The Consumer Voice in Europe

CONSUMER-CENTRED EU PHARMACEUTICAL STRATEGY

BEUC proposal

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EC register for interest representatives: identification number 9505781573-45

Co-funded by the European Union

Ref: BEUC-X-2020-085 - 14/09/2020

Why it matters to consumers

Medicines are essential to fulfil everyone's right to health. They help prevent diseases, get people cured and improve their quality of life. However, European consumers face barriers in accessing treatments and therapeutic innovations, depriving them from living healthier lives, even more so since COVID-19 hit. The European Commission's initiative on the Pharmaceutical Strategy has the potential to lift those barriers, provided it is ambitious enough.

Summary

BEUC calls for the EU Pharmaceutical Strategy to have the level of ambition that is necessary to ensure that everyone in Europe has **timely access to safe, effective and affordable treatment**. This should be the overarching goal of the future Strategy.

In this paper, we make concrete calls for action in the areas of medicines research and development, marketing authorisation, drug availability and affordability. BEUC policy recommendations are informed by reports from its member organisations on longstanding challenges faced by consumers, many of which have been exacerbated during the COVID-19 pandemic.

1. Introduction

European consumers have been facing longstanding challenges in accessing treatment:[1]

- **Medicines that patients need are not being developed**. Whilst there have been significant medical advances for some diseases, many patients are left with no effective treatment for their condition. The development of certain medicines is being neglected by the pharmaceutical industry because it does not consider them profitable enough.
- **The prices of medicines can be sky-high, threatening affordability**. For example, medicines to treat cancer and rare diseases are in the spotlight due to price tags that can amount to hundreds of thousands of euros. This is even more challenging in the face of the economic impact of the COVID-19 pandemic, which is affecting individual consumers and healthcare systems.
- **Medicines are increasingly out of stock** at pharmacies and hospitals. Supply disruptions affect all type of pharmaceutical products, from painkillers to anaesthetics.

While these unacceptable shortcomings have been existing for far too long, the COVID-19 crisis highlights even more the need for systemic change.

Above all, the current health crisis demonstrates that it is high time for health policy to be given higher priority at the EU level. BEUC therefore welcomes the European Commission's initiative on the Pharmaceutical Strategy, as a step in the right direction. Together with a strong EU4Health Programme, the future Strategy has the potential to help the EU to be better prepared to face longstanding and emerging challenges in healthcare.

For the Pharmaceutical Strategy to be people-centred, its overarching goal must be to ensure **Europe's timely supply of safe, effective and affordable medicines**. To truly meet the expectations and needs of European citizens, consumer and patient groups must be adequately included throughout the Strategy's inception and implementation. Likewise, close cooperation between the European Commission, Member States and the European Parliament will be essential to roll it out effectively.

BEUC supports the Commission's view that the Strategy should cover the whole lifecycle of pharmaceuticals. To meet the overarching goal of affordable access to medicines, it will be important to ensure that actions in one area are conducive to achievements in others.

2. Recommendations for a consumer-centred Pharmaceutical Strategy

2.1. Medicines research and development

The current innovation model is not delivering the medicines that patients need as much as it should. This happens when considerations about profitability by the private sector override the question of unmet medical needs. A well-known example is the little interest by the pharmaceutical industry to develop novel antibiotics. The COVID-19 pandemic also shows lack of attention to research into emerging infectious diseases before major outbreaks occur.[2]

[1] For more information, see BEUC position on Access to Medicines, 2015. Available at: https://www.beuc.eu/publications/beuc-x-2015-104_access_to_medicines.pdf

[2] Test Santé. Pourquoi nous n'étions pas mieux préparés au COVID-19, June 2020.

An additional barrier is that when medicines are developed, they might be out of reach due to sky-high prices. This happens in spite of the public contribution to drug development. The pledge led by the European Commission to raise funding for COVID-19 treatments shows the crucial role that governments play in biomedical research and development (R&D). In fact, the EU is one of the major funders of health research globally.[3] But too often, funding is disbursed with no requirements to ensure the affordability of end products. When this happens, consumers end up overpaying for their medicines: once by funding research on medicines as taxpayers, and then by footing a high bill – directly or indirectly- for these products.

