

## Preventing and Managing Medicine Shortages

Brussels – 07 October 2020



**“Medicine shortages are a serious, EU-wide challenge to be tackled in light of the current health emergency and beyond. Further cooperation and coordination among Member States is crucial when it comes to detecting shortages and managing stocks”**

**Ilka Wölfle**  
ESIP President

The ongoing COVID-19 pandemic has highlighted existing shortcomings in supply chains of medicinal products and medical devices in the EU. Both have been impacted by the crisis, increasing the risk of shortages of essential drugs and equipment and causing delays and disruption in treatments. The temporary or permanent unavailability of medicines severely affects patients' health and puts a serious strain on European healthcare systems.

Amid shared concerns about the disruptive impact of shortages, ESIP suggests a number of recommendations to secure availability and access to essential medicinal products. Although national healthcare systems are responsible for handling medicine shortages, in full respect of national public health priorities, joint action could be taken at EU level to increase the overall resilience and sustainability of healthcare systems across Europe.

### Enhancing supply across the EU

As a first step, ESIP calls for **a unified definition of strategically important and essential medicines and active pharmaceutical ingredients (API)**. We further advocate for **common criteria for the detection of shortages** and for an **evidence-based evaluation of supply bottlenecks**, building on increased transparency across the supply chain. Overall, a **coordinated reporting system** on stocks across European Member States would shed light on current and future shortages. At EU level, ESIP calls on the Commission to further **develop and simplify existing frameworks for joint procurement**, beyond COVID-19 treatments, and to introduce **mandatory sanctions for marketing authorisation holders who fail to secure supply** and do not comply with the current legal framework.<sup>1</sup>

### Monitoring and meeting demand

COVID-19 revealed that medicine shortages may occur due to sudden and unforeseen increases in demand for certain products. In this regard, ESIP supports the **exchange of real-time information** between stakeholders, including healthcare professionals, competent

<sup>1</sup> [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir\\_2001\\_83\\_consol\\_2012/dir\\_2001\\_83\\_cons\\_2012\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf)





authorities, payer organisations and wholesalers, to better manage shortages. ESIP also welcomes the recently adopted European Parliament's Resolution on Medicines Shortages: what the Parliament defines as "an emergency European pharmacy" reflects ESIP's call for a **"European stockpiling system for essential medicines"**.

### **Balancing diversification and relocation of production**

Finally, ESIP acknowledges that production sites are largely situated outside the EU, leading to increased dependency on third countries and potential disruptions in supply chains. Overall, ESIP supports the EU willingness to increase sovereignty in strategic sectors, including pharmaceuticals, by relocating production. However, ESIP also highlights the increased risk of shortages due to failures in the production process, where supply is dependent on too few production sites. Hence, a **balanced approach between diversification and relocation is needed**. In any case, **social standards on occupational health and safety** should be respected in all production sites. Finally, ESIP supports the discussions on **public production in Europe** of specific products, based on targeted guidelines.

ESIP welcomes the opportunity to exchange further with EU decision-makers on ways to tackle this important threat. More information is available in our [position paper](#).

Contact: [christine.dawson@esip.eu](mailto:christine.dawson@esip.eu)

