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BEUC The European Consumer Organisation

The Consumer Voice in Europe

ADDRESSING BARRIERS FOR CONSUMERS TO ACCESS MEDICINES IN THE EU

BEUC position paper on the revision of the EU general pharmaceutical legislation

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EC register for interest representatives: identification number 9505781573-45

Co-funded by the European Union

Ref: BEUC-X-2022-052 – 27/05/2022

Why it matters to consumers

Consumers in Europe encounter barriers when trying to access medicines they need to get healthier. For example, medicines are sometimes unavailable at the pharmacy or not reimbursed due to how expensive they are and the strain they put on public health budgets that have their own boundaries. The revision of the EU pharmaceutical legislation is an opportunity to address these and other challenges, and improve consumers' access to medicines across EU Member States.

Summary

The European Commission is planning to present a legislative proposal to revise the EU general pharmaceutical legislation at the end of 2022. This brings a unique opportunity to ensure there is better and more equitable access to medicines in Europe. To get there, the EU must:

Improve medicine marketing authorisation by adopting the following measures:

1. Require the submission of more robust evidence on a medicine's safety and efficacy.
2. Keep the scope of early approval schemes for medicines to limited and justified situations only and strengthening these schemes.
3. Improve the readability and content of medicine packages and leaflets.
4. Promote electronic product information as a complementary tool to the package leaflet for information on medicines, but not as a substitute.
5. Shift scientific advice to drug developers to the public domain.

Improve medicine availability by adopting the following measures:

6. Oblige pharma companies to develop and submit drug shortage prevention plans to competent authorities.
7. Require safety stocks to minimise the impact of drug supply chain disruptions on consumers.
8. Require earlier notification of drug shortages by pharma companies.
9. Facilitate that centrally-authorised products are available across the EU.
10. Improve the monitoring of medicines' supply and demand.
11. Promote better public communication on shortages.
12. Enable patients and consumers to report shortages.
13. Require Member States to set dissuasive penalties for companies that do not comply with these new obligations.

Increase medicine affordability by adopting the following measures:

14. Revisit the intellectual property incentives system and put in place safeguards to prevent abuses.
15. Refrain from implementing transferable exclusivity vouchers.
16. Facilitate the introduction of generics and biosimilars in the market through a revised 'bolar exemption'.

1. Introduction

At the end of 2022, the European Commission will table a proposal for a revised Directive on medicinal products, and a revised Regulation establishing the centralised marketing authorisation procedure and the European Medicines Agency (EMA).[1] This is a long-awaited and welcome revision after many years without major changes to the EU's legislative framework on medicines – leaving aside some specific legislation adopted in early 2022 on health crisis preparedness and response.

Since the Commission announced its plans on the revision of the general legislation, BEUC has contributed to the preparatory phase by giving input to public consultations to support the impact assessment. In this paper, we outline key measures the future framework must incorporate to address challenges consumers encounter in relation to access to medicines, which undermines their possibility to get healthier and/or have a better quality of life.

2. Problem description

2.1. Medicines that patients need are not being developed or do not always bring meaningful benefits

Over the years there have been significant medical advances in some areas, but today many patients are still left with no treatment for their condition. In addition, there is poor innovation in the development of novel antibiotics, undermining efforts to tackle the growing problem of antimicrobial resistance.[2]

At the same time, when companies bring new medicines to the market, these do not always bring meaningful benefits to consumers. In fact, some medicines are no better than existing treatments, have uncertain benefits or are not even recommended.[3],[4],[5] An independent an assessment of medicines authorised in Europe shows that in 2021, only 17 of 108 new medicines or uses (16%) constituted a notable therapeutic advance.[6]

BEUC member organisations have also looked into this issue. In 2016, Belgian consumer group Test Achats/Test Aankoop found that 11% of 6,500 medicines sold in Belgium were of questionable benefit and 2% were not recommended at all.[7] German testing organisation 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.[8]

