

1

Sustainable incentives for pharmaceutical production

PGEU welcomes the introduction of incentives to stimulate manufacturing of critical medicines in Europe. However, any public support must be accompanied by strong supply obligations and contractual performance clauses, to ensure the effectiveness of the resources invested in securing patients' continued access to critical medicines.

Ensuring coordination across various medicine supply security initiatives

2

The Act should avoid duplication of efforts between the already existing Medicines Shortages Steering Group and the proposed Critical Medicines Coordination Group. Additionally, the Act should clarify the interconnections between the different identified lists of medicines, ensuring coherence between European and national level lists and implement a common definition of medicine shortages. It is also important to better define the scope of the Act by developing a list of vulnerable medicines with real fragilities in their supply chain.

3

Strengthening oversight of supply obligations

EU and national authorities need enhanced oversight and enforcement capacities to ensure compliance with existing obligations and the effectiveness of the public financial support granted. It is important to guarantee patients continued access to medicines no matter where they live in the EU. This includes all Member States, including small countries.

4

Leveraging strategic spending packages for security

Reinforcing health security should be recognized as a strategic objective of the EU. PGEU supports using new funding sources, including the new EU's defense spending package and the Competitiveness Fund, to finance the Critical Medicines Act provisions on security of supply and preparedness.

5

Optimizing contingency stocks

Member States should optimize national obligations on contingency stocks of medicines through a coordinated European approach. PGEU recommends the harmonization and implementation of rolling contingency stocks at manufacturers level to avoid unnecessary waste of finished medicinal products.

6

Improving public procurement of medicines

Public procurement processes must shift away from a sole focus on lowest price. Incorporating non-price criteria, Most Economically Advantageous Tender (MEAT) criteria, and splitting awards among multiple suppliers will enhance supply security and contribute to ensure continuity of treatment for patients.

7

Swift adoption and implementation

PGEU urges the European Parliament and Council of the European Union to treat the Critical Medicines Act as a top priority and move quickly towards its adoption. Given the ongoing shortages impacting patients daily, while waiting for new legislative measures to enter into force, we invite all the stakeholders to do everything they already can, within their remit, to mitigate shortages.