The Consumer Voice in Europe

BEUC POSITION ON ACCESS TO MEDICINES

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Summary

Access to medicines is a growing concern for European consumers. A number of recent developments including the economic crisis, the ageing population, technological advances, increased consumers expectations and new health threats present major challenges for sustainability of national health care systems and the medicines they provide.

Consumers face three major challenges in accessing medicines:

1) Medicines that consumers need are not being developed

Recent medical innovation has made remarkable advances for a limited number of conditions while yielding unimpressive results in most other disease areas.

2) New life-saving medicines and older key medicines may be unaffordable

Expensive medicines (i.e. effective treatments for hepatitis C, rare diseases and some cancers) threaten to erode European health budgets. Recently, a number of cost-saving policies in EU Member States have shifted the financial burden of medicines to consumers. This move is one of the reasons why Spanish households now pay 58% more for their medicines in than in 2010. 39% of Portuguese consumers could not afford a medicine they needed in 2014.

3) Some medicines might be out of stock because of shortages

Two thirds of hospital pharmacists from across Europe reported that shortages affect their work on a daily or weekly basis. Patients facing drug shortages or unaffordable medicines must interrupt or forego important, sometimes lifesaving, care, such as chemotherapy. Negative consequences on safety and quality of care inevitably result.

In light of these challenges, the European Council Conclusions on Innovation for the Benefit of Patients (2014) encourage cooperation for sustainable health systems and equitable access to new medical innovations[1]. BEUC calls on national and European policy makers to see to it that consumers have access to safe and effective medicines in a timely and affordable manner. To do so, policy makers need to act to align Europe's priorities and allocate resources efficiently now and in the years to come.

To that end, BEUC makes the following recommendations:

For medicines development:

1. **Research financing should be directed to areas of public health in need.**

2. **Consumers should not have to pay twice for their medicines.** Profits should be balanced with affordability, especially when public money has funded drug research.

3. **'Early access' schemes for new medicines should always be the exception**, not the rule. A clear definition of an 'unmet medical need' should be agreed. Patients using 'early access' medicines deserve the same protection given to participants in a clinical trial.

For medicines affordability:

4. An EU-wide assessment of the added value of new and existing medicines – i.e. what benefits they have for patients compared to the alternatives – is needed to guarantee consumers get a good value for money.

5. Antitrust authorities at the EU and national levels should continue to monitor potential anticompetitive practices to protect consumers from artificially high drug prices.

6. Member States should explore new ways to share data on medicines prices **possible joint initiatives to drive end costs down**.

For medicines availability:

7. More investigation and transparency on the causes of shortages and more information to the general public on the implemented solutions are needed.

8. **Respect time limits for pricing and reimbursement decisions** set out in the Transparency Directive to avoid excessive delays in access to new medicines.

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1. Medicines development

Medical advances can protect and improve consumers' health in Europe. However, the current innovation model is not delivering the therapies that patients need.

> Current drug development and regulation in Europe often delivers marginal benefits for consumers

1.1 New medicines should bring added value compared to existing treatments

Recent medical innovation has made remarkable advances for a limited number of conditions while yielding unimpressive results in most other disease areas. One example is the threat of antibiotic resistance that drives our need for new antibiotics, but these medicines are generally not as profitable as others and innovation has stagnated.[2]

Many new medicines that enter the market do not offer consumers any additional benefit compared to existing treatment while exposing them to increased risks (because they are new and have been tested only on a small group of people). For example, only 2% of new medicines licensed on the French market between 2000-2013 offered a real advance for their approved indications.[3] (See graph below) The situation is similar in Germany and the Netherlands.[4]

> Only 2% of new medicines licensed on the French market between 2000-2013 offered a real advance for some patients.
>
> La revue Prescrire

