development and supply of products to diagnose, protect from, or treat conditions associated with serious health threats. At the same time, there is room

[3] European Commission, Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, 16.9.201.

[4] The Commission announced that other funding streams will contribute to the EU's overall activities on health emergency perparedness and response. Together with the €6 billion foreseen for HERA activities directly, this will amount to about €30 billion for 2022-2027.

for improvement in the decision to establish HERA and in the proposed regulation. For example, the texts fall short in promoting public health-oriented R&D models, in ensuring good public return on investment and good governance.

To ensure that HERA is effective in helping consumers have timely access to affordable critical medicines and equipment, the Commission and Member States must embrace the following measures.

2. How HERA can better help consumers

2.1. R&D and production processes must be steered and aligned with public health goals

HERA must ensure that R&D and production processes are well aligned with the goal of ensuring timely access to essential medicines and other medical products.

However, the decision to establish HERA and the proposed regulation fall short on promoting alternative R&D and production models that can help address unmet public health needs. For example, it does not refer to prizes to reward the development of products such as new antibiotics or manufacturing by public and non-profit entities to boost supplies of products for which there is little commercial interest.

Specific recommendations:

- In liaison with DG Research and Innovation, HERA must help ensure that the EU research agenda is well aligned with public health needs. Funding programmes should use a combination of 'push' and 'pull' mechanisms such as innovation prizes and support non-profit Product Development Partnerships.

- HERA should set up a network of public and non-profit entities that assists with the manufacturing and stockpiling of essential medical products including those for which there is less commercial interest.

2.2. HERA must ensure a good public return on investment

HERA must avoid repeating some of the mistakes committed during the COVID-19 pandemic, where despite the important role played by the public sector in researching and developing medicines, there is global vaccine inequity and increasing vaccine prices.

As it stands now, there is not enough emphasis on the need to ensure good public return on investment. For example, the proposed regulation foresees that IP licensing requirements should be the exception rather than the common approach in advance purchase agreements. This must be reversed.

Specific recommendations:

- As a general principle, public funding for R&D and/or production must be disbursed under conditions, such as requirements for sharing intellectual property and know-how. This is essential to ensure large-scale production of medicines and medical equipment during the preparedness and crisis phases.

- In addition, advance purchase agreements must include clauses that ensure companies' compliance with delivery schedules and be transparent.[5]

[5] BEUC, 'Making the most of EU advance purchases of medicines', 2 December 2021

2.3. HERA must be transparent

To enable public accountability, there must be transparency of HERA's activities during the crisis preparedness and response phase.

However, neither the Commission's Decision establishing HERA nor the proposed Regulation on a framework for emergency measures require HERA's governing bodies to be transparent about their rules of procedure and meetings.

Specific recommendation:

- The rules of procedure, agenda and minutes of meetings held by the HERA Board, other governance bodies and advisory groups must be publicly available.

2.4. Consumer groups should be well engaged in HERA's activities

Ensuring that consumer groups are well-engaged in HERA's activities is necessary so that decisions are well aligned with societal interests. It is also important for its legitimacy.

However, whilst the HERA Board will have to set up an advisory subgroup composed of industry representatives, there is no obligation to engage civil society groups in a similar way. This should be fixed, and HERA should provide equal opportunities for engagement among relevant stakeholders.

Specific recommendation:

- The HERA Board must set up a parallel advisory group of consumer, patient and healthcare professional representatives and ensure adequate consultation processes on topics as relevant as R&D agenda setting, criteria for prioritising joint procurement and EU stockpiling, and medicines shortages, among other points. Civil society must be consulted during the preparedness and crisis phases.

2.5. HERA should help the EU play a strong role in global health

Preventing, anticipating, and responding effectively to cross-border health threats requires strong global cooperation. Yet, whilst the decision to establish HERA mentions that it will help reinforce ''the global health emergency preparedness and response architecture'' it does not elaborate on how this will be achieved.

Although HERA's ''international dimension'' is explained more in detail in a Commission communication[6], it should put more emphasis on the need to enhance global coordination on R&D, procurement, and IP pooling.

Specific recommendations:

- HERA's activities should contribute to a greater availability and affordability of medical countermeasures at global level. This requires cooperating on R&D and procurement with the WHO, its members, and international initiatives, and supporting IP pooling and facilitating open trade flows for raw materials and finished products.

[6] European Commission, Communication from the Commission to the European Parliament, the European Council, the European Economic and Social Committee and the Committee of the Regions Introducing HERA, 16 September 2021.

Looking ahead: Whilst it is important that the Commission has launched HERA so it can start operating under the ongoing pandemic, HERA's current set up should be seen as a step towards a more defined and autonomous entity, with greater financial stability and resources. To that end, we call on the Commission to put forward a concrete proposal on how to reinforce the current system at the latest by 2025, during the review process foreseen in the Decision to establish HERA.

END

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