

GIRP response to the European Commission call for feedbacks on the establishment of the European Health Emergency Preparedness and Response Authority (HERA)

22/02/2021

GIRP would like to express its appreciation for the opportunity to comment on the establishment process of HERA. We consider HERA to be an important means to effectively and efficiently manage an EU approach to current and future health crisis.

We support forming HERA in line with policy option 3 "Full end-to-end Authority for streamlining of EU level initiatives on medical countermeasures for serious cross-border threats to health".

In advance of establishing HERA, careful examination of available policy solutions at national level needs to be carried out to determine what level of intervention at EU level could bring added value to citizens.

The following considerations should be studied when determining HERA's sourcing and stockpiling function:

1. Flexibilities in moving stocks of medicinal products between Member States (MS)

The European Commission (EC) should facilitate the movement of stocks managed by full-service healthcare distributors across Europe in emergency situations by pre-emptively setting a framework for swift regulatory flexibility in licencing and labelling rules.

2. Emergency import licences

Full-service healthcare distributors and pharmacists should be allowed to import medicinal products from outside the EU at short notice during public health emergencies.

The EC should encourage MS to issue emergency import licences at early stages of medicine / medical equipment unavailability to prevent an escalation of the shortage situation.

3. Licencing of medicinal products across the EU

The EC should facilitate wider application of licences across the EU in case of public health emergencies. For example, this should be done in a way that would have medicinal products sourced from outside the EU recognised in all MS regardless of the MS where the import originally occurred.

4. Relying on full-service healthcare distributors to optimise stock management

Full-service healthcare distributors have the possibility to hold rotating emergency stocks, preventing products from expiring by applying FEFO (first expired first out) principles, through the integration of emergency stocks into normal operations (thereby strictly respecting the agreed buffer quantities), which is a unique capability of our sector. In addition, information on available stock levels and quantities can be made transparent to authorities providing a real-time overview of the supply situation by demand demonstrable.

5. Build stockpiling structure balancing national and European stocks

The European stockpile must be built in adequation with existing national stocks. Most Member States already have structures in place, enshrined in Public Service Obligations to ensure a minimum buffer stock level for their country. The EU or regional stockpile should be built on the basis of a list of potentially critical medicinal products to complement the existing buffer stocks and should allow for swift dispatching across the European Union, notably through multi-market packaging or without final packaging.

HERA should be provided with the necessary power to act and react quickly to ensure the fast delivery of all medical countermeasures for serious cross-border threats to health to prevent and manage health crises. While an appropriate level of EU and national government and oversight is essential, and the need to interact with regulators and agencies crucial, HERA should be established in a forward looking, flexible, agile and proactive manner. Its function and decisions should be subject to the highest levels of transparency and

accountability to the public directly and not through EU and national governments. Relevant stakeholders should be involved in a supportive / advisory role from the outset.

See the submission online here: <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-/F1963992>