BEUC The European Consumer Organisation

The Consumer Voice in Europe

RECOMMENDATIONS FOR IMPROVING ACCESS TO MEDICINES IN EUROPE

BEUC position on the European Commission's proposal for a revised pharmaceutical legislation

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Why it matters to consumers

Medicines are an essential component of healthcare, but they do not always reach the patient. High medicine prices and the increasing problem of shortages are major contributing factors. On top, there is little commercial interest from the pharmaceutical industry to find new treatments for certain diseases, and new medicines do not always represent a therapeutic advance.

The EU institutions must make the most of the ongoing revision of the pharmaceutical legislation and ensure it leads to better and more equitable access to medicines across Member States.

Summary

The European Union is undergoing the revision of its rules on the authorisation and placing on the market of pharmaceutical products. This is the largest reform of the legislation in over 20 years. The objective of the European Commission is to make the regulatory system more agile and 'future proof', boost innovation, address unmet medical needs, and improve the availability and affordability of medicines.[1]

BEUC welcomes this revision and supports the Commission's proposal to pay greater attention to the problem of medicine shortages and inequalities in patient access. Consumer surveys by BEUC member organisations show that shortages have become a common problem and can have detrimental effects for people's health. At the same time, skyrocketing medicines prices are hindering equitable patient access to medicines and the financial sustainability of health systems.

In this paper, we discuss measures proposed by the Commission on the availability and affordability of medicines and issue recommendations for improvement where necessary. We also make proposals to reinforce the EU marketing authorisation framework, and we address the question of innovation in the pharmaceutical sector. Regarding the latter, we call for ensuring a balanced framework of intellectual property-related incentives, for promoting the development of new antibiotics in a fair way, and for supporting the role of non-profits in the development of new medicines.

It is high time to lift barriers that consumers face when trying to access the medicines they need. The EU institutions must ensure that the EU pharmaceutical legislation contributes more effectively to that goal.

[1] European Commission, Press release: '[European Health Union: Commission proposes pharmaceutical reform for more accessible, affordable, and innovative medicines']', 26 April 2023.

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BEUC RECOMMENDATIONS

1. Medicines marketing authorisation and pharmacovigilance

1.1. *New* does not necessarily mean *better:* make comparative trials mandatory

The European Union has one of the most advanced frameworks in the world for the authorisation and safety monitoring of treatments and vaccines. Under this framework, the European Medicines Agency (EMA) and national regulators have approved many medicines that save lives, reduce pain, and improve health.

In practice, an important question for healthcare professionals and patients is whether new medicines are better than existing treatments. This is also relevant for Health Technology Assessment (HTA) and for decisions on a medicine's reimbursement by the national public health system. However, drug developers seeking market approval do not often conduct clinical trials that compare the benefits and risks of treatments.[2] This situation creates an evidentiary gap in downstream decision-making, raises concerns about inefficiencies in the development of medicines as well as ethical questions.

To foster the conduct of comparative trials, the European Commission proposes granting a 6-month extension of data protection over a new product if the marketing authorisation holder carries out such a study. Whilst it is positive that the legislative proposal includes measures on this front, it does not go far enough. We consider that it should not be up to pharmaceutical companies to decide whether they conduct or not well-designed comparative clinical trials, but up to regulators to require so.

Recommendation 1:

Introduce an obligation for marketing authorisation applicants to submit data from randomised controlled clinical trials that are representative of the population to treat, use clinically meaningful endpoints, and the best proven intervention as comparator. These studies should be requested especially for new products and new indications.

Mandate the EMA to develop guidelines on criteria for identifying the best proven intervention(s) and to outline the grounds for any justified exceptions to the study design mentioned in the first paragraph. Ensure that these guidelines are developed in consultation consumer and patient groups, healthcare professionals, HTA bodies, and payers.

If in the end, the revised legislation includes an incentive to promote the conduct of comparative trials, it must be ensured that the overall period of data and market protection that a company can obtain for a new product does not go beyond the current length of these incentives. In addition, the incentive should be linked to a requirement for the company to meet the evidentiary needs of HTA bodies.

[2] Based on data extracted from European Public Assessment Reports of new active substances with first time approvals by EMA in 2015-2018. In Naci H., et.al. Generating comparative evidence on new drugs and devices before approval. The Lancet, 2020; vol.395.