1 Directive 2001/83/EC and Regulation 726/2004.
2 World Health Organization, 'Lack of new antibiotics threatens global efforts to contain drug-resistant infections', 17 January 2020 [online, accessed 25 April 2022].
3 Prescrire International. 'Drugs in 2021: a brief review', 17 May 2021 [online, accessed 16 May 2022].
4 KCE. 'Do innovative cancer medicines against cancer always have a real added value?', 2021.
5 Salcher-Konrad, M., Naci, H., & Davis, C. Approval of Cancer Drugs With Uncertain Therapeutic Value: A Comparison of Regulatory Decisions in Europe and the United States. *Milbank Quarterly*, 2020, 98(4), 1219-1256.
6 See reference 3. The assessment includes medicines authorised by the EMA. In 2020, the percentage of marketing authorisations that constituted a notable therapeutic advance was even lower (8%).
7 Test Santé. 'Médicaments à foison près de 900 sont du gaspillage'. num. 132, 2016.
8 Spiegel Gesundheit. 'Jedes vierte rezeptfreie Medikament fällt durch', 24 June 2019.

2.2. Medicines are increasingly in short supply

Consumers are increasingly paying the consequences of weaknesses in drug supply chains. Surveys by five BEUC members conducted in 2019 and 2020 show that between a fifth and almost half of households were unable to get the medicine they needed at least once in the previous two years.[9] In around nine in ten cases when there was a shortage, the medicine was prescribed, which indicates they were deemed essential or even life-saving.

Consumer surveys also show that shortages impact people in various ways. For example, between a third and half of the consumers unable to get the medicine they needed said the shortage had an impact on their health. For many, the shortage caused anxiety but could also lead to worsening of their symptoms and some people suffered side effects from alternative treatments. In addition, some consumers faced extra costs due to alternative treatments being more expensive and/or because they had to travel elsewhere to find their medicine.

2.3. High medicine prices threaten their affordability by consumers and public health systems

An additional problem is that the prices of some medicines go through the roof. It is particularly extreme in certain areas, such as for medicines for cancer and rare diseases which can cost up to hundreds of thousands of euros per year. But it goes beyond that. Some years ago, a very effective treatment for hepatitis C was rationed in many countries in Europe due to its exorbitant price. [10]

High medicine prices put strains on public health budgets, reducing funds available for other necessary health services and undermining the possibility for the state to reimburse certain medicines. When reimbursement by the state isn't possible, consumers must then bear the full cost of the medicine. For some people, and at some price levels, this is just impossible.

In addition, while the availability of generic medicines and biosimilars brings prices down, thus facilitating access, there are persisting barriers to the timely entry of these medicines in the market.

3. BEUC proposed solutions to identified challenges

The various challenges consumers encounter in accessing medicines is evidence of the need to update the EU's legal framework on pharmaceuticals.

To ensure consumers are in a better situation in the nearby future, the revised legislation must include measures that effectively contribute to the development of new and better treatments and that improve medicines' availability and affordability across the EU. In particular, it must incorporate the measures outlined below.

[9] Surveys carried out in 2019 and 2020 by the Spanish consumer organisation Organización de Consumidores y Usuarios (OCU), Test Achats/Test Aankoop (Belgium), Altroconsumo (Italy) and Forbrukerrådet, the Norwegian Consumer Council. See, BEUC factsheet 'Medicine shortages in the EU: alarming survey results from some countries', February 2022.

[10] BEUC. Position paper 'Time to lift the blindfold. Abolishing price secrecy to help make medicines affordable'. 2021.

3.1. Medicines' marketing authorisation

The EU has an advanced framework for the marketing authorisation of medicines, but there is room for improvement. The revised legislation must lead to better evidence on a medicine's safety, efficacy and added therapeutic value.

3.1.1. More robust evidence on medicine safety and efficacy

To make informed decisions on treatment, patients and healthcare professionals need to know how well a new medicine works compared to existing ones. However, companies do not routinely conduct the type of studies that allow to directly compare the benefits and risks of treatments. A study found that from 2015 through 2018, the annual proportion of new medicines that had at least one randomised control trial with an active comparator at the time of approval by the EMA ranged only from about a quarter to one-half.[11]

BEUC recommendations:

- Annex I point 5.2.5.1 in Directive 2001/83 should be strengthened. Marketing authorisation applicants must submit evidence from randomised controlled clinical trials versus standard treatment, unless exceptionally where justified and in line with the principles laid down in the Declaration of Helsinki. Regulation 726/2004 should include the same language or be bound to the previous article.

