BEUC The European Consumer Organisation

The Consumer Voice in Europe

Position paper

Stronger supply chains for improved access to medicines

July 2025

Why it matters to consumers

The COVID-19 pandemic and recent geopolitical events have shown the need to have more diversified and resilient supply chains for essential goods, such as medicines. Strengthening EU's supply security will help ensure that consumers can start a new treatment as soon as need it and continue it without interruption. The Critical Medicines Act proposed by the European Commission has the potential to become an important piece of the EU's policy toolbox against medicine shortages.

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The European Commission's proposal for a Critical Medicines Act seeks to tackle shortages by addressing supply chain vulnerabilities, such as poor diversification.[1] The initiative also aims at strengthening the availability and accessibility of medicines for which patients encounter specific barriers (e.g., treatments for rare diseases). BEUC considers that the proposal goes in the right direction but should be further aligned with consumers' needs and expectations.

This paper outlines our recommendations in relation to the:

[1] Regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795. Available here.

1. Introduction

From antibiotics to painkillers or pills to treat cardiovascular problems, there is growing concern that the medicines patients need are not always available in pharmacies or hospitals.

Consumer surveys in four countries show that, on average, about 40% of households experienced a medicine shortage between January 2023 and January 2024.[2] At the same time, the latest data from EU community pharmacists show they spent three times as many hours addressing shortages as they did a decade ago. This amounts to almost 11 hours per week on average.[3] Shortages have a negative impact on consumers and public health systems - they can lead to treatment delays or interruptions, patients suffering side effects from alternative treatments, and increased co-payments.[4]

Medicine shortages are caused by multiple factors including insufficient diversification (e.g., geographical, number of production sites) and market concentration.[5] Patients can also face shortages when companies choose to prioritise the supply of more profitable medicines.

Adopting measures that tackle vulnerabilities in supply chains is a must. While this is important for all medicines, those included in the Union List of Critical Medicines deserve special attention. This list includes about 280 selected substances based on the seriousness of the disease they target and alternatives' availability or lack thereof.

The European Commission's proposed Critical Medicines Act is an opportunity to address risk factors for these medicines. The plan is to promote investments in projects that increase manufacturing capacity in Europe, align public procurement with supply security needs, and promote global diversification. In addition, the Commission proposes expanding joint procurement beyond medical countermeasures to improve access to medicines for which there are specific challenges.

In this paper, we recommend measures to maximise public return on public investment, and to enhance transparency, solidarity, and consumer engagement in the implementation of the Regulation. As the file enters the co-legislative process, we call on the European Parliament and the Council to consider the recommendations we outline below.

[2] Surveys carried out by BEUC members in Spain, Italy, Belgium, and Portugal, as part of Euroconsumers. Out of Stock! Not available when you need it: the case of drug shortages, Euroconsumers, July 2024
[3] PGEU, PGEU Medicine Shortages Report 2024, January 2025
[4] EAHP, EAHP 2023 Shortage Survey Report, 2023. See also footnotes 2 and 3.
[5] Critical Medicines Alliance, Strategic Report of the Critical Medicines Alliance, European Commission, February 2025

2. Key recommendations

2.1. Objectives of the Regulation

Ensuring that medicines reach patients requires action in different areas. For this reason, we strongly support the Commission's proposal to set a dual objective for this Regulation:

1. Strengthening the supply security and availability of substances included in the Union list of Critical Medicines ("critical medicines")
2. Ensuring the availability and accessibility of medicines that present specific access challenges for patients ('medicines of common interest'). [6]

We also support the reference to medicines affordability in Article 1. However, the latter is not only important for 'medicines of common interest', but also for 'critical medicines'.

Recommendations (Article 1):

- Clarify in Article 1 that, in pursuing its objectives, the Regulation shall give due consideration to the need to ensure the affordability of both 'medicines of common interest' and 'critical medicines'.
- Paragraph 2 (a) should mention that the Regulation sets out a framework to facilitate investments in manufacturing capacity for critical medicines, their active substances and other key inputs "while seeking to maximise public return on public investment and transparency".

2.2. Designation of 'Strategic projects'

We agree with the Commission's proposal to consider as "Strategic Projects" those initiatives that create or increase manufacturing capacity in the EU for critical medicines (Article 5). However, to ensure that greater manufacturing capacity translates into concrete benefits for consumers, the promoter of a project should clearly show how this investment will contribute to the continued supply and availability of products contained in the Union List of Critical Medicines.

Recommendations (Articles 5 and 6):

- Article 5 should specify that a project is "strategic" if it meets at least one of the four criteria suggested by the Commission and "contributes to the security of supply and availability of the medicinal product(s) in the Union."