1.2. Maintain the renewal of marketing authorisations and the concept of 'medicines under additional monitoring'

At present, the marketing authorisation of a medicine approved through the standard (as opposed to early approval) procedure has an initial validity of 5 years, after which it is subject to a re-evaluation of the benefit-risk ratio. This is an important exercise, since new information on the safety, efficacy or use of the medicine might emerge during the post-marketing phase.

In addition, those medicines for which there is less information available on their safety profile or long-term use are more intensively monitored. To enhance reporting of suspected adverse drug reactions, the package leaflets of these medicines include a specific symbol with a note indicating that they are 'under additional monitoring'. The combination of these measures is an extra safeguard for consumers.

However, in an effort to simplify the regulatory system, the European Commission proposes abolishing the general requirement on marketing authorisation renewal. Instead, this would only apply to some products on a case-by-case basis.[3] In addition, the Commission removes the concept of 'medicines under additional monitoring'.[4]

Removing these measures will weaken the regulatory system at the expense of patients' safety.

Recommendation 2:

Maintain the current re-evaluation of the benefit-risk balance 5 years after medicines' approval, with the only possible exception of generics.

Keep in the legislation the concept of 'additional monitoring' and the notification in package leaflets. Add to the scope of additional monitoring medicines approved under a sandbox, temporary emergency marketing authorisations, and products that undergo a safety-related referral. In addition, mandate the EMA to consult with consumers and patients on best ways to communicate the concept of additional monitoring in package leaflets.

1.3. Strengthen the framework for conditional approvals

Medicines for serious diseases can be authorised by the EMA based on less comprehensive data than is usually required. Whilst early approval schemes can be justified in such situations, they must include safeguards to uphold patient safety.

The Commission's proposal to keep conditional marketing authorisations (CMA) for life-threatening and seriously debilitating diseases, as well as emergency situations, is welcome. Likewise, we support keeping in the revised legislation the following requirements for CMA approval:

1) the benefit of the immediate availability on the market of the medicine outweighs the risk inherent in the fact that additional data are still required.

[3] This is in addition to specific renewal requirements for medicines approved under 'exceptional circumstances' and 'conditional marketing authorisation'.

[4] Removing the concept of additional monitoring on the grounds that there is no strong evidence showing it had an effect on ADR reporting is not a valid argument. First, because regulators have not made improvements in relation to the symbol and explanatory sentence included in package leaflets. Second, because they have not raised enough awareness on the meaning 'additional monitoring' among the general population.

2) the benefit-risk balance is favourable, and the applicant is likely to be able to provide comprehensive data after initial approval.

However, it must be ensured that CMA goes hand in hand with stricter requirements on the fulfilment of specific obligations by the marketing authorisation holder. Moreover, the revised legislation must lead to better public communication on these approvals.

Recommendation 3:

Ensure that the time limit for compliance with post-marketing studies is always specified in the conditions to the marketing authorisation (Article 19 of the Regulation). In addition, require the Commission to impose financial penalties for unjustified situations of non-compliance with specific obligations, in particular regarding delays in the submission of study results.

Moreover, mandate that the EMA displays in a user-friendly database information on conditional approvals. In particular, information on the specific obligations to be fulfilled by the marketing authorisation holder, including timelines for study completion and any delays, as well as penalties and actions taken by the Agency and the Commission in relation to the conditional approval.

1.4. Enhance the transparency and independence of scientific advice procedures

Scientific advice from regulators to drug developers can help improve the design of clinical trials. However, to maximise the benefits of scientific advice and to strengthen public trust in the system, these procedures must be more transparent.

We welcome that the proposed Regulation provides that the European Public Assessment Report (EPAR) should include the key areas of scientific advice. However, we call on the co-legislators to better align the text with the European Ombudsman's view on how to enhance transparency and independence of EMA's pre-submission activities.[5]

[5] 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.

Recommendation 4:

Add in Article 58 of the Regulation that the EPAR must include a detailed log of pre-submission activities, including scientific advice. Make sure that information which marketing authorisation holders consider commercially confidential is published should there be an overriding public interest in disclosure.

Ensure that EMA publishes and updates regularly the list of products accepted for scientific advice with some basic information, along the lines done for medicines accepted under the Priority Medicines scheme (PRIME).

Require that, to the greatest extent possible, there is a separation between those experts responsible for providing scientific advice and those that are subsequently involved in the evaluation of the medicine. Pay special attention to the appointment of rapporteurs that assess a marketing authorisation and ensure that any exceptions to the general approach are documented in the EPAR.

