







Our organisations, representing patients, consumers, healthcare professionals and public health interests, very much welcome the INI report on the shortage of medicines voted by the European Parliament on September 17th 2020. We remind that shortages of medicines entail considerable risks for the health and safety of patients, the interests of whom must always come first in any policy aimed at fighting this global threat.

The report recommends several actions that shall contribute to better prevention and management of medicine shortages in Europe. Our organisations jointly call for prioritisation of the following initiatives:

- Carrying out a European study on the impact of shortages on patient care, treatment and health;
- Clarifying the supply and notification obligations for market authorisation holders and wholesalers under Directive 2001/83/EC and imposing dissuasive and proportionate sanctions in the event of non-compliance with these legal obligations;
- Setting up a centralised digital platform for declaring available stocks in the EU and for reporting shortages, including real-time communication to healthcare professionals and patients;
- Establishing harmonised shortage prevention and management plans for medicines of major therapeutic interest (MITMs) for which preventive and corrective measures should be taken in order to avoid or alleviate any disruption in supplies;
- Making sure that printed information leaflets remain always available for patients, even when complemented by an electronic version;
- Encouraging the implementation of procurement procedures that award a contract to multiple winners;
- Developing innovative and coordinated strategies, as well as good practice exchange in the area of stock management and stock transparency;
- Launching a Joint Action on the prevention of shortages to be funded by the new European health programme (EU4Health);
- Exploring the development of European non-profit undertakings, especially for essential medicines at high risk of shortage.

In addition, we believe that diversifying the sources of production of API, raw materials and finished pharmaceutical products is probably more important to fight shortages of medicines than the relocation of production alone, which may not prevent quality issues or problems on the production chain. Nevertheless, if pursued, public funding aimed at incentivising diversification and/or relocation of pharmaceutical production must always be fully transparent and conditioned to clear supply obligations on the European market, as well as accessibility and affordability of manufactured medicines.

We therefore invite the EU institutions and Member States to follow up on the above-highlighted priorities and we urge the European Commission to include them in the upcoming pharmaceutical strategy, as well as in other relevant EU policy actions.