

ESIP feedback to the Inception Impact Assessment of the new European Health Emergency Preparedness and Response Authority

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The European Social Insurance Platform (ESIP), representing statutory social security institutions in the EU, Switzerland and the UK, **supports EU action to improve the European crisis preparedness and response mechanism to common cross-border health threats and particularly the system of medical countermeasures.** As part of the European Health Union project, structural solutions in this field – including the creation of a new permanent Health Emergency Preparedness and Response Authority (HERA) – could **complement and support Member States’ crisis preparedness and response plans, in compliance with the subsidiarity principle.**

A **review of the existing EU legal framework and instruments** for coordinated actions in times of cross-border health emergencies – including on medical countermeasures – should be integrated in any new policy approach. **Advantages and disadvantages of centralising all the tasks** included in the Inception Impact Assessment (IIA) into one single body should be assessed and discussed. The **interplay between the new proposed authority and existing Agencies**, especially in light of their reinforced role and competences, should be examined.

- **Medical countermeasures**

We acknowledge the proposal to set up a standalone authority responsible for strengthening EU preparedness and response in terms of medical countermeasures. The new HERA would prioritise medical countermeasures and facilitate their timely development, production, procurement as well as purchase based on a sound assessment and anticipation of threats.

Capacity-building in this field should be adaptable to different risk scenarios and be accompanied by a thorough evaluation of effects on the public and private sectors, particularly when public funds are used for the development of medical countermeasures. In this regard we fully support the argument of **public return on public investment** as pricing and reimbursement decisions should reflect the use of public funds.

Common initiatives in the field of medical countermeasures, such as the deployment of rescEU and of the joint procurement mechanism, should uphold the principle of EU **solidarity** and contribute to the correct functioning of the single market. We welcome a

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review of the legal basis and mechanism of joint procurement. The existing framework should be further developed and simplified to involve Member States in the decision-making process and maximise their options to participate.

As part of the HERA's remit we support the creation of a **decentralised, digitally enabled, European stockpiling system** to overcome mismatches in demand and supply and to complement - not replace - Member States' national supplies. Besides stockpiling the IIA mentions coordinated manufacturing options. The setup of a mechanism for scalable and flexible manufacturing should be coupled with a preliminary **EU-wide mapping of production capacities** for medicines and medical devices capable of emergency activation. This would allow to scale up production when the health emergency occurs.

- **Action Plan on antimicrobial resistance (AMR)**

We welcome the preparatory action to be launched in the area of AMR and we acknowledge that it would feed into the new HERA functions.

The Commission highlights that the existing framework for **incentives and business-model are ill-suited** to innovations in the field of antimicrobials, as well as other crisis-relevant and technologically advanced products. In a recent position paper ESIP **called for a legal framework for AMR** and recommended new and alternative incentive mechanism, along with adequate surveillance, research & data collection on risks related to AMR, continued EU support to the development and use of rapid diagnostic tools, prudent prescription and dispensing, as well as the use of off-patent but still effective antibiotics.

ESIP looks forward to expanding on this feedback in the future public consultations.

You can find the submitted response on the European Commission's website [here](#).