The practice of scientific advice should go hand in hand with the swift update of scientific guidelines by regulators. It should be complemented by workshops that promote discussion on scientific developments between regulators, researchers, patients and consumers, healthcare professionals, and industry.

1.5. Introduce sandboxes only if they include robust safeguards

To promote innovation and ensure that the revised legislation is 'future-proof', the Commission proposes introducing regulatory sandboxes for testing innovative products and, where appropriate, for placing them on the market with specific conditions. Under the Commission's proposal, the marketing authorisation of a medicine developed under a sandbox could deviate from the general regulatory requirements.

Regulatory sandboxes could however lead to lower regulatory standards for drug approvals and compromise patient safety if they are mis-used or badly managed. If the revised legislation introduces sandboxes, they must be well-framed, uphold medical ethics and high standards of quality, safety, and efficacy. Sandboxes must be guided and closely monitored by regulators.

Recommendation 5:

Article 114 of the Regulation should specify that the marketing authorisation of a product developed under a sandbox cannot deviate from the requirements set out in the legislation in ways that could compromise patient safety or run contrary to ethical principles.

The legislation should add that medicines authorised under a sandbox shall be subject to 'additional safety monitoring'. The package leaflets of these medicines should explain the meaning of a sandbox in a way that is appropriate and easy to understand by non-professional users.

Member States and the European Parliament must be adequately involved in the adoption, implementation, monitoring, and assessment of a sandbox to ensure public trust and accountability.

2. Medicine package leaflets

2.1. Introduce electronic product information as a complementary tool only

The paper package leaflet is the easiest option and, for some consumer segments, the only option to read information on the appropriate use of medicine. Surveys from BEUC member organisations show that a large majority of consumers usually read the leaflet, either in-depth or focusing on some sections, when they take a medicine for the first time even if it was prescribed or recommended by a pharmacist.[6]

The surveys also show that on average, 79% of consumers think leaflets should be available inside the package even if there is an alternative QR code on it. Respondents felt this would otherwise disadvantage older people (81%) and would make society too dependent on the internet (70%).

The Commission's proposals to allow Member States to abolish paper package leaflets and replace them by electronic product information would pose a major risk to the safe use of medicines. Instead, we call for ensuring complementarity between the two tools, and for allowing exceptions only on specific cases and grounds. For example, when there are problems in respect of the availability of a medicine.

[6] Surveys conducted between June and July 2022 by Altroconsumo (Italy), DECO (Portugal), OCU (Spain) and Test Achats/Test Aankoop (Belgium) as part of the Euroconsumers group.

Recommendation 6:

Ensure that electronic product information (ePI) is introduced across the EU in ways that complement, but do not replace, paper package leaflets.

Allow only case-by-case exceptions to the obligation to provide a paper package leaflet in the national language(s), based on the grounds specified in Article 75 of the Directive.

Strengthen the provisions on the safe use of ePI in Article 63, by specifying that this tool should not be used for commercial purposes ''including advertising and marketing activities''. In addition, ensure that the Commission consults with the European Data Protection Board on ePI standards.

2.2. Ensure that package leaflets inform about medicine efficacy

Medicine package leaflets include information as important as the therapeutic indication, contraindications, potential adverse reactions, and conditions for the product's safe use. However, the current legislation does not mandate that leaflets include efficacy-related information. This prevents consumers from having a more complete picture on the effects of the product.

The revised legislation should ensure that leaflets inform as well about how the medicine can help patients, based on the data that regulators assessed.

Recommendation 7:

List in Annex VI of the Directive on the content of package leaflets efficacy-related information.

3. Availability of medicines across the EU

3.1. Push pharmaceutical companies to place their medicines across Member States

Some new medicines approved by the EMA do not reach patients in all countries, particularly small ones. Various factors contribute to this, one being that there are no measures at EU level to push marketing authorisation holders to enter markets across the EU.

To address this problem, the Commission proposes providing two years of additional data protection for a product if the company supplies the medicine in all those countries in which the marketing authorisation is valid. Whilst we share the Commission's aim of improving the availability of medicines, we are concerned about over-relying on IP incentives to achieve certain objectives.

For this reason, we propose introducing an obligation for pharmaceutical companies to file for pricing and reimbursement (P&R) in all countries within six months of the granting of marketing authorisation. Our proposal's scope is broader than the Commission's one which focuses only on 'new products': we suggest including for example new indications of old products. Another advantage of our proposal is that it could also be extended to biosimilar products. This is an important point for consideration, given that there is usually less competition for biologics than for other type of medicines.