[6] Defined in the Commission's text as a "*medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States*" (Definitions)

- Consequently, Article 6 should require the designated authorities in charge of recognising Strategic Projects to assess whether the initiative will contribute to the end goal mentioned in Article 5.

2.3. Financial support by Member States

An evidence-based approach to the provision of State Aid is necessary to ensure that taxpayers' money is spent wisely. Therefore, we endorse the Commission's proposal in Article 15 to prioritise State Aid for Strategic Projects that address a vulnerability in the supply chains of critical medicines, following a vulnerability evaluation. The Regulation should, in addition, require that State Aid is proportionate and goes hand in hand with commitments that maximise public return on public investment.

Recommendations (Articles 15, and new recital):

- Ensure that State Aid is proportionate to the financing needs of a Strategic Project and subject to transparency requirements including on conditionalities linked to return on public investment (Article 15).
- Require that an undertaking that has received financial support does everything at hand to ensure that the medicine becomes available in Member States where it is not on the market, upon request from their national competent authorities. This should happen on top of manufacturers making their "very best efforts" to ensure availability in Member States where the product is already commercialised.
- In parallel, it is important that the recitals acknowledge the need for an all-encompassing understanding of "very best efforts".
- Include in Article 15 that financial support should go hand with measures that contribute to the affordability of the critical medicine(s).
- Accordingly, this Article should entrust the Critical Medicines Coordination Group to develop guidance on the nature of such affordability measures. The Regulation could specifically require that, during a public health emergency, the Coordination Group should promote the use of non-exclusive licensing as was done in the Temporary State Aid Framework adopted during the COVID-19 pandemic.

2.4. Financial support from the Union

While we support that EU funding could be used for Strategic Projects (Article 16), we would also like to see that it comes together with conditionalities. In addition, we consider that the Regulation should supports means of production beyond industrial manufacturing, such as compounding. Hospital pharmacies play a crucial role in helping mitigate medicine shortages. The Regulation should therefore promote the use of regional development funds to equip public hospitals with the tools that are necessary to prepare medicinal products.

Recommendations (Article 16):

- Require that Union funding goes together with conditionalities on medicine availability and affordability.
- In addition, this Article should refer to regional development funds as a means to support the capacity of public hospitals' pharmacies to prepare critical medicines, in line with the practices described in Article 1, paragraph 5, of the revised Medicinal Products Directive (2001/83/EC)[7].

2.5. Award criteria in public procurement

"Critical medicines" are particularly important for health systems and have few or no alternatives. For this reason, we support the Commission's proposal (Article 18) to apply procurement requirements other than price-only award criteria that promote supply security.

As outlined in the proposal, supply-related criteria could include supply diversification, supply chain monitoring and transparency, among others. At the same time, to provide some flexibility to Member States, we call for keeping the possibility for derogations in paragraph 5. In addition to this, we call for introducing new measures in the Regulation that help ensure '**fair pricing'**.

Recommendations (Article 18):

- Keep the possibility for Member States to decide not to apply the obligation to consider supply-related criteria in the procurement of critical medicines, where justified by market analysis or considerations related to the financing of health services (paragraph 5).
- At the same time, there should be a new paragraph stating that competent authorities responsible for pricing and reimbursement, and procurement, can require Marketing Authorisation Holders (MAH) to submit, at any time, audited data on the R&D, production and distribution costs of a medicinal product. The MAH should fulfill the request within the specific timeframe set by the relevant authority.
- We suggest adding in Paragraph 4 that this Article shall not preclude contracting authorities from using additional qualitative requirements, including those related to environmental sustainability, social rights, "and transparency".

[7] Please note that this piece of legislation is currently undergoing trilogue negotiations.

2.6. Safety stocks

Safety stocks requirements help mitigate the impact of supply disruptions on consumers. However, it is important to ensure that national stock requirements do not have unintended consequences in other Member States. While we support that the Regulation calls for ensuring proportionality, transparency, and solidarity amongst national approaches on contingency stocks, we think Article 20 should include specific measures on how to get there.

Recommendations (Article 20):

- Keep the Commission's proposed principles. To reinforce the principle of solidarity, this Article should contain a reference to the "Solidarity Mechanism" managed by the EMA that facilitates stock-sharing when a country faces critical shortages.
- Require, in addition, that Marketing Authorisation Holders maintain a two-month safety stock of critical medicines in the Member States where they are commercialised.
- Specify that Member States should be able to adopt complementary measures on contingency stocks based on their own lists of medicines considered of major interest. It is critical to indicate that, where necessary, the Commission should establish criteria to ensure that any additional obligations on contingency stocks introduced at national level do not impact on the availability of medicinal products in other Member States.

