BEUC The European Consumer Organisation

The Consumer Voice in Europe

Permanent Representation to the EU

B- Brussels

By email

BEUC-X-2025-109 Brussels, 26 November 2025

Subject: The Council must show ambition to improve access to medicines

Dear Deputy Permanent Representative,

I'm contacting you on behalf BEUC, the European Consumer Organisation, regarding the meeting between Ministers of Health (EPSCO) that will take place on 2 December.

Over recent years, consumers across the EU have increasingly struggled to obtain the medicines they need. Shortages, including for critical medicines, have become more frequent and disruptive, while rising treatment costs raise concerns about long-term affordability and access. Patients for which there are no effective therapies continue to face uncertainty, and antimicrobial resistance remains a major public health challenge.

The ongoing negotiations on the **Pharmaceutical Package** offer a crucial opportunity to address structural gaps in the EU medicines framework. To achieve meaningful reform, EU institutions and Member States must place patients' and consumers' interests at the centre. BEUC calls for a more balanced system of incentives that delivers real and accessible innovation, timely market entry of generics and biosimilars, and robust measures to prevent and manage shortages, including mandatory prevention plans for all medicines.

The proposed **Critical Medicines Act** is vital to promote more diversified supply chains to the benefit of consumers. BEUC therefore calls for procurement rules that reward resilient suppliers. We also call for proportionate and conditioned funding for strategic manufacturing projects in the EU, and support for not-for-profit production models. This should be paired with harmonised approaches on safety stocks and more joint procurements to improve medicine availability across the EU.

Together, these legislative files can help build more resilient and accessible healthcare systems. Our recommendations are detailed in the Annex.

We count on Member States to reflect these priorities in the upcoming EPSCO discussions and in the negotiations on the Pharmaceutical Package and the Critical Medicines Act. We trust the Council will stand ready to ensure that consumers' interests are placed at the forefront.

I thank you in advance for taking our suggestions into consideration and remain at your disposal for any questions you may have.

Yours sincerely,

Agustín Reyna
Director General

(Annex below)

Annex

1. BEUC recommendations on the EU Pharmaceutical legislation

1.1. Strengthen competition

Rising treatment costs and delayed competition hinder patients' access to affordable medicines across the EU. The Pharmaceutical Package must expand the Bolar exemption to allow generic and biosimilar developers to prepare market entry earlier and participate in procurement tenders before the exclusivity on the originator product expires. This would improve supply readiness without infringing intellectual property rights. As proposed by the Council, it should go together with a modulated system of market protection for new medicines, that does not exceed the current maximum period of exclusivity (i.e., 10 years plus an additional one for a new indication).

Finally, if transferable exclusivity vouchers are introduced, they must come up with strong safeguards to mitigate their negative impacts. We recommend promoting sustainable innovation models such as milestone payments and subscription schemes, as proposed by the European Parliament. This would better align innovation with public health needs, while safeguarding access and stewardship.

1.2. Medicines reach all EU Member States

New medicines are not (timely) available across the EU, creating unequal access. Marketing authorisation holders must be pushed to place medicines on the market in all Member States. Thus, we support the Council's approach to require companies to file pricing and reimbursement applications upon request, with penalties including loss of regulatory protection for one year in Member States where medicines are not available. This is a good combination of the Commission's and European Parliament's proposals. Transparency is also key. The EMA database should include the list of countries where medicine is marketed.

We support the Council's proposal to allow earlier assessment of marketing authorisation applications for generics and biosimilars, starting six years after the beginning of data protection for the reference product, to enable timely market entry. However, this possibility should be extended beyond the proposed narrow approach and be always an option for generics manufacturers. This would allow scientific assessment procedures to begin earlier, without shortening data protection. It would avoid unnecessary delays in the evaluation process and ensure that, as soon as regulatory protections expire, generics and biosimilars can obtain marketing authorisation without further hold-ups, improving competition and patient access to affordable treatments.

1.3. Mandate comprehensive shortage prevention plans

Medicine shortages are increasingly frequent and disruptive, threatening patient care and treatment continuity. We support the European

Commission's and European Parliament's approach to require pharmaceutical companies to develop shortage prevention plans for all their products, ensuring continued supply and early identification of risks. These plans must include robust demand forecasting methodologies and meaningful involvement of patients and healthcare professionals in shaping guidance.

2. BEUC recommendations on the Critical Medicines act

As the Council is expected to reach a General Approach on **2 December** and move towards trilogues in 2026, we call for a final text that brings tangible benefits for consumers.

2.1. Attach strong conditionalities to State Aid

We call for ensuring that State Aid and EU funding for Strategic Projects is conditioned on strict obligations to ensure a fair return on public investment. Recipients should commit to affordable pricing and guarantee a reliable, long-term supply of critical medicines. This is essential to prevent unjustified profiteering from publicly funded projects and to ensure medicines remain accessible and affordable for patients.

2.2. Consider supply security in public procurement and ensure fair pricing

Procurement rules should apply MEAT criteria that reward bidders for diversifying supply chains. This should go together with measures that help ensure fair pricing and affordability. This approach supports stronger, more sustainable medicine supply and better patient access.

2.3. Facilitate joint procurement for medicines of common interest and critical medicines

We support introducing joint procurement mechanism for both critical medicines and medicines of common interest for which access barriers remain (e.g. rare diseases, expensive cancer treatments). In addition, the CMA should establish a revenue-guarantee scheme for antibiotics to incentivise their development and manufacturing while ensuring access. This scheme would provide predictable finance in a sustainable way for healthcare systems.

2.4. Adopt coordinated safety stock approaches

We recommend requiring companies to maintain a baseline two-month safety stock of critical medicines in each Member State and ensure that additional measures at national level do not have a negative impact on other countries. We also call for coordinated EU stock-sharing mechanism to allow solidarity in case of shortage. The Regulation should also mandate the Critical Medicines Coordination Group to include consumer, patient, and health professional representatives to oversee implementation.

2.5. Promote non-profit and public-interest manufacturing models

The Critical Medicines Act should encourage the development of non-profit and public-interest manufacturing initiatives. These models can be particularly helpful for treatments that are commercially unattractive yet vital for patients, ensuring continuous supply, reducing shortages, and keeping affordability and equitable access at the core.

For more information, please see our key recommendations for the Pharma legislation and our factsheet on the Critical Medicines Act.