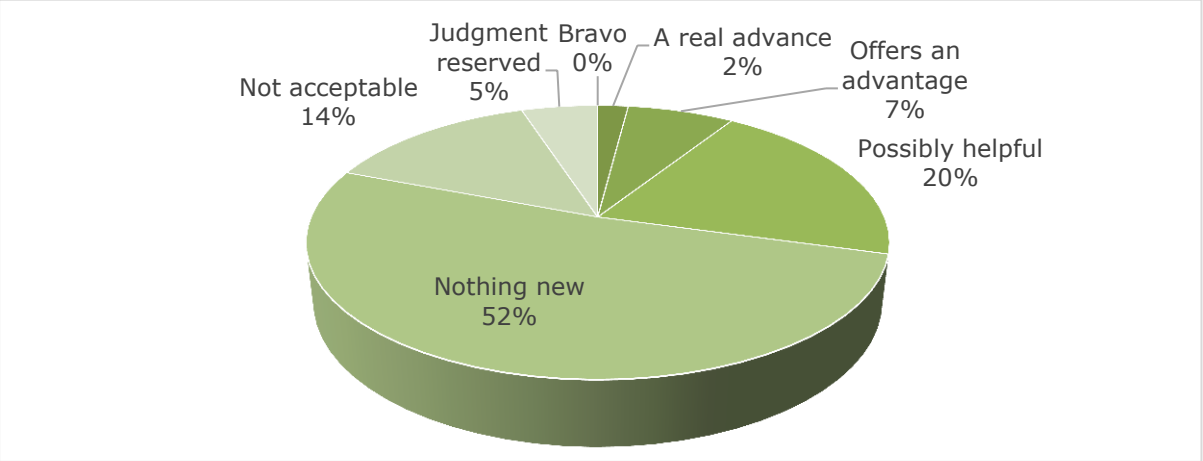

Fig 1. Added value of new medicines licensed in France between 2000-2013. Source: La revue Prescrire.

1.2 Innovation must benefit consumers

Public and private research priorities should be defined according to public health needs. For instance BEUC is concerned that the priorities of the largest EU public-private partnership for the development of medicines, the "Innovative Medicines Initiative"[5] so far focused on less than half of areas of medical need identified by the WHO.[6]

Moreover, we are concerned that governments and consumers will have to pay twice to access most products born of this partnership: the first time as the public's contribution to research by the European Commission and again through the healthcare system in order to purchase the medicine.

1.3 Early access to medicines: No access without safety

> Earlier access to an unproven medicine can be more dangerous for patients than no medicine at all.

Several "early access initiatives" are underway in the EU. The European Commission has recently convened an Expert Working Group on Safe and Timely Access to Medicines for Patients (STAMP) with Member States to exchange views and experiences and to find ways to use the EU regulatory tools for early medicines access.[7] Another initiative is the European Medicines Agency's Adaptive Licensing or Medicines Adaptive Pathways for Patients (MAPPs) **project to give early approval to a medicine for a restricted patient population with a smaller evidence base**. In this project, the market authorisation will be expanded as more is known about the medicine. At this stage, little information is available to understand how these projects work in practice. BEUC considers that sidestepping the standard benefit-risk assessment for licensing a medicine should only be done for a very limited range of medicines and only when there is no other available alternative.

Any move to bring medicines for which the safety and efficacy have not been fully demonstrated to the market sooner raises **many questions about consumer safety and protection.**

First, how will the scope of these programmes be kept sufficiently narrow so 'early access' remains the exception in EU drug regulation? BEUC believes that 'early access' programmes should be limited to subset of medicines to treat genuine unmet medical needs. This is because patients using 'early access' medicines are exposed to higher health risks associated with having less comprehensive safety and efficacy data when the drugs enter the market. On the other hand, scientists who are members of the European Medicines Agency (hereafter EMA) or its committees have stated that "*Adaptive Licensing is envisioned as the ultimate replacement for the current development and authorization process/model, and as such would be applicable to most new products*."[8] To avoid this slippery slope, **a clear definition of an 'unmet medical need' should be agreed** and the justification for an 'early access' approval should, without exception, include an explanation of the unmet medical need in question, the extent to which the product fulfils that need, and the strength of the evidence.

