FACTSHEET Access to medicines

Consumers should have access to safe and affordable medicines. However, budget cuts, an ageing population, expensive technological advances and increased consumer expectations are challenging the viability of national healthcare systems and access to medicines.

Medicines should benefit consumers

Not all medicines are sufficiently safe and effective. Today, the available scientific data is not always sufficient to determine that medicines treat diseases effectively without endangering patient health (i.e. do not cause severe, adverse side-effects). When available, the evidence may not be communicated in a timely or accurate way to healthcare professionals and patients.

What does BEUC recommend?

More and better scientific evidence throughout the entire medicine's lifecycle. Better organised clinical trials, increased medicine monitoring and continuous research would help better understand potential benefits and downsides of medicines to consumers.

Greater access to robust evidence about medicines. EU databases – such as EudraVigilance or the Clinical Trials Registry – must be continuously improved and promoted for use by researchers, industry, decision-makers, healthcare professionals, patients and consumers.

The same protection for patients using 'early access' medicines as for participants in a clinical trial, i.e. right to compensation, close monitoring, etc. Early access initiatives¹ seek to accelerate the approval process for new medicines, which means there is a higher clinical uncertainty about their effects. While such schemes can benefit patients who need new treatments quickly, they may also increase risks.

Medicines should be affordable

Some medicines are too expensive, for various reasons. While some ground-breaking medicines treat cancers or Hepatitis C, access to such treatments is often restricted by high prices. In some countries, the total cost of treating all patients with Hepatitis C would be equivalent to one year or more of the average annual wage of individuals.² While the high cost of some medicines may be driven by considerable R&D expenses, even medicines developed with publicly-funded research are becoming unaffordable.

As consumers must often pay out-of-pocket for medicines, rising prices mean that some people can no longer afford their medicines. In 2015, Spanish households paid 58% more for their medicines than in 2010, according to consumer group OCU.³ 39% of Portuguese consumers could not afford a medicine they needed, according to a 2014 survey carried out by consumer association DECO.4

¹Examples include the European Medicines Agency's Adaptive Pathways and PRIME schemes.

²lyengar, Swathi et al. "<u>Prices, Costs, and Affordability of New Medicines for Hepatitis Ci na Ocountries: An Economic Analysis</u>" PLoS medicine vol. 13(5): e1002032, 31 May 2016. ³OCU denuncia que el gasto en medicamentos ha crecido en un 58% en los hogares, 30 Sept 2015.

DECO Proteste, Farmácias, In the June 2015 volume of Test Saude.







The prices of some medicines have skyrocketed without justification. In Italy, the price of three cancer drugs for example jumped by 250% and even 1,500% within a few months, suggesting that the manufacturer may have abused its dominance in marketing these medicines.⁵

What does BEUC recommend?

The EU must approve the European Commission's proposal to establish an EU-wide assessment of the added value of a medicine. Besides giving consumers value for their money,⁶ a 'health technology assessment' helps public healthcare systems choose which therapy to reimburse and avoid investing in treatments which have only marginal benefits for patients. This would free up resources to reimburse truly innovative medicines.

Member States should invest more in generic and biosimilar medicines – they are cheaper and work just as well. Generics are copycats of an original medicine while biosimilars are highly similar versions. Cheaper generics and biosimilars can save costs and stimulate companies to innovate. A higher uptake of these alternatives can increase market competition, and thereby reduce healthcare expenditure.⁷ EU-facilitated awareness campaigns should help bust the myths about them.

The EU should make public funding for medicines conditional on them being accessible and affordable for patients. The European Commission should also develop rules under European research funding programmes to ensure that new health technologies, studies and findings of medical research projects are accessible to the public.

The EU must prioritise rigorous control of potential anti-competitive practices. National competition bodies also have a role in protecting consumers from artificially high drug prices.

Medicines should be available at the right place and at the right time

Medicines sometimes run out of stock. Shortages of medicines are a widespread problem around Europe, particularly for patients in hospitals.⁸ The longer these shortages last, or the fewer alternative medicines that are available, the greater the risk for consumers' health.

Shortages can be caused by manufacturing problems (i.e. a shortage of raw materials), supply problems (i.e. 'parallel trade', where cheap medicines are exported within the EU and sold at a higher price), an economic problem (i.e. financial crisis, pricing policies), or even blunt marketing strategies. An **unaffordable medicine** is just as out of reach for consumers as a **non-existent therapy.**

What does BEUC recommend?

All EU Member States must transpose without delay the EU requirement⁹ for pharmaceutical manufacturers to provide early notice of a temporary or permanent discontinuation of supply.

The EU, in collaboration with national authorities, must develop a common definition of medicine shortages and a centralised monitoring system. This will facilitate identification of common causes and responsibility for medicine shortages, and help preventing shortages early on.

Learn more in our position paper: <u>http://bit.ly/1MQMsNj</u>

⁸ EAHP's 2018 survey on medicines – Medicines shortages in European hospitals

⁹ Article 23a, Directive 2001/83/EC

⁵ Crisigiovanni L., <u>Lisa's story and the price of anti-cancer drugs</u>, on BEUC's blog, October 2016

⁶See BEUC, '<u>Making sure consumers access treatments that work at a fair price</u>', January 2019.

⁷ Smeeding J, Malone DC, Ramchandani M, Stolshek B, Green L, Schneider P. Biosimilars: Considerations for Payers. P & T 44(2). January 2019.