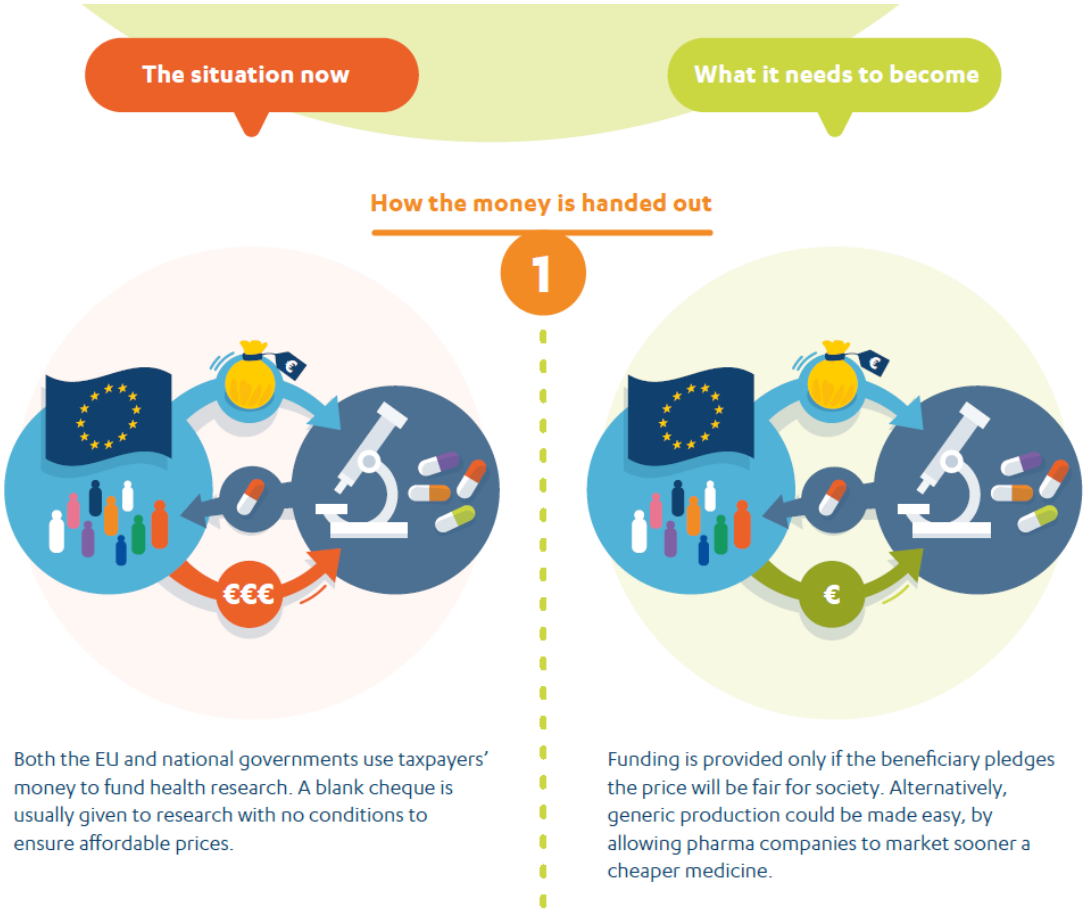

Image 1 Excerpt from BEUC infographic, June 2020

To make sure society reaps the rewards of its investment, it is crucial to **re-think how health research is financed**. The Pharmaceutical Strategy should put the EU on the path towards a research model that not only contributes to the development of treatments, but also to their availability and affordability for the European population.

BEUC's five priorities to maximise public return on investment:

1) The future Framework Programme (Horizon Europe) must prioritise research on public health needs, especially those areas that are neglected by the for-profit private sector. EU funding should contribute to the development of medicines that bring added therapeutic value.

[3] Viergever R.F, Hendriks T. The 10 largest public and philanthropic funders of health research in the world: what they fund and how they distribute their funds. *Health Research Policy and Systems,* 2016 volume 14, Article num. 12

2) Priority-setting and decision-making processes must be transparent and provide opportunities for meaningful involvement by citizens and consumer organisations.

3) The European Commission should exercise strong stewardship to ensure that the public interest is at the core of joint partnerships with the industry, such as the Partnership for Health Innovation.

4) Disbursed funding must go hand in hand with measures to ensure medicines' availability and affordability. The Commission should develop a general policy on such conditionalities, drawing lessons from the requirement for non-exclusive licensing in some COVID-19 related projects funded by Horizon 2020.

5) Compliance with requirements on open access to research publications and to project results in Horizon Europe must be ensured, in line with EU data protection rules and with strong data security mechanisms.

For additional information on the consumer view on research and innovation see When Innovation Means Progress: BEUC's view on innovation in the EU.