Recommendation 8:

Marketing authorisation holders should be obliged to file for P&R within six months from the granting of marketing authorisation, unless a Member State extends the application period or grants a product-specific waiver.

This obligation should apply to new products and indications including when the medicine is a 'hybrid product'. The legislation should allow for the possibility to extend in the future the list of products for which the obligation applies.

In addition, Article 138 of the Regulation should require that the database on medicinal products approved in Europe, which is managed by the EMA, includes information on the countries in which each product is placed on the market.

Should the legislation link the availability of medicines to a modulated system of incentives comprised of a baseline and of additional years of protection if certain goals are met, it must be ensured that the maximum cumulative period of exclusivity for a specific product does not exceed the current length of such exclusivity (i.e., 10 years).

4. Medicine shortages

4.1. Adopt a comprehensive EU list of critical medicines

To enhance supply security, the EU adopted an 'EU list of critical medicines' and will evaluate potential vulnerabilities in the supply chain of these products. The Commission's legislative proposal mentions this list, thus providing a legal basis for it.

We very much agree on the need to identify medicines for which there should be greater emphasis on shortage prevention. To maximise the benefits of this initiative on public health, the list must be comprehensive enough. The legislation should uphold this principle, and ensure that consumer, patient, and healthcare professional groups will be adequately engaged in the procedures for defining any future versions of the list.

Recommendation 9:

Ensure that the definition of 'critical medicine' includes a reference to products that 'satisfy priority health care needs of the population' (Article 2 of the Regulation)

Require more explicitly that EMA consults with patients and consumers in relation to the procedure for adopting future versions of the 'Union list of critical medicines.'

4.2. Require pharmaceutical companies to share shortage prevention plans

Whilst the current EU pharmaceutical legislation calls on pharmaceutical companies to ensure continued supplies of medicines, it does not oblige them to develop shortage prevention plans. This is a major problem, as having these plans in place could enable that competent authorities can identify risks in supply chains and promote mitigation measures. For example, require that manufacturers diversify the number of suppliers of active pharmaceutical ingredients or improve their demand forecasts.

In the last years, some Member States have introduced requirements on prevention plans.[7] We support that the Commission's legislative proposal extends this obligation across the EU, for all medicines. To make the most of this initiative, marketing authorisation holders should be obliged to share prevention plans with the competent authorities for their review, especially for critical medicines.

Recommendation 10:

Strengthen the Commission's proposal by introducing an obligation for marketing authorisation holders to share with national regulators and the EMA the prevention plans of critical medicines within a specific timeframe. The legislation should also specify that national authorities can request at any time the prevention plans of non-critical medicinal products.

Add in Annex IV of the Regulation that the prevention plans must include information on how the company plans to do demand forecasting.

Ensure that competent authorities carry out a proper follow-up of the prevention plans. They should issue binding measures and other recommendations for reinforcing the supply chains of medicines.

4.3. Mandate contingency stocks

Pharmaceutical companies should have adequate safety stocks for their products to mitigate the potential impact of supply disruptions on health systems and consumers.[8]

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7 For example, France and Spain.

8 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. For more information see: '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'.

Although it is positive that the Commission foresees the possibility to impose contingency stock requirements through an implementing act, it would be better to include an obligation directly in the Regulation.

Recommendation 11:

Introduce in the Regulation an obligation for marketing authorisation holders to maintain contingency stocks of finished critical medicinal products. The stocks should be sufficient to meet at least a two-month demand in each Member State where the product has been placed on the market.

Specify that Member States should be able to adopt complementary measures on contingency stocks based on their own lists of medicines considered of major interest. Indicate that, where necessary, the Commission should establish criteria to ensure that any additional obligations on contingency stocks introduced at national level do not impact the availability of medicinal products in other Member States.

4.4. Introduce earlier notification requirements for all supply disruptions

It is important that pharmaceutical companies notify medicine shortages to the authorities sufficiently in advance, so they can plan alternatives and reduce the impact of the supply disruption on public health.

For this reason, we support the Commission's proposals in Article 116 of the Regulation. This section includes a requirement to notify a temporary supply disruption six months in advance, or if not possible and where justified, as soon as the company becomes aware. Likewise, we support that companies have to notify the withdrawal of a product 12 months in advance and, for critical medicines, offer to an interested third party the transfer of the marketing authorisation. However, the Commission's text needs some improvement:

Recommendation 12:

Delete the Commission's proposal in Article 116 of the Regulation to link the notification of a temporary supply disruption to an expected minimum duration of the shortage of two weeks.

