European Alliance for Responsible R&D and Affordable Medicines

The prevention of medicine shortages in the EU: a key priority of the pharmaceutical legislation revision process

Executive summary

Along with high prices leading to unaffordable medicines, shortages are another critical obstacle to patients' access to medicines and optimal care. Therefore, it is imperative that the revision of the pharmaceutical legislation addresses this increasing problem as a key and integral part of the access to medicines strategy.

European Alliance recommendations for the revision of the EU pharmaceutical legislation on medicine shortages

The EU needs a bold patient-centered policy on the prevention and management of medicine shortages based on public health considerations and making the pharmaceutical industry accountable for the fulfillment of its duties. The transparency of supply chains should be at the core of this policy.

1. **Information on medicine shortages**

- Strengthen the obligation for pharmaceutical companies to notify both unexpected shortages and shortage risks as soon as they are identified to enable the implementation of management and/or prevention measures as early as possible.
- Require a long notice period – of at least one year – for withdrawals due to commercial reasons.
- Establish harmonized reporting criteria for shortages and shortage risks, including detailed information on key parameters (product details, shortage causes, expected impact and duration, etc.).
- Allow patients to report shortages of medicines, as this could provide valuable information on their impacts and could further support medicine shortage management.
- Ensure effective and transparent communication on medicine shortages in the EU through a comprehensive database, which is accessible to the public. This should include information on the shortage causes and expected duration.

2. **Prevention measures**

- Establish an independent and proactive monitoring system of stocks of medicines in the EU to help anticipate shortage risks upstream. This should include a legal obligation for pharmaceutical

companies to provide transparent and regular information on their stocks, as well as effective controls from the Medicine Agencies.

- Create a legal obligation for pharmaceutical companies to prepare and submit transparent shortage prevention and management plans with the input of competent authorities, patients, and healthcare professionals.
- Introduce a legal obligation for pharmaceutical companies to maintain relevant safety stocks of medicines of major therapeutic interest at EU-level.
- Adapt the model of joint procurement used for COVID-19 vaccines to buy medicines in limited supply and distribute them fairly among Member States, improving the transparency of the negotiation process and the contractual conditions.
- Promote public production strategies whenever needed to ensure the availability of essential medicines and therapies[1].

3. Mitigation measures and sanctions

- Adapt the regulatory framework to give hospital pharmacists clear authority for preparing and distributing medicines of major therapeutic interest in case of shortages, including in the event of withdrawal of a product from the market for commercial reasons.
- Ensure that pharmaceutical companies comply with their legal obligations and set up dissuasive sanctions in case of non-compliance.

Endorsing organizations

1. European Public Health Alliance (EPHA)
2. Asociación por un Acceso Justo al Medicamento (Spain)
3. Consumer Association the Quality of Life-EKPIZO (Greece)
4. Médecins du Monde (Spain)
5. Prescrire
6. AIDS Action Europe (AAE)
7. Organización de Consumidores y Usuarios (Spain)
8. La Ligue contre le cancer (France)
9. TRT-5 CHV (France)
10. AIDES (France)
11. France Assos Santé
12. Salud por Derecho (Spain)
13. Pharmaceutical Accountability Foundation (Netherlands)

About the European Alliance for Responsible R&D and Affordable Medicines

The Alliance is a civil society coalition gathering consumer, patient and public health organisations calling for the creation of an R&D system that is driven by public health needs and delivers medicines that are universally accessible and affordable.

[1] There are ongoing strategies in the field of advanced therapies that can serve as a reference and could be explored for other types of treatments.