

ESIP feedback to the proposal for a Regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU

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The European Social Insurance Platform (ESIP), representing statutory social security institutions in the EU, Switzerland and the UK, welcomes the legislative proposals on strengthening crisis preparedness.

While Member States (MS) are responsible for the definition of national health policies, we believe that situations of common public health concern require coordinated actions and cooperation. A reinforcement of the Union's mechanisms for tackling and preventing cross-border health threats is timely and crucial.

We support a **European unified approach that avoids fragmentation and fully respects national health competences.**

- **Preparedness and response planning**

We support the enhanced coordination of national preparedness and response plans, building on the exchange of best practices between MS in **the Health Security Committee (HSC)**. We welcome guidance on prevention and control of cross-border threats, provided that it remains **sufficiently flexible** and adaptable to national specificities and that MS's responsibilities in public health are preserved. Furthermore, cooperation and coordination between the HSC and the Integrated Political Crisis Response Mechanism (IPCR) should be improved to avoid duplication of effort.

To increase preparedness for cross-border health crises, the **joint procurement mechanism should be further developed** with the aim of preventing distortions in competition within the Internal Market and maximising the opportunities for MS to participate. Measures included in the proposal are a first step in this direction.

ESIP also welcomes measures to improve the monitoring of existing stocks and possible shortages of critical medicinal products and medical devices, as detailed in the Regulation on a reinforced role for the EMA. By way of **mandatory participation in a common reporting system**, we call for an **evidence-based evaluation of supply**

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throughout Europe and within the MS to (digitally) **enable a decentralised European stockpiling system**, amongst other measures to mitigate shortages.

- **A robust surveillance and monitoring system**

The new mechanism for crisis preparedness implies enhancing national surveillance systems. We welcome the use of digital tools to collect and process interoperable data. The swift establishment of the European Health Data Space could enable cross-border exchange of data to identify and monitor health hazards. While welcoming the use of new digital tools for risk assessment, we highlight that protecting data privacy and confidentiality remains key. In this view, **particular attention should be given to the use of artificial intelligence for data validation**.

We also support the proposal to create an **EU network of reference laboratories** as part of the reinforced responsibilities of the ECDC. The network would offer voluntary guidance on diagnostics/test protocols, material resources, quality assessments, facilitating validation as well as mutual recognition of tests. This would **alleviate pressure on healthcare systems and ensure the smooth functioning of the single market**, particularly free movement of people across borders.

Overall, a **sound impact assessment** of EU action during the current crisis is key to evaluating measures aimed at strengthening EU health competences in future cross-border health emergencies. **We also call for an assessment of the impact of the new legislative package on public health authorities and on health insurance systems.**

Finally, looking beyond pandemics, **other long-term challenges** – such as antimicrobial resistance (AMR), cancer and chronic diseases – are posing a threat to the resilience and sustainability of health systems. They also require a common approach, increased coordination and adequate support instruments. Particularly, we welcome the fact that **AMR** is included in the list of threats of biological origin and would thus be addressed in national response plans as well as by the new European Health Emergency Response Authority.

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