Allow in Article 24 of the Regulation that a Member State can extend a company's obligation to either offer to transfer a marketing authorisation to a third party when the withdrawal concerns a non-critical medicinal product, or to facilitate the filing for marketing authorisation application for such product.

4.5. Require Member States to set up IT systems for shortage prevention and monitoring

To do a proper assessment of the risk of medicine shortages, national competent authorities need to have a good overview of available stocks of medicinal products and demand data. Member States should be mandated to establish IT systems for data collection and monitoring, and ensure they are interoperable with the European Shortages Monitoring Platform (ESPM).

Recommendation 13:

The Regulation should mandate Member States to set up IT systems for the collection of data on supply and demand of medicinal products, in ways that ensure interoperability with the ESMP.

4.6. Ensure adequate public communication on medicine shortages and enable consumer reporting

Timely communication to the public on medicine shortages is essential to facilitate that healthcare professionals, patients, and consumers can plan alternatives and minimise the impact of supply disruptions on people's health and quality of life. However, still today a few Member States[9] do not have online registers on medicine shortages, and when they do, these registers are not always user-friendly and/or critical information is not systematically reported.

Whilst it is good that the legislative proposal requires that all Member States publish information on medicine shortages, the text needs some improvement. For example, publication requirements should not only focus on 'actual' shortages but also on 'expected', to ensure that consumers and healthcare professionals are informed about these events with sufficient notice.

Recommendation 14:

Require in Article 121 of the Regulation that Member States publish information on 'expected' or actual shortages.

Mandate that competent authorities publish 'user-friendly databases' that contain the most relevant information to consumers. This includes details on the duration of the shortage and its reasons.

In addition to introducing these improvements, the legislation should ensure that patients and consumers can report medicine shortages to their authorities.

Recommendation 15:

Require that the competent authorities of the Member States enable patient and consumer reporting on shortages through the provision of alternative reporting formats in addition to web-based formats.

4.7. Introduce dissuassive penalties for non-compliance with obligations

To promote compliance by pharmaceutical companies with their legal obligations in relation to the supply of medicines, Member States must have a system of dissuasive penalties.

[9] European Medicines Agency, Public information on medicine shortages, website (accessed on 4 December 2023).

Currently, the level of penalties varies across countries, and sanctions are not always dissuasive enough and/or enforced systematically.[10]
The revised pharmaceutical legislation must stress the need for introducing a common approach on penalties across the EU in ways that that mirror current best practices (e.g., highest existing penalties).

Recommendation 14:

Require that Member States and the Commission establish dissuasive penalties to promote compliance by marketing authorisation holders with their obligations on shortage prevention and management (Chapter X of the Regulation). Add that the Commission shall lay down criteria for establishing such penalties and consider existing best practices.

4.8. Facilitate preparations of medicinal products by pharmacies

Pharmacies can help mitigate medicine shortages by preparing the products themselves if they have the active pharmaceutical ingredient. This can be done in accordance with a medical prescription for an individual patient, or with the pharmacopeia.

To facilitate that hospital pharmacies can in some instances produce medicines in larger volumes, the Commission proposes that they can compound in advance on the basis of estimated medical prescriptions for the following seven days. Whilst we welcome the proposal, the timeframe is too restrictive. In addition, the legislation should be more precise regarding the situations that would allow such practice and should extend it to community pharmacists.

Recommendation 15:

Ensure that hospital pharmacists can prepare medicines in advance according to estimated medical prescriptions for an unspecified period of time, when there is a medicine shortage and when a pharmaceutical company withdraws a product from the market for commercial reasons.

Enable that community pharmacies can also compound medicines on a routine basis in the situations described above.

5. Incentives and measures for promoting innovation

5.1. Modulate the incentive system in a balanced way

Today, the combination of patents, supplementary protection certificates and regulatory incentives allows pharmaceutical companies to benefit from long periods of exclusivity over their products, that block generic competition.

[10] France Assos Santé, 'France Assos Santé salue les propositions d'une mission de l'Assemblée nationale', 24 June 2021.

In its proposal, the Commission suggests moving from a 'one size fits all' incentive system towards a more balanced and targeted one. We welcome the plan to introduce different periods of data protection and market exclusivity according to different factors e.g., unmet medical needs, new products vs drug repurposing or well-established uses. A positive aspect of the Commission's approach is that it prevents that one product could accumulate several long periods of market exclusivity for each orphan indication.