- In addition, these pieces of legislation should explicitly require that full marketing authorisation is granted upon clear demonstration of benefit based on clinically relevant outcomes, including adequately validated surrogate endpoints.[12]

- To safeguard patient safety, the revised legislation must maintain the concept of medicines' additional monitoring and the accompanying black triangle in package leaflets, aimed at enhancing reporting of suspected adverse drug reactions.[13]

3.1.2. Early drug approvals only in justified situations

Some medicines are authorised based on less scientific evidence, which means there is more uncertainty about their safety and efficacy. This can only be acceptable in specific and well-justified situations.

As such, conditional marketing authorisation, a tool applied by the EMA to authorise medicines before complete data are available, should in principle remain limited to:

- Emergency situations in response to public health threats, life-threatening or seriously debilitating diseases including orphan products, and

[11] The authors of the study extracted the data from European Public Assessment Reports of new active substances with first time approvals. In Naci H., et.al. Generating comparative evidence on new drugs and devices before approval. *The Lancet*, 2020; vol.395.

[12] Directive 2001/83 only includes language on ''clinically meaningful endpoints'' in the section on advanced therapy medicinal products, 5.1.6.

[13] The concept of additional monitoring was first introduced by the 2010 EU pharmacovigilance legislation. It applies to some specific medicines, for example those with a new active substance or a conditional marketing authorisation, and it means that they are more intensively monitored than other medicines.

- Conditions for which there exists no authorised satisfactory method of diagnosis, prevention, or treatment, or even if such a method exists, in relation to which the medicine concerned will be of major therapeutic advantage to those affected.[14]

However, even in these circumstances, it is important that the evidence at hand is re-assuring enough in relation to the benefit-risk profile of the medicine (including considerations on the 'unknowns') for medicines to be conditionally approved. In addition, to avoid exposing patients to treatment uncertainties for too long, pharmaceutical companies must submit to the EMA in a timely manner complete data for decision on full marketing authorisation. The revised EU legislation must put the emphasis on this, given reported delays or discrepancies by companies in the submission of post-marketing obligations.[15] [16]

BEUC recommendations:

- Regulation 726/2004 should be amended to require holders of a conditional marketing authorisation to provide conclusive evidence on benefits based on clinically relevant outcomes for full marketing authorisation in a timely manner.

- The EMA should set up a public, user-friendly and electronic database that centralises information about conditionally-authorised products, specific obligations to be fulfilled by companies, the timeframe for completion of studies and any deviations from it and applicable penalties if delays are unjustified.

3.1.3. Improved readibility and content of medicine packages and leaflets

For medicines to be used safely, consumers must be able to easily read and understand the information on medicines' packages and the leaflets that come within.

Whilst Directive 2001/83 (title V) requires that medicines' packages and leaflets are legible, clear and easy to use, a 2014 study for the European Commission found that the language used in leaflets, their design and layout are not always user-friendly.[17] Likewise, BEUC member organisations have received some consumer complaints about poor readability of medicines' packages such as expiry dates not being engraved with ink and the size of the letters being too small.

BEUC recommendations:

- The revised legislation should establish clear legibility criteria for medicines' packages and package leaflets, for example in relation to minimum font size, letter spacing and material surface and text/background contrast. Inspiration could come from the requirements for hazard pictograms in Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation).

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[14] As laid down in Regulation 507/2006. In our response to 2021 Commission's public consultation on the pharmaceutical legislation, we argued that while we found interesting the proposed option to include in the definition of 'unmet medical need' a situation of ''lack of access for patients across the EU to an authorised treatment.'', any proposal to link conditional marketing authorisation with such criteria would require further discussion.

[15] Banzi R. et.al. Approvals of drugs with uncertain benefit-risk profiles in Europe. *European Journal of Internal Medicine,* 2015 DOI:https://doi.org/10.1016/j.ejim.2015.08.008.

[16] Hoekman J. et al. Characteristics and follow-up of postmarketing studies of conditionally authorized medicines in the EU. *Br J Clin Pharmacol,* 2016; 82 (1).

[17] Van Dijk L. et.al. 'Study on the package leaflets and the Summaries of Product Characteristics of Medicinal Products for Human Use', 2014.