2.2. Medicines marketing authorisation

While some new medicines improve patients' health significantly, many bring little or no added therapeutic value.[4] In fact, BEUC member organisation Test Achats/Test Aankoop found that 11% of about 6,500 medicines sold in Belgium were of questionable benefit, and 2% not recommended at all.[5] Likewise, in Germany Stiftung Warentest rated a quarter of 2,000 over-the-counter medicines as 'unsuitable', because their therapeutic efficacy was either insufficient or low compared to the side effects.[6]

While the EU has one of the world's most advanced regulatory systems, it is important to revisit it and strengthen it further. The Pharmaceutical Strategy brings an opportunity to address gaps and promote concrete actions that **reinforce the five-year strategies adopted by the EMA and the Heads of Medicines Agencies**.

Here are BEUC's five priorities to ensure that medicines are effective and used safely:

1) Regulators must demand evidence from clinical trials that address those questions that are most relevant to patients (e.g. overall survival, quality of life) and are adequately representative of the population to treat. Randomised controlled clinical trials (RCTs) that compare an investigational drug against standard treatment should be further required.

2) 'Early access' schemes should remain the exception and be used only in situations of unmet medical need. There should be greater alignment between regulators, health technology assessment bodies and payers on the concept of unmet medical need, with input from patients and consumers. Medicines safety must be closely monitored by marketing authorisation holders and regulatory agencies, and patients be entitled to quick and adequate compensation in case of injury.

3) Evidence from observational studies should complement, but not replace, RCTs. When it comes to uses of 'real world data' or artificial intelligence in medicines development, the EU should assess the need for a supportive legislative framework which goes beyond the scope of the GDPR. All information systems

[4] Prescrire. Prescrire's ratings of new products and indications over the past 10 years, 1 April 2019. Available at https://english.prescrire.org/en/81/168/57229/0/NewsDetails.aspx [Accessed 20 July 2020].
[5] Test Santé. Médicaments à foison près de 900 sont du gaspillage. Test Santé, 2016 num. 132.
[6] See Spiegel online. Stiftung Warentest: Jedes vierte rezeptfreie Medikament fällt durch, June 2019. https://www.spiegel.de/gesundheit/diagnose/rezeptfreie-medikamente-jedes-vierte-mittel-faellt-bei-stiftung-warentest-durch-a-1273990.htm

where health data is generated, used or stored must be designed to meet high quality and safety standards.

4) Consumers must be adequately informed about the effects of medicines. This requires making European Public Assessment Reports and package leaflets easy to understand by consumers, whilst ensuring that they provide all relevant information. In addition, regulatory agencies in Europe should make eProduct information available as a complementary tool to the paper version (not replace it) and promote patient reporting of adverse drug reactions.

5) The Clinical Trial Regulation must be swiftly implemented, and regulators must actively monitor and enforce trial sponsors' compliance with transparency provisions.

For more information see BEUC position papers on:

- Artificial intelligence in healthcare https://www.beuc.eu/publications/beuc-x-2019-078_ai_must_be_smart_about_our_health.pdf
- Digital health, principles and recommendations https://www.beuc.eu/publications/beuc-x-2018-090_digital_health_-_principles_and_recommendations.pdf

2.3. Medicines availability

The COVID-19 pandemic and the response to it are causing important disruptions to the supply of medicines. However, medicines shortages is a longstanding challenge in Europe which got worse over the years.[7,8] Recent surveys by BEUC's member organisations in Denmark, Norway and Spain show that drug shortages impact consumers on many levels.[9,10,11] Shortages cause lack of access to treatment, which can lead to their interruption and disease worsening. In addition, consumers may face increased costs due to alternative treatments that are more expensive and/or not equally reimbursed. On occasions, they face travel costs when looking for available medicines.

Supply disruptions affect vital medicines, which can be life-threatening for patients. Drug shortages cause anxiety to affected individuals and might have spill-over effects for the healthcare system. For example, one might observe an increase in the number of visits to the doctor or pharmacy to get help or a sudden demand boost for the missing medicine once it is available.

Sometimes medicines are pulled from the market because companies lose commercial interest in them, whilst new medicines that were centrally authorised (i.e. by the European Medicines Agency, EMA) might not be marketed in all countries, thereby leaving a gap. This problem affects especially small countries.

The shortage of vaccines is particularly worrisome as they can diminish the coverage and ultimately lead to avoidable epidemics.

The Pharmaceutical Strategy must lead towards a **comprehensive approach to tackle drug shortages** and ensure that medicines are available when people need them.

