

Ref.: BEUC-X-2023-133/MGO/cm

Brussels, 17 October 2023

**Subject: BEUC recommendations for the European Commission's Communication on medicine availability**

Dear Commissioner Kyriakides,

I am writing on behalf of the European Consumer Organisation (BEUC) concerning the upcoming Commission's Communication on measures to enhance medicine supply security.

BEUC welcomes the Commission's plans to complement the revision of the EU pharmaceutical legislation with short- and mid-term actions to tackle shortages. For this initiative to be fit for purpose however, it will be important to ensure the following:

**1. Consumer groups must have the opportunity to help shape the list of critical medicines**

BEUC supports the adoption of a 'Union list of critical medicines' for which Member States and the EU cooperate on shortage prevention and responses. To ensure the list is comprehensive, regulators should involve consumer, patient, and healthcare professional groups in the procedure.

So far, stakeholders have been consulted in the early stages of that process under the Structured Dialogue on Supply Security. We call on the Commission, the EMA, and national regulators to provide more opportunities for stakeholders to comment on the initiative. This will help ensure that the list includes all medicines that are a priority for health care .

**2. Member States must have a good overview of available stocks**

We endorse the Member States' proposal to set up a solidarity mechanism between countries to alleviate the impact of shortages where they hit the most.<sup>1</sup> However, for this system to be effective, governments must have a good overview of available stocks.

Member States should gather this information already today and, in the mid-term, have in place electronic monitoring and early warning systems that are interoperable with the EMA's European Shortages Monitoring Platform.

**3. Public authorities must communicate effectively on drug shortages**

We also call on Member States and the EMA to communicate on shortages in a timely and comprehensive manner. This includes the reasons of the shortage, their expected duration and informing on potential alternative treatments.

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<sup>1</sup> Non-paper – Improving the security of medicines supply in Europe – (BE, AT, NL, LU, HU, CZ, ES, FR, DE, EE, SI, RO, LV, LT, EL, MT, PL, IT, PT), May 2023.

When medicines are missing, it is important to make it easier for pharmacists to prepare the medications. Consumers should not be asked to adjust formulations themselves as happened last winter when antibiotics for paediatric use went missing. When this happens, it undermines patient safety.

#### **4. The Commission must enable joint procurement and non-profit manufacturing**

To improve medicine availability, is also essential that the Commission puts in place a voluntary scheme for joint procurement beyond crisis situations. Such a scheme would be particularly helpful for the purchase of medicines for which pharmaceutical companies ask very high prices, and also for which there are few patients.

In addition, it is high time that the Commission follows up on the European Parliament's proposal to set up non-profit undertakings which operate in the public interest to manufacture medicinal products.<sup>2</sup> This can help improve the availability of medicines for which there is less commercial interest.

#### **5. Ensure an open discussion on strategic autonomy**

The Commission's report on the Structured Dialogue addresses the need to determine the level of third country dependencies of critical medicines, and to what extent supply security would require more manufacturing in the EU.<sup>3</sup> In addition, a group of Member States have called for a 'Critical Medicines Act'.<sup>4</sup>

We call on the Commission to ensure an open discussion on this proposal and to approach it first and foremost from a public health perspective.

We look forward to the Commission's Communication on measures to improve medicine availability and would be interested to discuss solutions further with you or your services.

Yours faithfully,

Monique Goyens  
Director General

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<sup>2</sup> European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI)).

<sup>3</sup> Commission staff working document, Vulnerabilities of the global supply - Structured Dialogue on the security of medicines supply, 2022.

<sup>4</sup> See reference 1.