- At the same time, Article 65 of Directive 2001/83 should be amended so it requires the Commission to update existing guidelines in relation to labelling and package leaflets in consultation with consumer and patient groups and draw up new ones, such as on best ways to communicate on the benefit-risk balance of approved medicines in regulatory information materials.

- In addition, Article 54 (j) in Directive 2001/83 should be expanded, to require package leaflets to always make the link between the correct disposal of medicinal products and environmental protection.

3.1.4. Electronic product information as a complementary tool only

Electronic product information (ePI) can be a valuable information tool for consumers on medicines, but **it must not replace the package leaflet**.

The paper leaflet is the easiest option and, to some consumers, the only option to read information on the appropriate use of medicine, for example, due to low digital skills among some consumers or lack of access to a mobile phone with internet. For these reasons, the revised legislation should promote ePI as a **complementary information tool on medicines, but not as a substitute**. Ensuring that medicines packages come with a leaflet is particularly important for consumers who use community pharmacies. [18]

BEUC recommendations:

- The revised legislation should promote the development of ePI only as a complementary tool to mandatory paper package leaflets in the national language(s). The exception should be where Member States need to urgently import medicines' packages that are in another language to respond to a shortage.

- In addition, the legislation must uphold the following safeguards in relation to ePI: medicines agencies are the bodies entrusted to manage a single portal for ePI as well as any apps developed to facilitate the provision of ePI; it is not possible to track personal data of people accessing the ePI; ePI is not used to deliver promotional information.[19]

- To ensure the highest level of data privacy and security, the revised legislation should require the Commission to develop guidance documents on how to ensure that electronic product information is fully aligned with EU data protection requirements.

3.1.5. Shifting scientific advice to the public domain

Regulators often provide advice about how to design clinical trials to drug developers. This can help improve the design of these studies. However, to maximise the potential of this practice and improve accountability, it must be much more transparent.

[18] If healthcare professionals agree to replace the paper package leaflet by the ePI for those medicines that are 'only' administered at the hospital, patients should at least be able to receive a QR code or link, and those who prefer so a printout of the package leaflet.

[19] BEUC. Letter 'Subject: EU key principles for electronic product information for medicines – a consumer perspective', 2019

At the very minimum, the revised EU legislation should include the 2017 suggestions from the European Ombudsman to the EMA on ways to enhance public trust when scientific advice to individual companies takes place in private, bilateral meetings.[20] Our preference is nonetheless for the legislation to promote a new model for scientific advice, that shifts this practice as much as possible to the public domain.[21]

BEUC recommendations:

- Regulation 726/2004 should, at the very minimum, embed the recommendations made by the European Ombudsman to enhance transparency and avoid conflicts of interest when the EMA provides scientific advice to individual companies:
    - To address the risk of bias, ensure to the greatest extent possible that there is a separation between those responsible for providing scientific advice to a medicine developer and those subsequently involved in evaluating a marketing authorisation application for the same medicine.
    - To enhance transparency, document the reasons for exceptions and publish the information in the EPAR, together with a detailed log of all relevant pre-submission activities.

- Directive 2001/83, which regulates the granting of marketing authorisations by national medicines agencies, should be amended to include the previous measures so they also apply to national scientific advice procedures.

- At the same time, the revised legislation should shift as much as possible the provision of scientific advice from private conversations with the companies involved to the public domain. This could be done by requiring regulators to prioritise the development and update of scientific guidelines for the conduct of clinical trials and other studies, the organisation of public workshops to promote discussion on scientific developments, and the publication of questions and answers on issues related to drug development when regulators issue their response, so all stakeholders can benefit from such guidance. Under this framework, individualised scientific advice to drug developers as we know today would be an exception.

3.2. Medicines' availability

Medicine shortages are a growing problem in Europe.[22] The current EU legal framework is not fit for purpose to tackle this issue, as it contains few and very general provisions to help prevent and mitigate shortages. To improve the situation, the revised legislation must include the following measures.

3.2.1. Obligation for companies to develop drug shortage prevention plans

To tackle the problem of drug shortages, pharmaceutical companies should have robust plans in place that effectively reduce the risk of supply disruptions.

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[20] European Ombudsman. 'Decision in strategic inquiry OI/7/2017/KR on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU', 2019.

[21] See for example this joint civil society call for a new framework: 'Recommendations on a new model for the provision of scientific advice', 2017.