Here are BEUC's five priorities to ensure medicines availability:

[7] Organización de Consumidores y Usuarios. OCU alerta del desabastecimiento de medicamentos, 13 February 2020.
[8] European Association of Hospital Pharmacists. 2019 EAHP medicines shortages report, April 2020
[9] Forbrukerrådet. Legemiddelmangel på norske apotek, December 2019
[10] Organización de Consumidores y Usuarios. Sin Medicación, pacientes angustiados, 2020.
[11] Forbrugerradet Taenk. Forbrugerpanelet om rejserettigheder, June 2020

1) The EU must have permanent and well-resourced systems for the prevention and management of shortages that build on the initiatives implemented during the COVID-19 pandemic. This includes having an effective mechanism for information-sharing on medicines shortages and stocks. Likewise, there should be a strengthened EU stockpiling mechanism of essential medicines during crisis situations and better coordination among national approaches.

2) The EMA's mandate should be formally extended so it can have a stronger role in the coordination of medicines shortages. Its listing of shortages should be turned into a comprehensive, user-friendly, public EU-wide database that provides timely information. Patients and consumer groups should be engaged in the setting up of the system and consulted about the provision of information on drug shortages to the public.

3) Changes in EU legislation are needed for a stronger and more harmonised response to drug shortages. This could provide an opportunity to strengthen supply obligations by pharmaceutical companies and distributors and mandate drug shortage prevention plans by marketing authorisation holders. Such plans should be made publicly available.

4) Best practices on alternative (public) production models across Europe should be identified and promoted by the European Commission and Member States.

5) The Commission should consider policy options which help ensure that centrally authorised medicines are marketed in all EU Member States (e.g. exploring the possibility to introduce obligations for originator companies). It should also evaluate the impact of parallel trade on medicines (un)availability and consumer access, open a reflection process and provide further guidance to Member States as necessary.

Patients and consumers must be at the centre of the EU policy response on medicines availability. For additional recommendations see BEUC paper:

Addressing Medicines Shortages during the COVID-19 pandemic and beyond: The Consumer Check list'

2.4. Medicines affordability

New medicines are not always available to patients in Europe due to their high prices, leading to inequalities. For example, there are important disparities from one country to another in accessing new cancer treatments.[12] At the same time, patients might see how the price tag of their old medicine goes through the roof from one day to another. This has happened for medicines that were approved for another indication (usually to treat a rare disease) or due to an abuse of dominant position by the company marketing the drug. For example, in 2014 Aspen raised the price of some cancer drugs by up to 1,500%.[13]

Ensuring medicines affordability is challenging when governments negotiate drug prices with a blindfold, as it happens now. The problem is that national authorities do not know the actual price another country paid for a medicine due to the confidential nature of discounts offered by the industry. This prevents governments from knowing that it might be possible to get lower prices. In addition, there is little transparency from the industry on medicines R&D costs. Such asymmetry of information hampers governments' capacity to negotiate prices that are fair for consumers.

[12] Cherny N, Sullivan R, Torode J. et al. ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe, *Annals of Oncology*, 2016, vol. 27 issue 8

[13] Following a complaint by BEUC's Italian member organisation, Altroconsumo, the antitrust authority fined Aspen with €5 million in Italy. More recently, the European Commission achieved that the company commits to reduce the price of their medicines by 73% in average in Europe. More information at Altroconsumo Anticancer drugs prices up to 1500% increase and BEUC, Pharma group Aspen accepts to cut prices of cancer drugs

Whilst health technology assessments help governments make more informed reimbursement decisions by measuring medicines' added therapeutic value, not all Member States have the same capacity to do such evaluations. As a result, consumers from those countries get less value for money. Channelling public funds to pay for superfluous drugs also means that there is less available budget for other medicines and healthcare services. Skyrocketing medicines prices are everyone's concern. The Pharmaceutical Strategy must include concrete actions that help **empower national governments in medicines price setting and ensure drug affordability.**

Here are BEUC's five priorities to ensure medicines affordability:

1) The Commission should actively promote and enable information-sharing among Member States on medicines pricing, reimbursement, and procurement policies. The EURIPID database – listing medicines prices - should continue to be supported through the Health Programme and expanded, so it reflects drug net prices paid by participating countries. In the mid-term, Directive 89/105/EEC ('Transparency Directive') should be revised to shed light on relevant factors such as R&D costs and the public contribution, and advance on the transparency of pricing and reimbursement decisions.[14]
2) Effective mechanisms that enable Member States to conduct joint negotiations on medicines prices and procurement should be in place, for situations of cross-border health threats and beyond, e.g. new innovative drugs.
3) Anti-competitive practices and agreements by the pharmaceutical industry - including pay-for-delay agreements or abuses of dominant position - must continue to remain a priority of the European Commission to ensure a competitive market of generics and biosimilars.
4) In addition, the Commission should explore how competition in the pharma sector can be strengthened through regulation. For example, by revising the Orphan Regulation to avoid misuses and abuses of IP-related incentives that delay the entry of generics. Any incentive granted to the industry to promote innovation should always be proportionate to avoid overcompensation and go hand in hand with obligations. For example, companies who want to benefit from orphan designation should submit data on R&D costs to competent authorities to justify lack of sufficient return on investment.
5) A permanent and impactful framework of cooperation on health technology assessment at the EU level should be up and running. The EU institutions must reach a swift agreement on the HTA Regulation.

