Position Paper on
Preventing and Managing Shortages of
Medical Devices and Personal Protective Equipment

European Social Insurance Platform (ESIP)

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About the European Social Insurance Platform (ESIP)

The ***European Social Insurance Platform*** **(ESIP)** represents over **50 national statutory social insurance organisations** in **17 EU Member States, the United Kingdom and Switzerland**, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

Statement regarding positions submitted by ESIP: ESIP members support this position in so far as the subject matter lies within their field of competence.

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Position Paper
Preventing and Managing Shortages of Medical Devices & Personal Protective Equipment

One of the preconditions to secure access to and delivery of healthcare in Europe is the availability of high quality and safe medicinal products and medical devices (MD). The European Social Insurance Platform (ESIP) welcomes the European commitment to secure continuous supply of medicines, medical devices and personal protective equipment (PPE) in the European Union (EU), building on experience gained in the COVID-19 crisis. Particularly, we welcome the Commission's focus on availability in the context of both the Pharmaceutical Strategy for Europe and the project for a European Health Union; the Parliament's report on shortages of medicines and medical devices; and the Portuguese Presidency of the EU Council commitment to draft Council Conclusions on Supporting Sustainable, Equitable and Universal Access to Medicines and Medical Devices.

As input to this discussion, ESIP reiterates some of the recommendations from its position on preventing and managing medicines shortages and proposes the following actions targeted to medical devices.

- **Make the Steering Group on Medical Devices an equivalent of the Steering Group on Medicinal Products**, that would be consulted for both public health and major events that may lead to shortages or affect the safety and quality of medical devices;

- Mandatory participation of all relevant actors to a **common reporting system** to enhance transparency regarding availability / non-availability of MD;

- **Continuation of common EU stockpiling** particularly of MD listed as critical based on epidemiological data, including testing and vaccination equipment;

- **Further use and increased transparency of the joint procurement mechanism** beyond pandemic contexts and before shortages occur, and maximising the options for Member States to participate;

- **Establishment of a legal and technical framework for emergency production of essential MD and PPE at EU-level**, accompanied by coordinated production plans and based on an EU-wide mapping of production capacities;

- **Increased mutual recognition and validation of medical devices** e.g. testing devices based on guidance from the new EU network of reference laboratories under the supervision of the European Centre for Disease Prevention and Control (ECDC).

General remarks

The COVID-19 crisis, especially in its first outbreak, had dramatic consequences on the supply of medicines, medical devices (MD) and personal protective equipment (PPE) across the EU, nationally and locally. Supply bottlenecks resulted in shortages, which directly impacted health professionals and patients' health and safety. Furthermore, independent and unilateral measures taken by some Member States – such as export bans, requisitions and excessive stockpiling – not only undermined the correct functioning of the internal market but also challenged the core principle of solidarity among Member States.

In light of the lessons learned in the early stage of the Covid-19 crisis, the European Social Insurance Platform (ESIP) outlines its proposals for securing the continuous supply of MD and PPE and tackling potential shortages. This paper builds upon ESIP's recent position on preventing and managing medicines shortages and takes stock of the measures specific to medical devices outlined in the legislative proposals on Building a European Health Union.

ESIP recognises that the European Union has played a key role in the management of shortages of medical devices and personal protective equipment during the Covid-19 pandemic, in particular with a view to monitoring and reporting, establishing a common European stockpiling system, launching joint procurement initiatives, scaling-up production and promoting mutual recognition.

1. Monitoring and Reporting

EU action: Creation of **the Commission Clearing House for COVID-19 medical equipment**, a platform to promote exchange of information on availability, supply and demand of medical devices.

ESIP welcomes measures to improve monitoring of stocks as well as prevention and mitigation of shortages of critical devices in situations of public health emergency, particularly with a view to the establishment of a new EMA Steering Group on Medical Devices.[1] Regarding major events (e.g. manufacturing issues, natural disasters and bioterrorism), we acknowledge that the Regulation only considers impact on safety, quality and efficacy of medicinal products and entitles the Agency to request assistance to the Executive Steering Group on Shortages and Safety of Medicinal Products. Consideration should be given to **further involving the Medical Devices Steering Group** with view to information and advice on the safety and quality of medical devices affected by major events, **in the same capacity as the corresponding Medicines Steering Group**.

