BEUC The European Consumer Organisation

What the EU's pharma reform must deliver for consumers

The EU has the opportunity to address the twin problem of **increasingly frequent medicine shortages** and **skyrocketing prices for new medicines** through its ongoing pharma reform.

Both of these problems are becoming more pressing, as our society ages, more people fall into poverty, growing competition for public money across different policy areas and pressure increases on national health budgets to meet our medical needs.

The Parliament and EU Member States must **improve** a Commission proposal which makes positive steps but **needs to go further** to substantially change the situation on the ground.

PROBLEM 1

Differences between richer and poorer Member States as to when a new medicine reaches patients

Romanians are accessing new, innovative medicines on average two years later than Germans. In the case of drugs used to boost the immune system to treat cancer, for example, use in poorer countries was between **a tenth and a fifth** of the one observed in wealthier countries. This can mean the difference between life and death.[1]

SOLUTION

Improve medicine availability across the EU

The pharma legislation should include an **obligation for companies to file for pricing and reimbursement across Member States** within a short timeframe. This should apply for example to medicines that contain a new active substance or are approved for a new indication. In addition, the European Medicines Agency should publish information on the actual availability of medicines on a publicly accessible webpage.

Introducing measures in the legislation that contribute to drug availability is much better than relying on the industry's voluntary commitments. A key problem is that companies often prioritise market launch in those countries where they can charge higher prices and only approach others much later (or not at all). Self-regulation does not ensure that such practices will end and will perpetuate inequalities in access.

PROBLEM 2

Skyrocketing price of new medicines & pressure placed on Member State budgets

New cancer treatments can cost hundreds of thousands of euros per patient, and the price tags of some orphan medicines can go beyond one million euros. [2] [3] **Skyrocketing prices are a major driver of inequalities in access to treatment in Europe** and put public health systems under huge pressure.

When governments do not reimburse medicines, **patients have to bear the costs**. In some Member States like Latvia and Hungary, people in 2016 have had to pay about half of the total cost of all prescribed medicines from their own pockets. This is four times the share that Spaniards paid and seven times the share Germans paid.[4] Some patients are simply unable to afford the medicines they need, which can have serious implications for their health and well-being, as testimonials from patients gathered by BEUC have shown.[5]

SOLUTION

Strike a better balance between regulatory incentives for innovation and affordable access. It is important to establish different and shorter **periods** of data protection according to the products and make it easier for public authorities to lift monopolies if necessary to protect public health.

Today, in Europe pharma companies benefit from long periods where they enjoy a **monopoly** on a medicine they have developed. By **shortening some of these protection** periods, patients will have easier access to the medicines they need, as competition can lower prices and increase supply.

Generics and biosimilars should also be able to enter the market on day 1 after the IP rights on the originator product expire so that cheaper medicines reach patients faster. Today, a generics company faces difficulties in starting and completing all the pre-marketing procedures by the time the patent in question expires.

Big Pharma's opposition to re-balancing the IP system is at odds with the huge revenues and profit margins reported by the sector, as well as the public subsidies that they often receive for developing medicines.[6] [7] [8]

PROBLEM 3

People across Europe, whether from richer or poorer countries, experience problems in getting the medicines they need because of shortages.

Notifications on shortages have **strongly increased** in the last five to ten years,[9] multiplying by twelve in countries like Spain over a decade.[10] Even when a medicine has been authorised and is getting reimbursed, there may be shortages around its supply.

Consumer surveys conducted by BEUC members show that **medicine shortages often have implications for a person's health**, as reported by between a third and a half of consumers across five countries.[11] Among the complications, consumers reported that shortages caused them anxiety and a worsening of their symptoms. They also reported that, in some cases, shortages led to extra costs. This was because alternative treatments could be more expensive.

SOLUTION

Oblige pharmaceutical companies to share drug shortage prevention plans with the authorities, and to have minimum levels of contingency stocks of critical medicines.

In addition, manufacturers should **notify shortages six months in advance instead of two months**, and a year earlier in case of commercial withdrawal, as the current periods don't give enough warning to authorities. These measures must go hand in hand with dissuasive sanctions to encourage compliance, and with greater transparency on the causes of shortages.

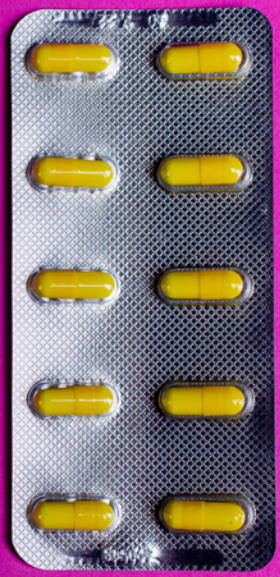
Whilst it is not uncommon to hear of pharma companies referring to 'demand surges' as a driver of shortages,[12] only by strengthening companies' supply-related obligations can patients' needs be better met.

PROBLEM 4

Bacteria are developing greater resistance to antibiotics.

The European Center on Disease Control (ECDC) estimates that more than **35,000** people die from antimicrobial-resistant infections every year in Europe.[13]

While we need new effective antibiotics, there is **little commercial interest from Big Pharma** in developing these products as their use would only be limited to people who do not respond to more common antibiotic treatments.



SOLUTION

The EU should support the development of novel antimicrobials, but in a fair way.