BEUC position paper on the European Commission's proposal for an HTA Regulation can be found here:
https://www.beuc.eu/publications/beuc-x-2019-004_beuc_position_on_hta_regulation.pdf

2.5. Build on lessons learned from the COVID-19 pandemic

The COVID-19 pandemic is a stress test for our healthcare systems and policy framework. In many ways, it has highlighted existing gaps such as insufficient research on infectious diseases before outbreaks occur, lack of well-established coordination mechanisms to tackle drug shortages and effective tools that prevent consumers from being exposed to misleading claims about disease and treatments.

[14] Advances in this area should contribute to the implementation of the World Health Organisation Resolution on 'Improving the transparency of markets for medicines, vaccines, and other health products.

We are concerned that consumers are being exposed to scams and online disinformation regarding the pandemic and the measures to contain it.[15] This information is disseminated mainly via social media and advertisements.[16] However, despite the efforts made by concerned platforms, more needs to be done to prevent the dissemination of misleading information regarding the health crisis caused by COVID-19, as shown in a recent report by the European Commission.[17] From BEUC's perspective, this cannot be tackled effectively without looking at the advertising-based business models of online platforms.[18]

Overall, the Pharmaceutical Strategy should build on lessons learned from the response to the pandemic and take forward those initiatives that can help improve access to medicines (such as cooperation around joint procurement). Ways to strengthen and expand the scope of the Joint Procurement Agreement should be identified. In addition, the Pharmaceutical Strategy should call for an assessment of the EU vaccine's strategy and advance purchase agreements to evaluate their impact and inform potential future similar initiatives.

The COVID-19 pandemic also shows that EU action alone is not sufficient to overcome all the challenges we face. Boosting international cooperation, through the WHO and WTO, is essential for improved medicines accessibility. In particular, the Strategy should:

- Promote plurilateral trade negotiations on medical goods, for improved medicines availability and affordability. Such an initiative could be positive as long as it includes the consumer interest, is conducted transparently and allows engagement from civil society.
- Support the possibility for Member States to import medicines under compulsory licenses, by reversing the opt-out of article 31bis of the World Trade Organization agreement on trade related aspects of intellectual property rights (TRIPS).[19] Situations like the COVID-19 pandemic show how important it is to ensure that Member States can import cheaper versions of urgently needed medicines.
- Promote and help implement, closely with Member States, WHO initiatives for improved access to medicines during the COVID-19 pandemic and beyond.

3. Conclusion

The Pharmaceutical Strategy brings momentum to put forward ambitious measures to ensure that everyone in Europe has timely access to safe, effective, and affordable treatment. Outlining specific actions throughout the lifecycle of pharmaceuticals will be essential to reach that goal. In doing so, it will be important to ensure that actions lead to achievements in successive phases. Likewise, adequate engagement of consumer groups in the implementation of the Strategy will be crucial to ensure that consumers' rights, interests, needs, and expectations are fully taken on board. END

[15] For more information, see BEUC's feedback to the European Commission's roadmap consultation on the Digital Services Act, available at: http://www.beuc.eu/publications/beuc-x-2020-058_roadmap_and_inception_impact_assessment_on_the_digital_services_act.pdf

[16] See, for example this publication by BEUC member organisation Which? '' Fraudsters can create scam Facebook and Google ads within hours, Which? reveals'', 6 July 2020 https://press.which.co.uk/whichpressreleases/fraudsters-can-create-scam-facebook-and-google-ads-within-hours-which-reveals/

[17] European Commission. Disinformation: EU assesses the Code of Practice and publishes platform reports on coronavirus related disinformation. Press release, 10 September 2020. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1568

[18] BEUC. What is the link between behavioural advertising and fake news?, April 2018. http://www.beuc.eu/publications/beuc-x-2018-036_what_is_the_relation_between_behavioural_advertising_and_fake_news.pdf

[19] For more information see the joint civil society letter from 7 April 2020 asking 37 WTO Members to declare themselves eligible to import medicines manufactured under compulsory license in another country, under 31bis of TRIPS Agreement. Available at https://www.keionline.org/32707

This publication is part of an activity which has received funding under an operating grant from the European Union's Consumer Programme (2014-2020).