ESIP feedback to the proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

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

While Member States are responsible for the definition of national health policies, we believe that situations of common public health concern require coordinated actions and cooperation. We support a **European unified approach to tackle cross-border health threats that avoids fragmentation and respects national health competences**.

In this context an extension of the mandate of the European Medicines Agency (EMA) is timely and crucial.

- **Monitoring and mitigating shortages of medicines and medical devices**

  With a view to the monitoring and prevention of shortages, we welcome the establishment of the EMA Executive Steering Groups on medicinal products and medical devices, responsible for preparing **lists of crisis-relevant products**. Such lists should be **limited in time and in terms of subject matter to specific incidents and should be established in liaison with the ECDC**, responsible for the monitoring of epidemiological data. This would contribute to a timely response to health emergencies and limit the risk of shortages.

  We also recommend consulting the Medical Devices Steering Group in the same capacity as the Medicines Steering Group with regard to **information and advice on the safety and quality of medical devices related to both public health crisis and major events**.

  We support an approach that implies cooperation with national authorities, marketing authorisation holders, device manufacturers and notified bodies for monitoring supply and demand of essential products. We particularly welcome a reinforcement of the obligations on producers to report on issues that could result in

ESIP aisbl
Maison Européenne de la Protection Sociale
Rue d'Arlon 50 • 1000 Bruxelles • +32 2 282 05 60 • +32 2 282 05 98
esip@esip.eu • www.esip.eu • @ESIP_EU • VAT: BE 0808.072.950

supply bottlenecks. Sanctions could also be introduced in the case of non-compliance with such provisions.

As national authorities would be requested to provide sensitive health-related information, **this mechanism should build on a strong, safe and trustworthy data infrastructure**. **Participation in a coordinated electronic reporting system should be made mandatory to all relevant actors**, to enhance transparency across the supply chain. **The European Health Data Space should be swiftly established based on a robust legislative framework**, to enable exchange, use and processing of data including in health crisis contexts, in full compliance with the GDPR.

- **Increased coordination of clinical trials**

We acknowledge that the EMA would be mandated with the provision of scientific advice and support to clinical trial protocols, as well as with the rolling review of evidence in the context of public health emergencies, as part of the remit of the new Emergency Task Force. This would **respond to the urgent need to bring crisis-relevant products on the market**.

While exceptional measures could be justified to develop and approve urgently needed medicinal products in crisis contexts, **quality, safety and efficacy of treatments must remain the key priority**. Particularly, the **use of real-world data (RWD) should be limited to complementing data generated from randomised controlled trials when the effectiveness of medicinal products is questioned**.

Overall, a sound impact assessment of EU action during the current crisis is key to evaluating measures aimed at strengthening EU health competences in 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 cross-border challenges** – such as antimicrobial resistance, cancer and chronic diseases – are posing a threat to the resilience and sustainability of health systems across the EU. They also require a common approach, increased coordination and adequate support instruments, including financial support from relevant EU programmes.

You can find the submitted response on the European Commission's website here.