

The Consumer Voice in Europe

BEUC-X-2024-085

Brussels, 7 November 2024

Subject: The Council must ensure the pharmaceutical legislation delivers for consumers

Dear Health Attaché,

I am writing to you on behalf of the European Consumer Organisation (BEUC) on the revision of the EU pharmaceutical legislation.

We are concerned that the Council's position will fall short of addressing the needs of consumers in relation to medicines. The reluctance of some Member States to allow that generics can enter earlier the market for certain products is particularly worrying.

Trends in pharmaceutical expenditure are alarming. Public payers point to medicine [price increases](#) as the main driver of growing spending. They warn that if the situation continues, health systems will face greater sustainability challenges. Without more competition in the pharmaceutical sector, consumers will face greater barriers to affordable treatment. The revision of the EU legislation is an opportunity to fix this.

Consumers also need effective solutions against medicine shortages. Supply disruptions have become a major issue, impacting people's health and pockets. The Council should strengthen, instead of watering down, the measures proposed by the European Commission on medicine shortages.

Ahead of the Working Party meeting on the pharmaceutical legislation on 12 and 13 November, we call on the Council to make progress in this direction:

1. Ensure the right balance between regulatory incentives to innovation and generic competition

Member States must agree to shorten the period during which a new medicine is protected from generic competition. A meaningful reduction of the baseline period for 'data protection' is necessary to bring savings to public health systems.

The modulated system of incentives should not allow companies to go beyond today's maximum length of data protection (8 years).

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2. Oblige companies to file for pricing and reimbursement

To improve medicine availability across the EU, the legislation must include an obligation for companies to file for pricing and reimbursement following marketing authorisation.

In addition, as proposed by the Hungarian Presidency, the 2-year 'market protection' should be lifted in those Member States where a company has not made its product available as requested.

3. Introduce prevention plans for all medicines and stock requirements

The Council should support the proposal of the European Commission and the European Parliament to oblige companies to develop shortage prevention and mitigation plans for all medicines.

This will help guarantee that companies fulfil their obligation to ensure continued supply for any product they have on the market. In addition, the legislation should oblige companies to hold 2 months of safety stocks for critical medicines.

4. Promote antibiotic development in fair ways

Member States should agree to promote antibiotic development through a scheme of push and pull incentives coordinated by HERA. Such a system should consist of research grants, milestone prizes, and joint procurement with payments that de-link revenue from sales volume (revenue guarantee).

We thank you in advance for considering our recommendations, and remain at your disposal for any questions you may have.

Yours sincerely,

Ancel·la Santos
Deputy Head of Food, Health and Safety