[22] European Commission, 'Future-proofing pharmaceutical legislation- study on medicine shortages', December 2021.

At present, whilst EU legislation calls on drug marketing authorisation holders to ensure continued supplies of medicines, it does not oblige them to develop shortage prevention plans and submit them with regulators. This is a major gap in the current framework, as such prevention plans could enable authorities to identify risks in supply chains early on and promote mitigation measures. For example, there could be a requirement for manufacturers to diversify the number of suppliers of active pharmaceutical ingredients.

On the positive side, at national level there have been some steps forward in that direction. For example, a few years ago France started requiring pharmaceutical companies to develop and share shortage prevention and management plans with regulators for some products.[23] Spain also put in place requirements on prevention plans. The revision of the EU legislation provides an opportunity to promote similar measures at EU level.
BEUC recommendation:

The revised EU legislation should require companies to develop and submit drug shortage prevention and management plans to national competent authorities, following a common EU template, and to the EMA for centrally authorised products.

3.2.2. Mandatory safety stocks

Pharmaceutical companies should have adequate levels of safety stocks for their products to mitigate the potential impact of supply disruptions on health systems and consumers.

To ensure that they do so, this requirement should be embedded in EU law.[24] A coordinated EU approach on safety stocks would also ensure that measures in one Member State do not have unintended consequences in other countries.

BEUC recommendation:

Directive 2001/83 should require that companies maintain safety stocks according to some common criteria that builds on existing best practices and considering the global dimension of drug supply chains. [25]

3.2.3. Earlier notification of drug shortages

Early notification by pharmaceutical companies on drug shortages is important to plan alternatives and minimise as much as possible the impact on consumers.

Whilst EU legislation requires pharma companies to notify Member States no less than two months if a drug ceases to be placed on the market either temporarily or permanently, some countries require earlier notification. For example, in Italy companies should in principle notify shortages four months in advance. Whilst in France, there is a one-year notification period when a medicine 'major therapeutic interest' is withdrawn.

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[23] In France, marketing authorisation holders have had to do this progressively since 2017 in the context of medicines of 'major therapeutic interest'. In Spain, the national medicines agency requires that companies submit prevention plans for those products that could cause a therapeutic gap in case of shortage [Problemas de suministro de medicamentos, accessed 19 May 2022]. For more information on BEUC position on prevention plans, see 'Addressing medicines shortages during the COVID-19 pandemic and beyond: the consumer check-list', 2020.

[24] Interestingly, in France there is a mandate for companies to hold safety stocks from two to four months for medicines of 'major therapeutic interest'. For other types of medicines, companies in France could be required to stockpile medicines for up to a month. More information at 'Mise en oeuvre de l'obligation de stockage des médicaments pour les industriels: une avancée majeure pour assurer aux patients un accès pérenne aux traitements' [accessed 19 May 2022].

[25] The EU should also call for initiatives on safety stocks by third parties to consider the global dimension of drug supply chains and global demand.

At the same time, the EMA and HMA recommend that companies notify the authorities as soon as the shortage or the impending/anticipated shortage is confirmed.[26] The revised pharmaceutical legislation should build on all these developments.

BEUC recommendations:

- Article 23 (a) in Directive 2001/83 should be amended and require companies to:

    1. notify Member States about anticipated shortages as soon possible, and in any case no less than a pre-defined notification period that is the same across the EU;
    2. provide a justification if exceptionally they cannot comply with the pre-notification period whilst ensuring that the shortage or impending/anticipated shortage was reported as soon as confirmed.

- The new and earlier notification period should be established according to best practices identified among Member States. For product withdrawals, the notification period should be one year.

- To ensure harmonisation in the reporting of shortages, and thus facilitate EU-level collaboration, the revised directive should also outline in a new article the type of information that companies must submit to competent authorities. The HMA and EMA guideline on the notification of shortages should be used as a reference for that purpose.[27] However, the scope of the article should also cover withdrawals due to commercial reasons.

3.2.4. EU-wide availability of EMA approved medicines

To improve equitable access to medicines across the EU, pharmaceutical companies with an EU marketing authorisation should be pushed to enter all Member States.

However, at present some new medicines approved by the EMA do not reach patients in all countries, particularly small ones. Various factors contribute to this, one of them being lack of measures at EU level to push marketing authorisation holders to enter markets across the Member States. This should be reversed.