Second**,** *how will patients be sufficiently informed of the potential benefits and risks of using these medicines if they are not all known*? Consumers implicitly trust the current regulatory system to ensure that the benefits of licensed medicines outweigh their risks. Raising consumers' awareness of the higher risks associated with early access initiatives can prove difficult and, if not properly done, it can expose patients to health risks they did not understand they were taking.

Third, *how will medicines safety and efficacy be monitored?* Evidence from Canada's early access policy shows that there is little oversight of manufacturers' duties to confirm medicines' clinical benefits in post-marketing studies. Studies are executed for some medicines in as early as 1.4 years after authorisation, while for other medicines these commitments were still unfulfilled after seven years.[9] All early-access initiatives in the EU must rapidly address the knowledge gaps about medicines safety and efficacy, and quickly disseminate this information to regulators, prescribers and patients. In this way, patients can be assured that their contributions will benefit future patients.

Fourth, *how will patients be protected if they are harmed by 'early access' medicines?* Due to less testing and greater uncertainty, patients using these medicines take health risks comparable to participants in clinical trials, but without the guarantee that they will be afforded the safeguards, such as damage compensation, in the Clinical Trials Regulation. What's more, some EMA scientists and committee members have indicated that 'a prohibition on product liability suits, except for gross negligence, during the initial marketing period' might apply to some 'early access' medicines.[10]

Fifth, *how will these medicines be financed?* The so called "managed entry agreements" or risk sharing schemes are arrangements between public funders and drug companies to finance "unproven" medicines that hold promise for treating certain conditions. These can entail agreements for public authorities to pay the drug manufacturer depending on the amount purchased or how well the medicine worked. Concerns have been raised about the potentially high administrative costs, lack of transparency, possible conflicts of interest, the danger that public payers could end up funding a part of private drug development[11] and the misleading effect these schemes have on the external reference pricing (ERP) system.[12] Currently, there is little evidence about whether these schemes actually do improve access to medicines and at what cost.[13]

2. Medicines affordability

Medicines prices are rising quickly and some EU health systems are spending more than ever to finance pharmaceuticals.[14] Spanish households now pay 58% more for their medicines in than in 2010, according to a consumer survey in 2015 by BEUC's member OCU.[15] 39% of Portuguese consumers could not afford a medicine they needed in 2014, shown in a survey by BEUC's member DECO Proteste.[16] In light of budget constraints, public payers face an ethical and economic dilemma: Which treatments will be financed and how much can be paid to extend a life? One industry commentator aptly illustrated this predicament: The price of just one pill of the expensive, new medicine to treat Hepatitis C is nearly equal to the cost of all the recommended immunizations for one Belgian against infectious diseases.[17]

> Spanish households now pay 58% more for their medicines in than in 2010.
>
> OCU

Setting medicines prices is not an exact science; it is a **negotiation between drug manufacturers that usually set an 'asking price' (i.e. often the highest price the market will bear) and insurers that may set a maximum price**. Insurers often regulate prices so as to limit the amount they will pay for a medicine. Cost-effectiveness tools exist for public payers to understand what society is paying for clinical and societal gains[18] and these tools can be used to maximize health benefits within limited budgets. This approach values everyone's health gains equally, regardless of the rarity of the disease.[19] Medicines can become more cost-effective if they yield greater health gains or are sold at lower prices. Therefore, **the cost of a medicine and price negotiation are important factors in affordability.** Against the backdrop of an aging Europe, expensive, new medicines and shrinking public budgets, these tools should be fully exploited.

> 39% of Portuguese consumers could not afford a medicine they needed in 2014.
>
> DECO Proteste

2.1 Pricing & reimbursement: Consumers deserve value for money

Now more than ever, consumers expect value for money for their medicines. As a competence of EU Member States, medicines pricing and reimbursement is aided by national assessments of the value of a new medicine. **Health technology assessments** or other comparative and cost-effectiveness tools can identify the safest, most clinically-effective treatments. They also **help public payers avoid substantial investments in medicines with only marginal benefits for patients**. However, the diversity of values, assessment methods and resources across the EU can lead to a medicine being reimbursed in one Member State and not in another, frustrating patients and raising questions about healthcare equity in the EU. This diversity also leads to different prices of the same medicine in different EU Member States.