However, the Commission's proposal on the modulation of incentives needs some fine-tuning.

Recommendation 15:

Add in the proposed definition of 'medicinal products addressing an unmet medical need' a reference to meaningful improvement of quality of life as this is an important outcome for patients. Avoid adopting a very broad definition on 'unmet medical needs' to ensure the proposed extension of data protection is a targeted and effective incentive.

Ensure that the modulation of data and market protection for products that create a new 'global marketing authorisation' does not go beyond the current period of 10 years (11 years with a new indication). Ideally, reduce the length of the protection period.

Regarding drug repurposing, we consider that it would be fairer if incentives are granted to compensate for costs incurred by the company in relation to clinical studies.[11] Following this rationale, granting five years of market exclusivity for well-established use orphan product applications based only on bibliographic data is exaggerated.

Recommendation 16:

Specify in Article 84 of the Directive that pharmaceutical companies can only benefit from data protection for repurposed products if they conduct adequate clinical studies.

Consider modulating incentives for drug repurposing for rare diseases, provided the incentive is used only once, for an old product, and its length is substantially lower than the period of exclusivity that orphan indications of established products benefit from today.

Reduce the five-year market exclusivity for well-established use applications for orphan medicinal products.

[11] Under the Commission's proposal, a company could receive 4 years of data protection in respect to a new therapeutic indication not previously authorised in the Union, provided that adequate non-clinical or clinical studies were carried out demonstrating significant clinical benefit (Article 84 of the proposed Directive).

5.2. Facilitate compulsory licensing

The current EU system of IP incentives does not include strong safeguards to prevent abuses and facilitate patients' access to affordable medicines. For example, the pharmaceutical legislation does not include the possibility to waive regulatory incentives if a competent authority grants a compulsory licensing (CL). This undermines the potential of this tool to safeguard public health.

For this reason, we agree with the proposal in Article 80 of the Directive to waive data and market protection if a competent authority in the Union grants a compulsory licensing. However, the scope of this proposal is too narrow as it only applies to 'public health emergencies' which in EU terms is mainly understood as a major cross-border health crisis.

Instead, we propose removing a reference to 'public health emergencies' to better align the pharmaceutical legislation with TRIPS flexibilities.[12] This would facilitate that Member States can use compulsory licensing if necessary to ensure affordable access to medicines outside a crisis of a cross-border dimension.

In addition, we consider that the legislation should allow waiving data and market protection for products that are not protected by a patent, if this is necessary to safeguard public health. This is because for these products, a CL cannot be issued as this tool is linked to patents.

Recommendation 17:

Delete in Article 80.4 of the Directive the reference to 'public health emergencies'. Add the possibility to waive market exclusivity to facilitate compulsory licensing for orphan products.

Include the possibility for competent authorities in the Union to reduce the duration of data and market protection, and market exclusivity, for medicinal products that are not protected by a patent or a supplementary protection certificate, where this is necessary to safeguard public health.

6. Medicine affordability and timely access to generics and biosimilars

6.1. Enhance transparency of public research funding

The public sector is a major supporter of health research and plays an important role in the development of medicines in various ways.[13] However, this is not reflected in medicines' prices, which are often very high for new therapies and can bring huge benefits to pharmaceutical companies. Focus groups commissioned by BEUC in three EU Member States show that consumers do not approve of excessive pharma profits, and even less when the public sector has contributed to drug development. [14]

[12] Under the TRIPS Agreement, there does not need to be an emergency for a compulsory licensing to be triggered. WTO stresses that the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting a CL, and to determine what constitutes a national emergency.

[13] BEUC, Report: 'Time to lift the blindfold: abolishing price secrecy to make medicines affordable', 2021.

[14] BEUC, Report: 'What consumers think of medicine prices today: Results from focus groups carried out in Italy, the Netherlands and Spain', 2022.

To contribute to medicine affordability, the European Commission proposes requiring marketing authorisation holders to disclose any direct public funding they received for developing a medicine. However, under the proposed legislation, companies would not be required to publish information on tax advantages for R&D, even if these incentives play an important role in supporting drug development.[15] [16]

To have a more comprehensive picture of the public sector's role in R&D, companies should also report about tax incentives and list any entity from which they obtained a license in relation to the product or acquired it at an early stage of the R&D product.

Recommendation 18:

Specify in Article 57 of the Directive that the marketing authorisation holder shall also declare to the public any indirect financial support they received i.e., tax incentives.