BEUC recommendations:

- The legislation should be amended and require originator companies that obtained a market authorisation by the EMA to inform regulators about their market launch plans.

- In addition, these companies should be obliged to file for pricing and reimbursement in all EU Member States within a short timeframe, and any exceptions must be approved by national competent authorities on a case-by-case basis.

- The legislation could also provide originator companies that do not want to place a product in a specific market with the alternative to enable generic companies to enter earlier, under fair and reasonable licensing conditions. The legislation should facilitate these processes.

- To ensure transparency, the Commission should set up a public database that reports at least on the availability (placed on the market) of EMA approved medicines across the EU.

[26] EMA. '[Guidance on detection and notification of shortages of medicinal products for marketing authorisation holders in the Union]', 2019

[27] See reference 26.

Whilst in our recommendations we focus on the availability of new (innovative) medicines, some of these measures could also be considered, and adapted as necessary, for generic products with a central marketing authorisation.

3.2.5. Dissuassive penalties for non-compliance by companies

Dissuasive penalties are necessary to promote companies' compliance with their legal obligations in relation to the supply of medicines.

However, at present penalties are not dissuasive enough and/or enforced systematically.[28] This means penalties do not really function as deterrents.

BEUC recommendation:

The revised pharmaceutical legislation should require Member States, and the Commission where applicable, to lay down dissuasive penalties for new established obligations and report publicly about any applied sanctions.

3.2.6. Improved monitoring of medicines' supply and demand

Competent authorities should have a good overview of available stocks of pharmaceutical products and demand volume to be able to assess the risk of shortages and apply mitigation measures.

However, well-established monitoring and early warning systems are generally lacking at the national level. At the same time, whilst the new regulation reinforcing the EMA's role requires it to set up a platform to collect this type of data, the scope of the regulation is restricted to crisis situations. The revision of the pharmaceutical legislation is an opportunity to reinforce and expand the system, so it also covers 'everyday' types of shortages.

BEUC recommendations:

- Directive 2001/83 should be amended to require Member States to set up electronic monitoring and early warning systems on drug shortages.

- These systems should be interoperable with the European Shortages Monitoring Platform (ESMP) that will be set up by the EMA for the prevention and management of shortages in public health emergencies and major events as required in the new Regulation on a reinforced role for the Agency. In addition, the revised legislation should require that the scope of the ESMP is expanded progressively to other medicines.

3.2.7 Better public communication on drug shortages

Good public communication on drug shortages is essential to ensure that healthcare professionals, patients and consumers can take action to minimise the impact of stockouts on care, for example, by identifying potential treatment alternatives.

[28] OCU. 'OCU alerta del desabastecimiento de medicamentos', 13 Feburary 2020; and France Assos Santé 'Renforcer et rendre publiques les sanctions : France Assos Santé salue les propositions d'une mission de l'Assemblée nationale', 24 June 2021.

Although most Member States have online registers on drug shortages, they are not always user-friendly and/or critical information is not systematically reported.[29] As for the EMA catalogue, its scope is limited.[30]

To fix this, the revised pharma legislation should set specific measures on good public communication on drug shortages, building on the EMA and HMA's 'Good practice guidance for communication to the public on medicines availability issues'.

BEUC recommendations:

- Directive 2001/83 should be amended to require that all EU Member States set up a public and user-friendly database on drug shortages. The databases should contain critical information such as the start and end dates of the shortage, a detailed description of the causes including commercial reasons, and recommendations for healthcare professionals and patients/consumers.

- Regulation 726/2004 should be amended to mandate the EMA with setting up a public European database that collates information about drug shortages reported at the national level for all reasons.

3.2.8 Enabled consumer reporting on drug shortages

Enabling consumer reporting on drug shortages is important to collect data that can help understand better their societal impact, and to improve drug shortage management.

However, today many Member States do not have a system that allows consumers to report shortages. The upcoming revision brings an opportunity to reverse this and, in doing so, allow consumers to become more proactive stakeholders in issues concerning the availability of the medicines they take.

BEUC recommendation:

Directive 2001/83 should be amended to require Member States to facilitate patient and consumer reporting of medicine shortages.