> An unaffordable medicine is just as out of reach for consumers as a non-existent therapy

In response, the European network for Health Technology Assessment (EUnetHTA) was established in 2009 to support Member States to produce objective, timely, transparent and comparable assessments of new health technologies up for reimbursement. EUnetHTA aids EU countries to pool their resources to exchange data, to conduct joint assessments and to make the results widely available. As EUnetHTA is about to enter the third and final Joint Action, we are reminded that enduring cooperation between Member States to assess medicines added value is needed. Political support, technical expertise and clinical data are necessary to assess comparative effectiveness as early in the drug development process as possible. After all, **it is unethical to expose patients to the risks of new medicines that are of no tangible benefit compared to existing treatments.**

In spite of the growing number of tools to aid reimbursement decisions, examples show these processes have been sidestepped, dedicating scarce healthcare resources to unproven therapies. **Pressure from manufacturers has led governments to abandon the standard 'value for money' assessments and hastily reimburse some medicines**.[20] Past experience with anti-virals for H1N1 flu show that excessive pressure on European governments can see large quantities of medicines purchased in the absence of convincing evidence that they work. This practice not only depletes drug budgets but diverts funds away from other proven treatments.[21] Decisions not to reimburse medicines for certain conditions have also been overturned owing to media attention and public opinion, sometimes guided by drug makers.[22]

Expanding the role of stakeholders in regulatory decisions can further increase undue corporate pressure on decision makers. For this reason we oppose the inclusion in the Transatlantic Trade and Investment Partnersip (TTIP) of an Annex on procedural fairness provisions similar to those introduced in the Korea-US[23] and Australia-US agreements. More generally we consider that pricing and reimbursement decisions should have no place in TTIP. Please see BEUC's position on TTIP & Health for more information about how TTIP can impact medicines in Europe.[24]

2.2 More transparency is needed

> Doing more for patients does not always equate to spending more

Transparency of how drug prices are set and how reimbursement is determined is crucial for consumers to know and to trust that these decisions make the most optimal treatments accessible. Added transparency can also empower Member States to negotiate and set prices to control medicines costs.

An external reference pricing (ERP) system is often used by Member States who base prices in their own country on prices in other 'reference' EU countries. In spite of its benefits, the ERP system incentivises manufacturers to launch their medicines first in

expensive markets and, if necessary, to negotiate hidden discounts and rebates to keep reference prices high.[25] ERP can also motivate companies to increase their prices in low-price markets or remove their products from these markets all together, as has been seen with older, lower-priced antibiotics.[26]

One way to support lower prices is through greater transparency. **Publishing contracts between drug manufacturers and government buyers could increase the quality and extent of competition from other bidders, allowing governments to purchase medicines on the best terms**.[27] Moreover, how public funds are spent, such as on which medicines and for which prices, should be open for public scrutiny. More generally we consider that the pharmaceutical sector needs a big dose of transparency. BEUC also supports the Council of Europe's recent resolution calling for absolute transparency of the links between the pharmaceutical industry and all health sector players and recommending that those with a conflict of interest be excluded from 'sensitive decision-making processes'.[28]

Another way to stimulate lower prices and ease pressure on public budgets that is currently being explored could be to purchase medicines together with other EU Member States in large quantities. Recently, Bulgaria and Romania[29] have teamed up to purchase expensive pharmaceuticals while Belgium, the Netherlands and Luxembourg[30] will jointly procure medicines. Evidence generated from these pooled procurement pilots should be collected and made publicly available to assess their success.

