BEUC The European Consumer Organisation

The Consumer Voice in Europe

Permanent Representation to the EU

B - Brussels

Ref.: BEUC-X-2024-041/SMA/cm

Brussels, 15 April 2024

Subject: The EU must step up action in 2024-2029 to improve equitable access to medicines

Dear Deputy Permanent Representative,

I contact you on behalf BEUC, the European Consumer Organisation, regarding the meeting between Ministers of Health that will take place on 23 and 24 April.

Over the last years, consumers across the EU have faced increasing challenges when trying to access the medicines they need. Medicine shortages are on the rise, and the price tags of new treatments are skyrocketing. In addition, there are patients with no effective treatment options and antimicrobial resistance is a major public health problem. All this contributes to worsen inequalities in the EU and people's well-being.

As the major of its kind in 20 years, the ongoing revision of the EU pharmaceutical legislation brings an opportunity to address current gaps. To do so meaningfully, the EU institutions must put patients' and consumers' interests at the centre of the revision. This requires having a more balanced system on IP incentives, facilitating timely market entry for generics, adopting measures to prevent medicine shortages, and boosting research where is needed the most.

A more consumer-centric EU pharmaceutical legislation will help improve access to medicines, but it is not the only tool at hand. Building on the Pharmaceutical Strategy for Europe, in 2024-2029 the EU must step-up action to tackle vulnerabilities in drug supply chains, reinforce HERA, make greater use of joint procurement, promote more transparency and cooperation on medicine pricing and reimbursement, and support an ambitious EU Health Programme. Our recommendations are detailed in the Annex to this letter.

We call on Member States to reflect BEUC's priorities in the Council Conclusions on health announced by the Belgian Presidency, and in the pharmaceutical legislation. Regarding the latter, we hope the Council makes good progress with its own negotiations and meets the European Parliament at trilogues soon after its new mandate starts.

I thank you in advance for taking our suggestions into consideration and remain at your disposal for any questions you may have.

Yours faithfully,

Sylvia Maurer
Director, Sustainability, Food, Health, Energy & Safety Department

Annex

1. BEUC recommendations on the EU Pharmaceutical legislation

1.1. Reinforce the prevention and mitigation of medicine shortages

At present, pharmaceutical companies are not required by EU law to develop medicine shortage prevention plans. This undermines their duty to ensure continued supplies. To fix this, the revised pharmaceutical legislation must oblige companies to have such plans in place for all medicines. Competent authorities should, at least, assess the prevention plans for critical medicines and issue recommendations where necessary to strengthen supply chains. The prevention plans for other medicines should be shared by companies as soon as requested.

In addition, the legislation should oblige marketing authorisation holders to have some contingency stocks for critical medicines. These stocks act as a safety net, helping to mitigate the impact of supply disruptions on consumers. Stocks should be sufficient to meet at a minimum a two-month demand in each Member State where the product has been placed on the market.

To be able to plan alternatives properly when shortages occur, competent authorities should receive early notifications. Pharmaceutical companies should notify temporary supply disruptions 6 months in advance or, if not possible and were justified, as soon as they become aware of it. Market withdrawals should be communicated 12 months in advance.

1.2. Modulate the incentives system in ways that allow early generic entry

Today in the EU, between patents, supplementary protection certificates and regulatory incentives, pharmaceutical companies benefit from long periods of exclusivity over their products. This delays access to cheaper generics and biosimilars, at a time where public health budgets struggle to keep up with raising costs.[1] To strike a better balance, the pharmaceutical legislation should modulate the incentives system, starting with a meaningful reduction of the baseline (6 years as proposed by the Commission).

Whilst we support the modulation based on unmet medical needs, we favour introducing an obligation for companies to conduct comparative clinical trials with the best-proven intervention, and to file for pricing and reimbursement across the EU. In any case, the legislation should not allow pharmaceutical companies to go beyond today's maximum period of data and market protection.

More details on these and other recommendations on how to strengthen the legislation can be found in our position paper.[2]

2. Recommendations on other EU priorities in 2024-2029

2.1. Promote diversification of medicine supply chains

The launch of the Critical Medicines Alliance (CMA) brings an opportunity to identify and introduce additional measures at EU level to improve medicine availability. Diversifying supply chains has already been proposed as a means to enhance supply security.[3] Diversification is important at the geographical level, in terms of suppliers, and within supply chains. The EU should implement concrete actions on that front, in ways that uphold competition rules and are aligned with public health objectives. To ensure that, the CMA must facilitate engagement by consumer, patient, and healthcare professional groups.

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[1] International Association of Mutual Benefit Societies. Interview to Petra van Holst, CEO of Zorgverzekeraars Nederland (ZN) "Dutch insurers apply AIM's fair pricing calculator by default when negotiating drug prices with companies", February 2024.

[2] BEUC, 'Recommendations for improving access to medicines in Europe. BEUC position on the European Commission's proposal for a revised pharmaceutical legislation, 2023.

[3] European Commission, Staff Working Document, Vulnerabilities of the global supply chains of medicines. Structured Dialogue on the security of medicines supply, 2022.

2.1. Turn HERA into a more independent and resourced entity

Launching HERA in its current form was necessary during the COVID-19 pandemic. However, to ensure HERA contributes effectively to strengthen the EU's capacity to prevent and respond to future crisis, some changes are needed. HERA must become a more independent entity, with greater resources to work on the identification of potential threats, and the development, availability, and affordability of medical countermeasures. To help fight the growing problem of antimicrobial resistance, HERA should coordinate and support research activities in Europe through a scheme of push and pull incentives. For example, research grants and milestone prizes with access conditions. HERA should also do more to help Member States have in place more resilient healthcare systems.

In addition to strengthening HERA, the European Health Union should be complemented by a workable EU scheme on compulsory licensing.

2.2. Make more use of joint procurement

Currently, the EU joint procurement scheme is focused on cross border-health threats and medical countermeasures, such as vaccines. Whilst joint procurement for MCMs is important and must be reinforced, it should go beyond that. The scope should cover as well expensive innovative medicines, such cancer treatments, and orphan drugs. This would help improve equal access to medicines across the EU by increasing the purchasing power of participatory Member States.

2.3. Increase cooperation and transparency on medicine pricing and reimbursement

To get better deals during price negotiations with industry, Member States should have a better overview of the prices paid in other countries and on R&D costs. National authorities should exchange further on pricing and reimbursement polices through the NCAPR network, and share more data through the EURIPID project. As we stress in our position paper on this topic[4], more transparency can be achieved by means of revising Directive 89/105/EEC[5] and implementing the 2019 WHO Transparency Resolution.

2.4. Adopt an ambitious EU Health Programme

A key lesson from the COVID-19 pandemic is that we need more EU action on health policy, not less. Having a strong EU Health Programme with substantial funding in place is thus essential to reinforce the European Health Union and build on the Pharmaceutical Strategy. In the years to come, the EU must ensure that the ambition shown with the adoption of the 2021-2027 EU4Health Programme does not decay. European citizens must get the message that the EU continues prioritising their health which also requires meaningful financial investments.

[4] BEUC, 'Time to lift the blindfold. Abolishing price secrecy to help make medicines affordable', 2020.
[5] Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.