Require that the MAH identifies any independent legal entity from which it obtained a license or acquired the medicinal product in its previous phases of development. The holder of the marketing authorisation should, as much as possible, report about any public funding received by the independent entity for research activities in relation to the product.

6.2. Shed light on R&D costs from pharmaceutical companies

The incentives granted by the EU pharmaceutical legislation provide exclusivity periods over a product to marketing authorisation holders. This enables companies to charge prices that are much higher than when competition kicks in. To facilitate that during these periods of exclusivity national competent authorities can negotiate affordable prices, they should be able to enter these negotiations on equal footing with companies. However, there is an asymmetry of information on important factors for fair pricing such as R&D costs.

To improve medicine affordability, the pharmaceutical legislation should require that MAHs share with them upon request data on R&D costs. This information would also be useful to the Commission in the context of joint procurement and would prevent industry from publicising average R&D cost figures which are twice the amount of independent estimates.[17]

[15] SOMO and Wemos, Report: Overpriced, Drugs Developed with Dutch Public Funding, 2019.
[16] Test Achats/Test Aanskoop, Article: 'Médicaments. Vous les payes deux fois', TestSanté.
[17] BEUC, Report: 'Time to lift the blindfold: abolishing price secrecy to make medicines affordable', 2021.

Recommendation 19:

Introduce a new article in Chapter VII of the Directive obliging marketing authorisation holders (MAHs) that benefit from data and market protection to share upon request with P&R authorities and the Commission an electronic report with detailed and audited information on their R&D expenditure related to the medicinal product. Require MAHs to make a summary of the report publicly available.

Ensure that the same requirements are introduced in the Regulation, in relation to market exclusivity for orphan products.

In addition, request the Commission to adopt an implementing act laying down the methodology and format in which MAHs should report and publish the information on R&D costs.

6.3. Expand the bolar exemption to benefit generics and biosimilars

To ensure timely patient access to cheaper medicines, generics companies should be able to put their products on the market as soon as the IP rights of the originator product expire. However, today these companies face difficulties in starting and completing all the pre-marketing procedures on time.
To improve the situation, the Commission proposes expanding the so-called 'bolar exemption' so generics companies can, for example, 'generate data' for an application for P&R whilst the originator product is still protected by a patent. The Commission's proposal goes in the right direction but is not comprehensive enough. Generics companies should not only be able to 'generate data' but also take part in administrative processes.

Recommendation 20:

Expand the scope of Article 85 in the Directive to ensure that the conduct of studies for the following activities, and the participation in these processes, is not regarded as an infringement of patent rights or supplementary protection certificates: Marketing authorisation application, HTA, pricing and reimbursement, tenders.

7. Antimicrobial resistance

7.1. Support the development of priority antimicrobials in a fair way

The European Center on Disease Control estimates that more than 35,000 people die from antimicrobial-resistant infections every year in Europe.[18]

[18] European Centre for Disease Prevention and Control, Press release: '35 000 annual deaths from antimicrobial resistance in the EU/EEA', November 2022.

While we need new effective antibiotics, there is little commercial interest from Big Pharma in developing these products. The reason is that the use of these products should be limited to situations where common antibiotics do not work, to prevent excessive use and new resistances.

To promote the development of these essential medicines, the Commission proposes creating a scheme of 'transferable exclusivity vouchers' (TEV). Under this system, a company which has developed a priority antimicrobial would receive a voucher that allows it to extend data protection on another, more lucrative product, or to sell it to another company so it can do the same.

Transferable exclusivity vouchers raise a lot of concerns, as they would come at a huge cost to healthcare systems and delay access to cheaper generics in other disease areas.[19] Instead of pursuing this idea, the co-legislators should support the development and access to antibiotics through a scheme of research grants and milestone prizes, joint procurement, and payment models that de-link de-link volumes from profits. Put together, these measures could help biotech companies bring new antibiotics to the market, and safeguard drug affordability.

Recommendation 21:

Replace the Commission's proposal on TEV by a requirement to set up a scheme of push and pull incentives along the lines described in the 2023 Council Recommendations on AMR.

Ensure that HERA becomes an 'R&D coordinator' for priority antimicrobials, and secure sustainable funding including as necessary through 'play or pay fees'. That is, a fee charged to marketing authorisation applicants that conduct research activities but are not investing in the development of priority antimicrobials.