2.3 Fair competition

Ensuring fair market competition can lead to lower prices. The European Commission's Pharmaceutical Sector Inquiry in 2009 found that **generic competition, for example, can encourage a 40% drop in prices** within two years of patent expiry.[31] Even now, generic medicines entering the market in 2014 drove the price of originators prior to patent expiry down by 61%.[32]

> Generic medicines entering the European market in 2014 drove the price of originators prior to patent expiry down by 61%.
>
> IMS Institute

BEUC questions high medicines prices and price hikes, when the rationale for these changes is unclear or not justified on the basis of objective reasons. **Price jumps by the only manufacturer of a medicine or through speculation is an unfair risk to consumers** who rely on these medicines. Recently our Italian member Altroconsumo filed a complaint with the Italian Antitrust Authority when a shortage of four oncological drugs was noted in Italy in 2014 and, after these medicines returned to the market months later, their prices curiously jumped by 250% up to 1500% of their price before the shortage.[33] Aspen Pharma, the manufacturer of all four medicines, is currently under investigation for abuse of a dominant position.

> The price of four essential cancer drugs suddenly rose by 250% to 1500% in an unethical company move, which is being investigated the Italian Antitrust Authority.
>
> Altroconsumo

3. Medicines availability

> Profits should not govern where and when European consumers can access medicines

A number of recent cases show that access to medicines is no longer a challenge for developing countries alone. European consumers are also facing difficulties in accessing medicines in Europe. For example, medicines stock-outs are hitting European pharmacies leaving patients unable to access medicines they need in a timely way. In Belgian pharmacies, an average of 42 medicines are sold out every month. Shortages concern cancer therapies, antibiotics and vaccines – all of which require timely administration and strict adherence. While some of these drugs can be substituted, others cannot.[34] Data from two Belgian hospitals showed that shortages cost an additional 117,281 Euro in staff time to manage the stock-outs plus the higher costs of alternative medicines.[35] Two thirds of hospital pharmacists from across Europe reported that shortages affect their work on a daily or weekly basis. Three out of four respondents agreed that medicines shortages in their hospital have a negative impact on patient care, such as delaying or interrupting chemotherapy treatment, causing avoidable side effects and increasing the risk of healthcare-acquired infections.[36]

> 3 of 4 pharmacists surveyed across Europe agreed that medicines shortages in their hospital have a negative impact on patient care.
>
> European Association of Hospital Pharmacists

Shortages can be caused by one or a combination of problems in manufacturing (i.e. shortage of raw materials), distribution and supply (i.e. parallel trade from a low-price to a high-price market in the EU), or economics (i.e. the financial crisis, pricing policies, or marketing strategies).[37] The fact that there is no harmonized definition of drug shortages makes it difficult to monitor and report on supplies in a comparable way. **A comprehensive response to drug shortages is needed at the EU level**, particularly because they can put Member States in direct competition with one another for sufficient medicines supplies, and ultimately risk the continuity of patient care.[38]

Medicines shortages may have deepened since the financial crisis. Reports of medicines shortages at hospitals and outpatient pharmacies in Greece surfaced in 2013 after price cuts and unpaid bills allegedly motivated a number of drug companies to limit medicines shipments.[39] Although EMA monitors manufacturing problems[40] for medicines licensed by the agency, there is little pan-European information about all medicines stocked out for reasons including financial difficulties**.**

3.1 Unethical anti-competitive practices by companies curb access to affordable medicines

Unfair commercial practices and price speculation are unethical and put profits above consumers health. The recent case involving two medicines to treat age-related macular degeneration, bevacizumab (Avastin®) and ranibizumab (Lucentis®), show that companies can use unethical anti-competitive strategies to keep prices artificially high at the expense of consumers. In this case, the Italian Antitrust Authority fined two companies a total of €180 million for running a cartel to block Avastin sales, an equally effective but cheaper alternative to the pricy Lucentis. This added burden on the Italian healthcare system amounted to over €45 million in 2012 alone and increaded future costs for more than €600 million per year. Following this case, BEUC called for the European Commission to investigate whether consumers in other Member States have been affected by these anti-competitive practices.[41]

> The anticompetitive agreement between Roche and Novartis to promote the sales of Lucentis, an expensive treatment for blindness, at the expense of the cheaper alternative Avastin caused the Italian health system additional expenses for over €45 million in 2012.
>
> Italian Antitrust Authority