2.7. Collaborative procurement

By teaming up in joint procurement, Member States increase their bargaining power and their chances to secure more affordable prices. For smaller Member States, getting together is also an opportunity to ensure that companies will launch their products in those countries. We therefore support the Commission's proposal to facilitate joint procurements beyond medical countermeasures - as is the case today – and cover both "critical medicines" and "medicines of common interest". However, we suggest some improvements to make the most of this initiative.

Recommendations (Recital 32 and Section II)

- Recital 32 on collaborative procurements should mention medicines for rare diseases, antimicrobial and expensive new treatments for other therapeutic areas such as oncology as examples of "medicines of common interest".
- Ensure under Article 21 that the Commission is able to not only facilitate cross-border procurement for a group of Member States, but also joint price negotiations i.e. in case they prefer to conduct separate procurement procedures (as in the BeneluxA initiative).

- It is also important to mention in Section II that collaborative procurements (in any of their modalities) need to consider multi-winner tenders to avoid market concentration.

- In addition, there should be a new article in this Section stating that the Commission should set up a "pull incentive" to reward the development of priority antimicrobials upon request from interested Member States. This incentive should consist of collaborative procurement and a revenue guarantee (RG) payment model. A similar RG scheme could also be implemented to improve access to older antibiotics.

2.8. Critical Medicines Coordination Group

We support the creation of a body composed by Member States and the Commission that facilitates coordination in the implementation of the Regulation. To ensure that its activities are well-aligned with the needs and expectations of those most affected by medicine shortages, it is important that consumers, patients, and healthcare professionals can take part in this body.

Recommendation (Article 25):

- Allow consumer, patient, and healthcare professionals representatives to be part of the Coordination Group.

- Request that its members must have no financial or other interests that could affect their impartiality.

2.9. Transparency

Ensuring transparency in the implementation of the Regulation is necessary for public accountability purposes. This principle should be mainstreamed across the text.

Recommendation (Articles 26 and 29, and new recital):

- Entrust the Coordination Group (Article 26) to ensure transparency in the implementation of the Regulation, including through specific public accountability provisions for Chapters III (Enabling conditions for investment) and IV (Demand side measures, including collaborative procurements).

- Article 29 on the "Obligation of the market actors to provide information" should mention the existence of an "overriding public interest in disclosure" as an exception to commercial confidentiality in paragraph 3.

- A new recital should be introduced, acknowledging the importance of taking common steps by Member States towards achieving the goals of the World Health Assembly Resolution on "Improving the transparency of markets for medicines, vaccines, and other health products" of May 2019.

2.10. Penalties

Recommendation (new Article):

There should be a specific Article requiring Member States and the European Commission to lay down rules on penalties applicable to infringements of the obligations set out in the Regulation. The criteria which lead to penalties must be sufficiently clear to ensure a high-level of protection and coherent level of enforcement across the EU.

To ensure that the obligations set out Regulation are complied with, there should be effective, dissuasive, and proportionate penalties.

2.11. Evaluation

We support the proposal to conduct an evaluation of the Regulation five years after the date of application, and every five years thereafter. In addition:

- Article 30 should specify that in conducting such evaluation, the Commission must assess the extent to which the use of supply-related criteria in public procurement has contributed to addressing medicine shortages in the EU, while safeguarding the financial sustainability of public health systems.
- Following up on the European Parliament's 2020 Report on medicine shortages, the Regulation should require the Commission to explore the feasibility of creating, with Member States, one or more European non-profit pharmaceutical undertakings which operate in the public interest and manufacture medicinal products.8 The Commission should submit this report to the European Parliament and the Council 12 months after the application of this Regulation
- In this regard, we propose acknowledging in the recitals that different models of production can contribute to strengthening EU medicines' supply security and should therefore be supported.

We encourage supporting the recommendations outlined above to ensure that the Critical Medicines Act is well-aligned with public health interest. An effective EU response to shortages will also require that this initiative is matched by strong obligations for industry in the EU pharmaceutical legislation. For example, an obligation to develop shortage prevention plans for all medicines and to notify authorities of supply disruptions at an earlier stage. Adopting a strong chapter in the pharma legislation on shortage prevention and mitigation is essential, given that the scope of products covered in the Critical Medicines Act is more limited.

END

[8] European Parliament, Resolution of 17 September 2020 on the shortage of medicines — how to address an emerging problem (2020/2071(INI))