BEUC The European Consumer Organisation

The Consumer Voice in Europe

Ms. Stella Kyriakides
European Commissioner for Health and Food Safety
European Commission
Rue de la Loi 200
B- 1049 Brussels

Ref.: BEUC-X-2023-017

14 February 2023

Subject: Consumers need EU pharma reform now

Dear Commissioner Kyriakides,

I write to you on behalf of BEUC to urge the European Commission to publish the much-awaited proposal for a revised EU pharmaceutical legislation no later than March 2023.

Consumers across Europe face real difficulties in accessing the medicines they need. Unfortunately, many patients do not get satisfactory treatment for their condition, medicine shortages are common across Member States, and the prices of new medicines are skyrocketing. These are serious problems that require urgent and effective solutions.

For this reason, BEUC supports the Commission's plans to revise the EU pharmaceutical legislation. This process is an opportunity to introduce new measures that contribute more effectively to the development of new and better treatments, and to improve medicines' availability and affordability. The sooner the EU can put in place a stronger legislative framework, the better for consumers across the continent.

This is why we call on the Commission to avoid further delays in the presentation of its proposal, which was scheduled to be published in March. While we understand that there might be controversial elements in the text, it is essential that the file is now officially referred to the co-legislators and that a democratic discussion is initiated in order to make significant progress during this legislature.

In the meantime, there are a couple of important aspects we would like to raise for the consideration of the legislator and hopefully the Commission will still integrate these elements in the proposal.

First, ensuring that consumers have easy access to product information approved by regulators is essential for the safe use of medicines. Surveys conducted by four BEUC member organisations[1] show that medicine leaflets are an important source of information to consumers and that electronic product information (ePI) should only complement, not replace, paper leaflets. We share the results and conclusions from the consumer surveys for your consideration in the annex.

However, it is our understanding that the European Commission is going to propose that Member States may choose to replace paper package leaflets with digital information across the board, rather than only in exceptional cases. We are concerned with such an approach, as it would not only damage patient information but also lead to a different level of protection within the EU.

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[1] Surveys conducted between June and July 2022 by Altroconsumo (Italy), DECO (Portugal), OCU (Spain) and Test Achats/Test Aankoop (Belgium) as part of the Euroconsumers group.

Second, we are concerned about the Commission's plan to go ahead with the introduction of transferable exclusivity vouchers to promote the development of novel antimicrobials despite strong reservations raised by multiple stakeholders, including consumer groups and Member States. As we have previously stressed, these vouchers would come at a huge cost to health systems, hamper competition and delay patient access to cheaper generics and biosimilars in other disease areas.[2]

Finally, we would like to take the opportunity to support the Commission's intention to propose a shorter baseline for data and market protection with the possibility to extend it if a medicine addresses an unmet medical need. We also support including measures in the revised legislation that will help prevent and manage medicine shortages more effectively, and provisions that contribute to the availability of medicines across Member States.

We look forward to the publication of the proposal in March.

Please note that we will address these points also in a letter to Commissioners Reynders and Breton.

Yours sincerely,

Monique Goyens
BEUC Director General

[2] BEUC, Transferable exclusivity vouchers for medicines: disrupting markets, unfair to consumers, 2022. https://www.beuc.eu/sites/default/files/publications/BEUC-X-2022-101_Transferable_vouchers.pdf

Annex – Results of consumer surveys

The surveys were conducted simultaneously between June and July 2022 by BEUC members Altroconsumo (Italy), DECO (Portugal), OCU (Spain) and Test Achats/Test Aankoop (Belgium) as part of the Euroconsumers group. In total, they received more than 4.200 valid answers.[3]

The results show that a large majority of consumers usually read the leaflet, either in-depth or focusing on some sections, when they take a medicine for the first time even if it was prescribed or recommended by a pharmacist. The surveys also show that leaflets are the first source of information that consumers consult if they suffer suspected, mild, side-effects from medicines.

When asked about digital information, 79% of consumers said leaflets should be available inside the package even if there is an alternative QR code on it. Respondents felt this would otherwise disadvantage older people (81%) and would make society too dependent on the internet (70%). At the same time, the survey results show some preferences for digital information mainly from more educated and younger consumers. On average, 35% of respondents said in their case QR codes would be very useful. The surveys also show that there is some room for improvement in paper leaflets, for example in terms of the size of the letters and use of technical language.

A key takeaway from these surveys is that digital product information should complement, not replace, paper package leaflets. Ensuring complementarity in the revised pharmaceutical legislation is important for various reasons, including to avoid discriminating consumers with low digital skills and no access to smartphones. A very recent survey conducted by our member in Norway, the Norwegian Consumer Council, shows that 5% of consumers did not have a smartphone. The main reason given by many of those who reported not using digital tools to buy or obtain something was a lack of internet access.[4]

Based on the results of these surveys, we stress the need to avoid providing digital-only information on the safe use of medicines. We also call on the Commission to ensure that the introduction of ePI as a complementary tool will not allow neither the identification or tracking of consumers, nor its use for advertising and other commercial purposes. We stress the need to ensure that ePI will be approved by regulators and stored on the websites of medicines agencies.

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[3] Available at https://assets.ctfassets.net/iapmw8ie3ije/2JAU6RW11FPIn6tlusnTYF/4e22536be5338328b0a13a62ebe029be/Digital_Rules___Labelling.pdf

[4] Survey conducted by Forbrukerrådet between December 2021 and January 2022. Available at https://storage.forbrukerradet.no/media/2023/01/forbrukerradet--outsiderness-in-the-consumer-markets-en.pdf