Under European law, the benefits and risks of a medicine must be evaluated and licensed for each condition it is used to treat. Unlicensed or off-label prescribing is only possible in exceptional cases and generally discouraged as no evaluation has yet taken place. Given that Lucentis is up to 100 times more expensive and equally effective as Avastin[42], some European governments like Italy and France now reimburse the more affordable Avastin for use outside of its approved indication.[43]

3.2 Pricing & reimbursement delays hamper timely access

> Consumers need medicines that are available at the right place and the right time

Several concerns have also been raised about the timeliness of marketing and reimbursement decisions. Regarding the latter, each Member State's health system has its own procedure to judge a medicine's 'value for money'. These differences have led, in part, to time lags in drug access. One study shows that it took anywhere from 6 months (in the Netherlands) to 12 months (in France) to reach a decision for a selection of medicines approved between 2010-2011.[44]

4. Recommendations

Innovation: Drug development must deliver substantial benefits for consumers

- **Research financing should be directed to areas of public health in need**.
- **Consumers should not have to pay twice for their medicines.** When public funds have co-financed the development of medicines, the end products should be licensed such that consumers and governments do not have to pay twice to access these medicines.
- All drug developers should be fully transparency about the real costs of their research.
- Greater transparency and timely information about the ongoing 'early access' projects and specific products is needed. **'Early access' initiatives should always be the exception**, not the rule.
- **Patients using 'early access' medicines deserve the same protection given to participants in a clinical trial,** including additional safety monitoring and an appropriate method to seek compensation for any serious negative effects.

Affordability: Doing more for patients does not always equate to spending more

- Potential **anticompetitive practices need to remain on the European Commission's radar** to protect consumers from artificially high drug prices. EU and national antitrust authorities should act on suspected anticompetitive practices in the pharmaceutical sector, in particular by imposing 'dissuasive penalties for any illegal practices'.
- The **pharmaceutical industry should provide all relevant clinical data to inform national pricing and reimbursement decisions**, particularly to ensure the safest, most clinically and cost-effective alternative is available to patients.
- The Council of Europe recommends that Member States consider limiting reimbursement to only those medicines with a proven added therapeutic value compared to existing alternatives.[45]
- Cross-national dialogue on the 'added therapeutic value' concept and the exchange of HTA information should be promoted from greater health equity in the EU.[46]
- Member States should explore new ways to share data on medicines prices and other joint initiatives **to drive end costs down**.
- Exclude pricing and reimbursment issues from trade negotiations.[47]

Availability: Consumers need drugs that are available at the right place and the right time

- To avoid excessive delays in access to new medicines, Member States should respect the time limits for pricing and reimbursement decisions set out in the Transparency Directive.
- **Drug shortages should be uniformly defined and investigated at the EU level** to find their common causes and possible solutions.
- When shortages do occur, the pharmaceutical manufacturers should communicate as early as possible with regulators about impending and ongoing drug shortages to ensure patient safety.
- Consumers should be able to access a reader-friendly catalogue of all shortages of medicines marketed in the EU. This could be addressed by expanding the EMA's Shortages Catalogue.

5. Conclusion

The pending access to medicines 'crisis' in Europe shows no signs of abating. Flaws in the current innovation, regulatory and price setting models have led to **exorbitant drug prices that are unaffordable for European health systems and consumers**. Medical research is delivering little added value for many unmet health needs and new regulatory models will bring **faster, but not necessarily safer or better, medicines**. Some national health authorities still operate with limited comparative information, leading them to finance marginally effective drugs or pay unnecessarily high prices. Unfair commercial practices, drug shortages and delays in pricing and reimbursement decisions continue to impair medicines availability, affecting high-quality patient care.

> The time to act is now to guarantee high-quality patient care today and sustainable European health systems in the future.

Coordinated action at the EU level is urgently needed to respond to the divergent approaches to medicines innovation, regulation, pricing, reimbursement and supply that can be detrimental to consumers and perpetuate health inequalities across the EU. A patient-centred approach will commit scarce resources to therapies proven to be safe and effective. This can be achieved by dedicating research and health budgets to truly innovative products with a clear added therapeutic value. The time to act is now to guarantee high-quality patient care *today* and sustainable European health systems in the *future*.

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