BEUC's 10-point plan

A CONSUMER CHECKLIST

HOW THE EU PHARMA REFORM SHOULD WORK FOR CONSUMERS

Across Europe, consumers are struggling to access the medicines they need, either because of their high price, because a medicine is in short supply, or because some medicines are not being developed for commercial reasons (for example novel antibiotics). Surveys conducted by BEUC members in five countries have alarming results.[1] In some countries, almost half of the respondents had been unable to get their medicine at least once in the last two years. But shortages can also affect people's pockets; for example, because alternative treatments are more expensive.

High medicine prices lead to inequities in access to treatment within and across countries. The results of focus groups BEUC carried out with some of its members show that consumers regard medicines as essential goods and do not approve of excessive pharma profits.[2] Consumers also think that it is unfair that some medicines are not developed because of commercial reasons, and are surprised by the fact that new drugs aren't always better than the treatment already available.

The Commission is coming forward with a major reform of pharma legislation as a response. It is an important opportunity to solve some lingering market failures & health policy issues.

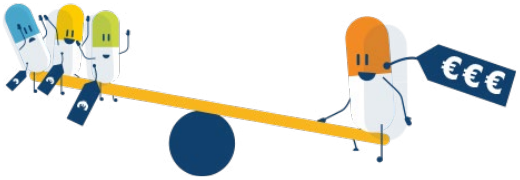
IMPROVE MEDICINE AVAILABILITY

1 OBLIGE PHARMA COMPANIES TO DEVELOP AND SUBMIT DRUG SHORTAGE PREVENTION PLANS TO COMPETENT AUTHORITIES

To reduce the incidence of shortages, companies should develop prevention plans that strengthen their supply chains. Whilst some EU Member States have started requiring companies do that, this measure should apply across the EU. Ensuring that competent authorities have access to these plans would help them issue recommendations on how to make supply chains more robust.

2 REQUIRE PHARMA COMPANIES TO HOLD SAFETY STOCKS

At present there is no EU obligation for companies to have safety stocks, which undermines their duty to ensure continued supplies of the product. The revised legislation should require companies to build up stocks on their products and to help mitigate the impact of supply chain disruptions on consumers.



3 INTRODUCE REQUIREMENTS FOR EARLIER NOTIFICATION OF DRUG SHORTAGES

The current 2-month notification period in EU law does not always ensure competent authorities have enough time to plan for shortages. This is why some countries have already introduced earlier notification requirements. Building on these best practices, the revised pharma legislation should require a timelier notification of shortages. When companies decide to withdraw a drug from the market, they should report this withdrawal 12 months in advance. This would allow finding new means of supplying the medicine.

4 MAKE IT EASIER FOR CENTRALLY-AUTHORISED PRODUCTS TO BE AVAILABLE ACROSS THE EU

Medicines approved by the European Medicines Agency are not always available in all EU Member States or enter some markets much later than others. One reason for this is that pharma companies are less interested in entering smaller and less wealthy markets. To address inequalities in access to medicines, pharma companies should be obliged to file their medicines for pricing and reimbursement in all EU Member States within a short timeframe.

[1] BEUC factsheet, 'Medicine shortages in EU: alarming survey results from some countries' (February 2022).
[2] BEUC report, 'What Consumers Think Of Medicine Prices Today: Results from focus groups carried out in Italy, the Netherlands and Spain' (November 2022).

INCREASE MEDICINE AFFORDABILITY

5

REQUIRE PHARMA TO SHARE DATA ON R&D COSTS WITH THE AUTHORITIES

There is insufficient information available about what it costs to develop a new medicine. With this information at hand, authorities would enter negotiations with pharma companies on the price of new medicines from a fairer position. To enable that, the pharma legislation should require that companies share data on R&D costs at EU level when they get intellectual property incentives like data and market protection for a medicine. National pricing and reimbursement authorities could then access such data, which would help prevent excessively high drug prices.

6

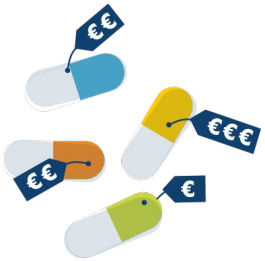
ENSURE THE INTELLECTUAL PROPERTY INCENTIVES SYSTEM IS MORE BALANCED, TARGETED, AND INCLUDES SAFEGUARDS TO PREVENT ABUSES

In addition to the patent protection pharma companies get for developing a new medicine, they also get 10 years of data and market protection on these new medicines. These protections, combined with other incentives, excessively delay the entry of generics onto the market. Generics companies produce the same or a similar medicine that another pharma company has produced, but at a much lower price. To make the system more balanced, data and market protection periods should be reduced and change according to the type of medicine. This is part of the reason why the pharma industry's heavy push for 'transferable exclusivity vouchers' is so worrying and must be resisted by the EU. These vouchers would grant a pharma company exclusivity for longer on a medicine of its choice if it develops a new antibiotic.

7

MAKE IT EASIER FOR PRODUCERS OF GENERICS AND BIOSIMILARS TO ACCESS THE MARKET

Generics companies also face obstacles that prevent the entry of cheaper medicines on the market on the day after intellectual property protection on the originator product expires. The revised pharma legislation should fix this by removing any obstacles that prevent generics companies across the EU from easily carrying out the studies and procedures necessary for registering and launching generics. This will help ensure consumers get quicker access to cheaper medicines.



DEVELOP NEW MEDICINES

8

REQUEST DRUG DEVELOPERS TO CONDUCT CLINICAL TRIALS THAT COMPARE THE BENEFITS OF NEW MEDICINES AGAINST THE BEST AVAILABLE TREATMENTS

Pharma companies do not routinely conduct the type of studies that allow the direct comparison of the benefits and risks of two treatments. If they did, it would be easier for authorities to decide on which medicines to reimburse. By requesting that drug developers conduct clinical trials that compare the benefits of new medicines against the best available treatments, the authorities would increase the possibility for patients to have access to the best possible treatments, and would improve the financial sustainability of health budgets.

9

USE SCHEMES FOR EARLY DRUG APPROVAL IN JUSTIFIED SITUATIONS ONLY

Big Pharma is pushing hard to get medicines approved faster in the EU which carries many risks if the authorisation process is weakened. Although early approval can help patients who have life-threatening and other serious diseases, it should not become a general rule. The revised pharma legislation should improve marketing authorisation standards, not weaken them. The latter would only benefit pharma, not patients.

10

INTRODUCE ELECTRONIC PRODUCT INFORMATION (EPI) AS A COMPLEMENTARY TOOL ONLY

Consumers rely on paper leaflets inside a box of medicines which is the easiest way to make sure consumers read the information before the medicine is taken. Adding a digital version online would be welcome only if people´s privacy is guaranteed and if it will not replace the paper leaflet.

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