This can be done by **introducing an EU-coordinated scheme of research grants, inducements** in exchange for meeting some milestones along the R&D chain, **joint procurement and payment models** that de-link volumes from profits. Put together, these measures could **steer research and development (R&D) in the right direction**, help biotech companies bring new antibiotics to the market, and safeguard drug affordability.

Instead, Big Pharma's proposal on '**transferable exclusivity vouchers**' will delay access to generics in other disease areas and come at a huge cost, as pharma will use it to extend their monopoly on very expensive drugs. For example, granting one extra year of exclusivity for an expensive drug that treats several immune system conditions could represent an extra bill of one billion euros to EU health systems.[14]

PROBLEM 5

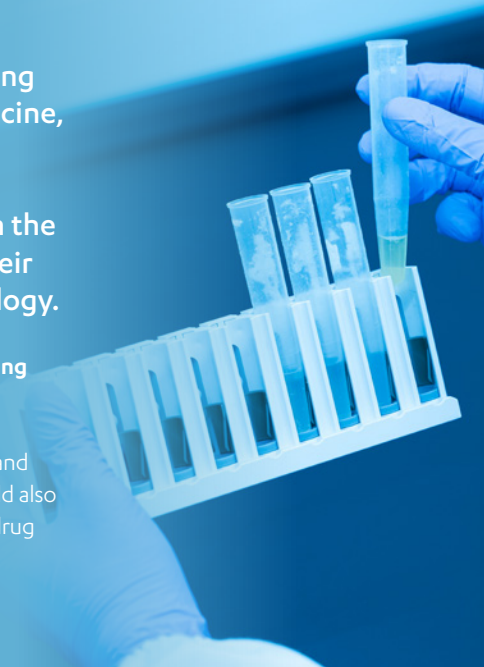
Member States struggle to negotiate fair medicine prices with the pharma industry

National authorities do not get information that could help them set medicines prices that are fairer for public health systems and consumers. A key reason for this is **poor transparency regarding R&D costs**.

This lack of transparency enables pharmaceutical companies to demand very high drug prices. Focus groups commissioned by BEUC in three EU Member States show that consumers do not approve of excessive pharma profits, and even less when the public sector has contributed to the drug development. R&D costs are seen as important information that governments should have to be able to negotiate fairer drug prices with pharma companies.[15]

SOLUTION

Oblige pharma companies to publish information on any public research funding they received for developing a new medicine, and information on tax incentives they received for research.
In addition, companies should share with the pricing authorities audited reports on their R&D costs following an agreed methodology.



These measures would **prevent industry from publicising average R&D cost figures which are twice the amount independent estimates**; for example, $2.6 billion on average to develop a new drug (including cost of failure and opportunity costs) versus $1.3 billion on average.[16] It would also raise public awareness about taxpayers' contribution to drug development and the need for 'fair pricing'.

Endnotes

1 POLITICO, 'Romania gets new medicines 2 years after Germany. Here's why', 13 September 2023.
2 BEUC, Report: 'Time to lift the blindfold: abolishing price secrecy to make medicines affordable', 2021.
3 Civio, 'El medicamento más caro que cubre la sanidad pública cuesta exactamente 1.340.000 euros por dosis', 11 April 2023
4 Organisation for Economic Co-operation and Development, 'Out of pocket spending: Access to care and financial protection', April 2019.
5 BEUC, Video: 'Why should we all be concerned about medicines high prices', 2021.
6 Fierce Pharma, 'The top 20 pharma companies by 2022 revenue', 18 April 2023.
7 United States Government Accountability Office, 'Drug Industry. Profits, Research and Development Spending, and Merger and Acquisition Deals', 2017, page 19.
8 SOMO and Wemos, Report: 'Overpriced: Drugs Developed with Dutch Public Funding, 2019.
9 Technopolis Group, Ecorys BV, Milieu Law & Policy Consulting, Study: 'Future-proofing pharmaceutical legislation – study on medicine shortages', December 2021 (commissioned by the European Commission).
10 OCU, Press release: 'OCU alerta del desabastecimiento de medicamentos', 13 February 2020.
11 BEUC, Factsheet: 'Medicine shortages in EU: alarming survey results from some countries', February 2022.
12 Medicines for Europe and the International Generics and Biosimilar Medicines Association, Press release: 'IGBA taking action to tackle shortages of antibiotic medicines', 22 December 2022.
13 ECDC, '35 000 annual deaths from antimicrobial resistance in the EU/EEA', November 2022.
14 BEUC, Factsheet: 'Transferable exclusivity vouchers for medicines: disrupting markets, unfair to consumers', October 2022.
15 BEUC, Report: 'What consumers think of medicine prices today : Results from focus groups carried out in Italy, the Netherlands and Spain', November 2022.
16 See reference 2, pages 11–12.

Monique Goyens,
Director General, BEUC

Consumers are facing growing difficulties in accessing medicines and the market has failed to solve these problems. EU decision-makers now have to decide, when they amend these proposals, if they are going to further improve access to medicines or buy into Big Pharma's heavy-handed lobbying.

BEUC The European Consumer Organisation

Contact details

@beuc
www.beuc.eu
+32 2 743 15 90
press@beuc.eu

Co-funded by the European Union

Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or EISMEA. Neither the European Union nor the granting authority can be held responsible for them.