

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

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.

Impact on patients

Shortages of medicines have dramatic consequences for patients in terms of worsening of symptoms, disease progression, as well as reducing protection from infectious diseases. They can also lead to suboptimal patient care, substitution with less effective and/or more toxic treatments, increased medication errors and risk of exposure to counterfeit medicines. Indeed, faced with drug shortages patients sometimes turn to unreliable supply sources, especially through online purchases.¹

Shortages also create problems for healthcare workers and pharmacists, who must spend an enormous amount of time and resources to find alternative treatments for their patients, not always with success. As a result, shortages affect patients, health systems and society as a whole.²

An increasing problem in the EU

The rapid rise in medicine shortages over the last few years³ represents one of the most blatant shortcomings of the current EU pharmaceutical legislation. In reaction to this, several countries have enacted legal and non-legal measures to prevent or deal with shortages, including:

- notification obligations for both actual and potential shortages, as well as longer notification periods in case of market withdrawals for commercial reasons;
- an obligation for pharmaceutical companies to keep safety stocks of medicines of high therapeutic interest;
- developing management and prevention plans⁴;
- imposing sanctions in case of infringement of obligations.

¹ <https://www.france-assos-sante.org/wp-content/uploads/2019/02/Penuries-medicaments-Resultats-BVA-dec2018.pdf>

² https://www.eahp.eu/sites/default/files/eahp_2019_medicines_shortages_report.pdf

³ In France, the number of shortages for medicines of major therapeutic interest went from 871 in 2018, to 1,504 in 2019 and to 2,446 in 2020; in the Netherlands there were 769 shortages in 2018 compared to 1,492 shortages in 2019, ; and in the Czech Republic 1,630 in 2018 compared to 2,208 in 2019. See <https://epha.org/wp-content/uploads/2020/04/epha-a2m-medicine-shortages-position.pdf>

⁴ <https://ansm.sante.fr/actualites/disponibilite-des-medicaments-lansm-publie-les-lignes-directrices-pour-lelaboration-des-plans-de-gestion-des-penuries>

European Alliance for Responsible R&D and Affordable Medicines

However, fragmented national rules and initiatives have not been able to prevent the huge increase in medicine shortages in the EU. A pan-European approach, embedded in the revised pharmaceutical legislation, has much to offer in this area.

Incentives for the relocation of raw materials, active pharmaceutical ingredients (API), or drug manufacturing are also being discussed at the EU level as a possible measure to reinforce the supply chain.

EU initiatives so far

The COVID-19 pandemic provided an additional impetus for setting the basis for an EU management of shortages, especially with:

- The adoption of the European Parliament Report on the shortage of medicines⁵.
- The publication of the study⁶, commissioned by the European Commission, to support the design of policies to address shortages of medicines in the EU.
- The extension of the mandate of the European Medicines Agency, which allows the Agency to monitor and mitigate shortages of medicines and medical devices during major events and public health emergencies⁷.
- The structured dialogue⁸ on security of medicines supply.

While the structured dialogue - chiefly coordinated by pharma companies and pharma associations - blatantly failed to represent the full range of stakeholder' views, the regulation on the extension of EMA's mandate includes the participation of patients and healthcare professionals in the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). **We welcome this approach that we consider essential for ensuring equitable access to medicines across the European Union, and we hope that forthcoming proposals and initiatives will continue to strengthen the meaningful participation of patients and healthcare professionals in the prevention and management of shortages.**

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

⁵ https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.html

⁶ Future-proofing pharmaceutical legislation — study on medicine shortages <https://op.europa.eu/en/publication-detail/-/publication/1f8185d5-5325-11ec-91ac-01aa75ed71a1/>

⁷ Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0123>

⁸ https://ec.europa.eu/health/medicinal-products/pharmaceutical-strategy-europe/structured-dialogue-security-medicines-supply_en

European Alliance for Responsible R&D and Affordable Medicines

- 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 therapies⁹.

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.

Several of these proposals have been partially incorporated in the report "Future-proofing pharmaceutical legislation — study on medicine shortages", which can be used as a basis for further discussions on the legal measures to be adopted in the revised pharmaceutical legislation.

Endorsing organizations

1. European Public Health Alliance (EPHA)
2. Asociación por un Acceso Justo al Medicamento (Spain)

⁹ 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.

European Alliance for Responsible R&D and Affordable Medicines

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.

Annex: Further resources on shortages of medicines by members of the Alliance

- No es Sano: <http://noessano.org/en/news/medicine-shortages-are-increasing-and-there-is-a-lack-of-transparency-for-the-reasons>
- BEUC: https://www.beuc.eu/publications/beuc-x-2020-034_addressing_medicine_shortages_during_the_covid-19_pandemic.pdf
- EAHP: https://www.eahp.eu/sites/default/files/eahp_survey_on_the_future_crisis_preparedness_of_hospital_pharmacies.pdf
- ECL:
 - [ECL reflection paper on the policy dynamics on medicine shortages](#)
 - [ECL statement on the reflection paper on forecasting demand for medicinal products in the EU/EEA](#)
- EPHA:
 - <https://epha.org/wp-content/uploads/2019/05/shortages-letter-17-may-2019-final.pdf>
 - <https://epha.org/wp-content/uploads/2020/04/epha-a2m-medicine-shortages-position.pdf>
- Medicines Law and Policy: <https://medicineslawandpolicy.org/2019/02/faced-with-unreasonable-medicines-prices-the-netherlands-introduces-pharmacy-exemption-in-patent-law/>
- Prescrire:
 - <https://www.prescrire.org/fr/3/31/58711/0/NewsDetails.aspx>
 - [Prescrire “Drug shortages: report the sometimes serious adverse events they cause” *Prescrire International* 2020; 29 \(218\):220-222](#)
- France Assos Santé:
 - <https://www.france-assos-sante.org/wp-content/uploads/2019/07/190708-CP-FAS-plan-de-lutte-contre-penuries-medicaments.pdf>
 - https://www.france-assos-sante.org/bon_mauvais_point/penuries-de-medicaments-renforcer-et-rendre-publiques-les-sanctions-france-assos-sante-salue-les-propositions-dune-mission-de-lassemblee-nationale/