[1] COM/2020/725 final. *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.*

ESIP also supports an approach that implies cooperation with device manufacturers, notified bodies and national authorities for the monitoring of stocks as well as volume of demand for essential products. Participation in a **coordinated electronic reporting system should be made mandatory to all relevant actors and would enhance transparency across the supply chain**, building upon and developing the existing Commission Clearing House for COVID-19 medical equipment.

2. Common European stockpiling

EU action: Concrete expression of EU solidarity via the deployment of RescEU, reinforcing the Civil Protection Mechanism through common stockpiling of essential medical equipment such as ventilators and masks.

ESIP encourages the European Commission and Member States to continue the common stockpiling of essential MD and PPE. **Crisis-relevant devices should be commonly identified** and ESIP supports the establishment of lists of critical products as part of the responsibilities of the new Executive Steering Group on Medical Devices. We also support the proposal to better liaise the Medical Devices Steering Group with the European Centre for Disease Prevention and Control (ECDC) in order to forecast medical device needs based on epidemiological data. In light of the current crisis, **particular consideration should be given to equipment needed for testing and vaccination** such as test kits, reagents, vaccine carriers, waste containers, injecting devices, disinfectants, personal protective equipment and anesthetic consumables.

3. Joint procurement

EU action: Joint procurement of essential equipment – such as gloves, masks, laboratory equipment, ventilators as well as tests – via greater use of the provisions laid down in Decision 1082/2013.

In order to increase EU preparedness for future cross-border health crises, ESIP believes that **this mechanism should be further developed** with the aim of preventing distortions in competition within the Internal Market and maximising the options for Member States to participate. Measures included in the proposal for a Regulation on serious cross-border threats to health[2] are a first step in this direction.

As COVID-19 testing policies and vaccination strategies become more inclusive, the need for MD will grow accordingly. ESIP supports the joint procurement of rapid

[2] COM/2020/727 final. *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU.*

antigen tests via the Emergency Support Instrument. Furthermore, we believe that **joint procurement could also be extended to non-pandemic contexts,** particularly with a view to medical equipment for vaccination.

ESIP believes that **joint procurement should ideally be used before acute needs and/or shortages occur**. The additional competences foreseen for the European Medicines Agency regarding the monitoring and prevention of shortages, including of MD, could support informed decisions on early triggering of the joint procurement mechanism.

Finally, as information on orders placed so far has been fragmented and incomplete, ESIP underlines that **transparent and comprehensive information** should always be provided on the characteristics of supplies secured through common procurement procedures and their prices.

4. Scale up production

EU action: Encouraging the rapid production of high-quality PPE in Europe through measures related to standards, such as free access to European standards, the publication of harmonised standards for essential PPE (such as masks, drapes, suits) and the issuance of technical guidance for emergency production of MD.

ESIP considers that the capacity to quickly upscale the production of high-quality medical devices and personal protective equipment is key to the EU's pandemic preparedness. Based on recent experience, ESIP recommends the **establishment of a legal and technical framework for emergency production of essential MD and PPE** at EU-level. This should be accompanied by **coordinated production plans** to be deployed in the event of future pandemics. A preliminary **EU-wide mapping of production capacities and operational procedures** would help ensure the rapid production of essential supplies, as mentioned in the European Parliament's report on shortages.[3]

5. Mutual recognition of medical devices

EU action: Initiatives to **ensure a coordinated approach to the quality and mutual recognition of MD – particularly testing diagnostics – as well as the interpretation of results,** such as the Commission's recommendations on (antigen) tests. These

[3] European Parliament [2020/271 (INI)]. *Report on the shortage of medicines – how to address an emerging problem.* Cfr. https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.html

coordinated initiatives are, as underlined by the European Commission, a prerequisite for uniform product quality and the smooth functioning of the internal market.

ESIP **welcomes the proposal to create an EU network of reference laboratories** as part of the reinforced responsibilities of the European Centre for Disease Prevention and Control (ECDC).[4] The new network would offer guidance on diagnostics/test protocols, material resources and quality assessments. Particularly we support recommendations of the ECDC on the use of specific medical devices, such as technical guidance on antigen tests. This would facilitate validation as well as mutual recognition of tests, alleviating pressure on healthcare systems while ensuring the smooth functioning of the single market and free movement of people across borders. This pooling and sharing of resources is at the core of European cooperation and could be of key added value in the event of a new pandemic.

[4] COM/2020/726 final. *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control.*