BEUC The European Consumer Organisation

The Consumer Voice in Europe

Permanent Representation to the EU

B - Brussels

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Brussels, 8 June 2023

Subject: BEUC recommendations ahead of EPSCO Council 12-13 June 2023

Dear Deputy Permanent Representative,

I am writing to you on behalf of BEUC - The European Consumer Organisation, to share our recommendations on two important topics that are on the agenda of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) Council on 12-13 June. These are:

- **The European Health Data Space (EHDS) proposed regulation**

A recent BEUC survey[1] indicates that despite the high uptake of digital health platforms, consumers are very selective when sharing their health data. Consumers want to decide what personal data they give access to, who they give it access to, and for what purposes. Therefore, the EHDS regulation must ensure consumers are requested to give their **explicit consent before their personal electronic health data is shared for supporting healthcare delivery** to them.

In relation to **secondary uses of health data** such as for scientific research, regulatory purposes or public health monitoring, **consumers should at the very least be asked whether they wish to opt-out from sharing their health data**. In addition, any use of health data for marketing and advertising purposes should be prohibited and neither genetic data nor person-generated data from lifestyle and wellness apps and medical devices should be made available for secondary use.

Finally, the EHDS must ensure that consumers have enforceable rights in case of infringements of the regulation, introducing a right to compensation for damages suffered and ensuring the EHDS is added to the annex of the Representative Actions Directive (EU) 2020/1828 to benefit from the existing collective redress mechanism. For further information, please refer to our full position paper and factsheet.

- **Exchange on equitable access to medicines**

Regarding the exchange of views on "Strengthening the pharmaceutical ecosystem in support of competitiveness and equitable access to medicines", we would like to stress two points. First, the need for the Council to **make substantial progress in the upcoming months on the revision of the EU pharmaceutical legislation**. Consumers across Europe should not have to wait long to benefit from an updated legislative framework that leads to better access to safe, effective, and affordable medicines. In the annex, we outline concrete recommendations for a more consumer friendly pharmaceutical legislation.

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[1] The consumer organisations which contributed to the survey are Test Achats/Test Aankoop (Belgium), dTest (Czech Republic), UFC-Que Choisir (France), vzbv (Germany), EKPIZO and KEPKA (Greece), Altroconsumo (Italy) and OCU (Spain) and DECO Proteste (Portugal).

In parallel, it is necessary to make use of the full policy toolbox and apply additional and shorter-term measures for improved access to treatment. In particular, the **EU must urgently step-up action to tackle the growing problem of drug shortages** and its impact on consumers' health and pockets.[2] For this reason, we welcome the initiative that 19 Member States put forward recently on 'Improving the security of medicines supply in Europe.'[3]

An interesting element of this initiative is the proposal to establish a solidarity mechanism among countries to alleviate the impact of shortages where they hit the most. We also consider important to make progress in the definition of a list of critical medicines and the identification of supply chain vulnerabilities. For these measures to be fit for purpose, however, they should be defined in consultation with consumer groups. Likewise, there should be an open discussion on the proposal to adopt a 'Critical Medicines Act' to strengthen European manufacturing.

We will follow with great interest the discussions at the EPSCO Council on pharmaceuticals and the EHDS, and remain available for a follow-up meeting with the Permanent Representation.

Yours sincerely,

Monique Goyens
BEUC Director General

[2] BEUC, 'Medicines shortages in EU: alarming survey results from some countries', February 2022.
[3] 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.

Annex – Recommendations for a more consumer-friendly EU pharmaceutical legislation

1. Medicine approval

New medicines do not always bring meaningful benefits to consumers.[4] In addition, drug developers do not routinely conduct the type of studies that allow to directly compare the benefits and risks of treatments. The revised legislation must lead to better evidence on a medicine's safety, efficacy and added therapeutic value.

Recommendations:

1.1. Require that drug developers submit evidence from randomised controlled clinical trials versus standard treatment, unless exceptionally where justified.
1.2. Specify in the legislation that marketing authorisation should only be granted upon clear demonstration of benefit based on clinically relevant outcomes.
1.3. Maintain the concept of 'Medicines under additional monitoring' and the accompanying black triangle in package leaflets, to raise awareness on adverse drug reaction reporting.
1.4. Ensure that schemes for early drug approval are available for justified situations only, and safeguard patient's safety.
1.5. Set up an EMA database with information on all conditionally authorised products, attached obligations, timeframes for completion for studies, potential deviations, and applicable penalties in case of unjustified delays.
1.6. Improve the readability of paper package leaflets and introduce electronic product information as a complementary tool, as opposed to a substitute.
1.7. Enhance the transparency of scientific advice procedures and avoid conflicts of interest.

2. Medicine availability

Medicine shortages, which are on the rise, impact consumers in many ways. Surveys conducted by BEUC members show that shortages can cause anxiety, disease worsening, and lead to patients' suffering side effects from alternative treatments.[5] The EU must adopt new rules to improve the availability of medicines across the EU.

Recommendations:

2.1. Require companies to develop drug shortage prevention and management plans, and share them with competent authorities.
2.2. Introduce an obligation for manufacturers to maintain safety stocks.
2.3. Oblige pharma companies to report drug shortages earlier and notify product withdrawals for commercial reasons one year in advance.
2.4. Introduce measures in the legislation that contribute to medicines' market launch across the EU.
2.5. Require the setup of monitoring and early warning systems on drug shortages at national level, and enhance coordination through the EMA.
2.6. Make it mandatory for Member States to have user-friendly databases on medicine shortages, that provide the most relevant information for consumers.
2.7. Enable consumer reporting of medicine shortages to competent authorities.
2.8. Ensure there are dissuasive penalties to promote compliance by pharma companies with their legal obligations in relation to the supply of medicines.

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[4] Prescrire's ratings of new drugs in 2022, accessed on 5 June 2023 https://english.prescrire.org/en/81/168/66185/0/NewsDetails.aspx

[5] Surveys conducted in November 2020 by BEUC members Altroconsumo (Italy), DECO (Portugal), OCU (Spain) and Test Achats/Test Aankoop (Belgium) as part of the Euroconsumers group, and in December 2019 by Norway (Forbrukerrådet).

3. Innovation and medicine affordability

Many patients are still left with no satisfactory treatment for their condition and antimicrobial resistance poses a great risk to public health. Whilst incentivising drug development is important, for new medicines to be accessible to patients they must be affordable. Thus, the revised pharmaceutical legislation should find the right balance between incentivising innovation and ensuring medicine affordability.

Recommendations:

1. Ensure that incentives for drug development are more proportionate and the system does not enable abuses.
2. Allow waiving data and market protection if a competent authority issues a compulsory license, so generic production can be effectively enabled.
3. Remove any obstacles that prevent the market launch of generics and biosimilars on day-1 after IP protection on the originator product expires.
4. Refrain from introducing 'transferable exclusivity vouchers' and promote instead the development of novel antibiotics through fairer means. For example, by introducing a 'pay or play fee' system in the legislation to raise funding for R&D activities through HERA.

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