For more information on BEUC's position on medicine shortages see: Addressing Medicines Shortages during the COVID-19 pandemic and beyond: The Consumer Check list

3.3. Medicines' affordability

Incentivising drug development is important, just as it is ensuring that once on the market medicines are affordable. It is also important that generics can enter the market in a timely way. To fix today's shortcomings, the revised pharmaceutical legislation must do several things.

3.3.1 Targeted provisions on data and market protection

The EU must ensure that intellectual property (IP) incentives granted to pharmaceutical companies are proportionate and go together with safeguards to prevent abuses and excessive prices.

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[29] BEUC. 'Addressing medicine shortages during the COVID-19 pandemic and beyond: the consumer check list', 2020

[30] To situations that have been assessed by one of the Agency's scientific committees. https://www.ema.europa.eu/en/documents/other/decision-tree-escalation-national-european-level_en.pdf

Today, between patents, supplementary protection certificates, data and market protection, the EU provides originator companies with long periods of IP rights. At the same time, there are increasing concerns about high drug prices that threaten patient access and put strains on public health budgets.

BEUC recommendations:

- Article 10 in Directive 2001/83 should be amended and lay down different data and market protection periods, with the longest protection for medicines for serious diseases/health threats for which there is less commercial interest (e.g., novel antibiotics). Protection periods beyond the current maximum period should only be granted if:
    - Companies share data on R&D costs for these products with competent authorities and justify the need for additional protection.
    - The legislation includes possibilities for reducing the protection period if necessary to prevent excessive profits e.g., 'revision clause'.
- At the same time, for other products the current protection period of 10-years could either be reduced somewhat or maintained but then with the possibility to reduce it if necessary to prevent abuses. This requires that companies share information on R&D costs with the authorities.
- A new article should be introduced in the Directive allowing Member States to waive data and market protection at any time if they trigger compulsory licensing.

On a general note, the EU must also support the development, availability and affordability of novel antibiotics and other medicines through public research funding that includes conditions on IP sharing.[31] Data and market protection should not be a barrier in these situations.

3.3.2 Refrain from introducing transferable exclusivity vouchers

In the context of the revision of the legislation, there have been some proposals to introduce 'transferable exclusivity vouchers' to incentivise the development of novel antibiotics. This means that companies obtaining marketing authorisation for such a product would get a voucher that could extend data exclusivity for another product.

We oppose this incentive as it would delay the entry of generics for other medicines and could increase substantially costs for public health systems.[32] Alternative solutions should be considered.

BEUC recommendation:

The revised legislation must not introduce the concept of transferable exclusivity vouchers.

3.3.3 Facilitate market entry of generics and biosimilars

To ensure timely consumer access to cheaper medicines, generics and biosimilars must be able to enter the market on day 1 after IP protection on the originator product expires.

[31] Horizon Europe and national research funding programmes should use a combination of push and pull mechanisms, such as innovation inducement prizes with access provisions.

[32] Ardal C., Lacotte Y. and Ploy MC. 'Financing pull mechanisms for antibiotic related innovation: opportunities for Europe', *Clinical Infectious Disease*, volume 71, 2020.

To get there, generic companies should be able to conduct the necessary studies for obtaining marketing authorisation early on, without this being considered an infringement of IP rights.

Whilst the EU allows this through the so-called 'Bolar exemption', Member Sates apply it in different ways, with some having adopted a more restrictive approach.[33] The revised pharmaceutical legislation should address this.

BEUC recommendations:

- Article 10(6) in Directive 2001/83 should be amended so it clearly requires that the exemption applies across the EU to finished medicinal products and APIs for activities related to R&D, marketing authorisation and those other that are necessary for effective day-1 market entry. The directive should also clarify that originator companies can benefit from this exemption so they can do studies that compare an investigational product with other on-patent medicines (in this case, the use of on-patent drugs for HTA related activities should also be covered).

- In addition, the directive should outline some criteria in relation to the application of the Bolar exemption to ensure more harmonisation (and use) across the EU.

END

[33] For example, some Member States have not allowed the supply of active pharmaceutical ingredients (APIs) to EU-based generic manufacturers for the purpose of seeking marketing authorisation. See European Commission, 'Commission Staff Working document: A Single Market Strategy for Europe - Analysis and Evidence', 2015.

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