

The Consumer Voice in Europe

Ref.: BEUC-X-2019-079/ASA/cm

3 December 2019

**Subject: To protect consumers health, the EU needs an ambitious, comprehensive policy on medicines shortages**

Dear Health Attaché,

On 9 December, the EPSCO Council will discuss the issue of medicines shortages. BEUC, The European Consumer Organisation calls upon Member States to seize this opportunity and **set the EU on the path to effectively manage and prevent disruptions in the supply of medicines.**

Medicines shortages are a growing **public health threat**, affecting consumers' health and their quality of life. BEUC's members, national consumer organisations, report increasing cases of shortages due to an array of problems, ranging from manufacturing issues, poor planning by companies to meet demand forecasts, parallel trade and product withdrawal for commercial reasons.<sup>1 2</sup> In many cases, supply shortages affect essential medicines.<sup>3</sup>

Drug shortages are a multi-factorial problem affecting old and new medicines alike. To effectively manage and prevent disruptions in the supply of medicines, the EU therefore needs a comprehensive, common policy. We welcome that the Finnish Presidency has taken this important debate to the EPSCO Council. We call upon the Council to send a clear signal on the way forward for a **common, ambitious policy on drug shortages** that ensures:

1. Better monitoring of medicines' supply and understanding of the root causes of shortages;
2. Prevention of drug shortages;
3. Effective management of supply disruptions when these occur;
4. Effective reporting mechanisms and communication on shortages; and,
5. Preventing that consumers pay the financial consequences that shortages may cause.

A common policy on shortages requires specific action at the EU level, including legislative proposals where needed. Solutions must also be found at the national level, yet in close coordination with other Member States. As a starting point, BEUC calls for a standardised and transparent reporting mechanism on the causes of medicines shortages to strengthen evidence-based policy-making. In parallel, it is essential that common terminology on drug shortage is developed and included in the EU pharmaceutical framework.

.../...

<sup>1</sup> Organización de Consumidores y Usuarios. Desabastecimiento de medicamentos ¿por qué?. November 27, 2018 <https://www.ocu.org/salud/medicamentos/informe/razones-desabastecimiento-medicamentos>

<sup>2</sup> Test-Achats. Pénuries de médicaments: la position de Test-Achats. October 7, 2019. <https://www.test-achats.be/action/nos-actions/opinions/tekorten-geneesmiddelen>

<sup>3</sup> See reference 2.

To improve cooperation, the EU should moreover establish a pan-European database on shortages. This could help share information on supply disruptions more easily, identify common shortages and better coordinate the responses in ways that ensures equity. It is also crucial that all Member States mandate early notification from manufacturers of products that will cease to be on the market either temporarily or permanently, in line with Directive 2001/83/EC.

The upcoming EPSCO discussion should not be a one-off. To ensure that there is proper follow-up, Member States should explore ways to institutionalise a stronger cooperation within the EU.

As the main victims of drug shortages, **patients and consumers must be at the centre of the debate on shortages**. The European Consumer Organisation and its member organisations look forward to working closely with the Council and national governments to address a problem that has a huge impact on consumers.

We thank you in advance for your consideration and remain at your disposal for further information.

Yours faithfully,

Ancel.la Santos  
Senior Health Policy Officer