7.2. Strengthen the provisions on the prudent use of antimicrobials

The inappropriate and excessive use of antimicrobials accelerates the emergence and spread of resistance. This, combined with insufficient efforts to develop novel antimicrobials, represents a major public health threat.[20]

We welcome the focus on the appropriate use of antimicrobials in the Commission's legislative proposal. For example, the requirement for companies that apply for the approval of an antimicrobial to submit a stewardship plan with measures to mitigate AMR. We also support the Commission's proposal that these products come with an 'AMR awareness card' for patients.

[19] BEUC, Factsheet: 'Transferable exclusivity vouchers for medicines: disrupting markets, unfair to consumers', 2022.

[20] European Centre for Disease Prevention and Control, Technical Report: 'Proposals for EU guidelines on the prudent use of antimicrobials in humans', 2017.

However, we are concerned that Member States could decide making the awareness card available only electronically. We have additional concerns with the Commission's proposal that pharmaceutical companies provide 'educational materials' to healthcare professionals on the use of the antimicrobial including through 'sales representatives'. We propose improving the Commission's text as follows:

Recommendation 22:

Ensure that information materials for healthcare professionals are subject to prior vetting and are not distributed by 'sales representatives'. Specify that these materials and the stewardship plan must be published on the website of the competent authority.

Require that the awareness card for patients is made available in paper format, in addition to electronic format.

7.3.Prescription status of antimicrobials

Making antibiotics available on prescription-only helps avoid excessive and inappropriate use. In general, these medicines are only available to patients with a prescription and rightly so.

However, the Commission's proposal to make all types of antimicrobials available only on prescription, even those that treat mild to moderate ailments like cold sore, might be challenging to apply in some Member States. Specially, if there are shortages of healthcare professionals and long waiting lists as:

- patients may not get a prescription quickly enough for products which today are usually available over the counter.
- there is a risk of creating even longer waiting lists in primary healthcare. [21]

For this reason, we recommend that the legislation offers some flexibility so Member States can decide about the prescription status of certain antimicrobials according to risk of resistances and the specificities of the healthcare system.

Recommendation 23:

Ensure that all antibiotics are automatically subject to medical prescription, as well as all antimicrobials of systemic administration.

Specify that other antimicrobials (topical application) could be subject to prescription if the national competent authority of a Member State decides so. In that case, pharmaceutical companies should not be allowed to advertise these products to the general public.

[21] In countries like Spain, the primary care system is already strained. According to a survey conducted by the consumer organisation OCU, only 3 out of 10 appointments for primary care took place within the recommended timeframe of 48 hours. For more information, see 'Largas esperas en atención primaria' , 22 May 2023.

8. Allow for stricter requirements on pharmaceutical promotion

Rational use of medicines is essential to protect patient safety and the financial sustainability of healthcare systems. Yet, consumers are exposed on a daily basis to ads from the pharmaceutical industry on their products.

Advertising, which aims at maximising sales for the company, is allowed in the EU for over-the-counter medications. Exposing consumers to promotional materials risks contributing to the overuse and misuse of medicines.

To enhance the rational use of medicines, Member States should be able to ban anytime the advertising of over-the-counter medicines, regardless of whether they can be reimbursed e.g., if prescribed by a doctor.[22] We propose that such a ban could apply to a specific medicine or a group of products.

In addition, given the increasing use of social media in our society, the EU should adopt specific provisions on the advertising of medicines through these channels.

Recommendation 24:

Specify in Article 177 of the Directive that Member States shall be entitled to ban, anytime, advertising to the public of medicinal products that are available over the counter, regardless of whether their cost can be reimbursed.

Ensure that at national level there is a system of prior vetting of advertisements to the general public (Article 186).

Regarding social media, call on the Commission to adopt implementing acts with specific provisions on the advertising of medicines in those channels and on consumers' exposure to such type of content.

9. Support the role of non-profits in medicine development

With adequate support, the not-for-profit research sector (e.g., academic institutions) can play a key role in the development of new treatments, be it advanced therapeutic medicinal products or new indications of old products. In addition, these entities can help improve affordable access to medicines, given that the treatments they develop are cheaper than those commercialised by the industry.[23]

[22] The Commission's legislative proposal mantains the current provision in the EU Directive on medicinal products that allows Member States to ban the advertising to the general public of OTC medicines ''the cost of which may be reimbursed.'' An example of such a medicine could be ibuprofen.

[23] No es Sano, Report: 'Medicamentos para el cáncer: Altos precios y Desigualdad', 2018.

For these reasons, we support the Commission's proposal to facilitate the submission of clinical evidence by not-for-profit entities to the EMA or national authorities for a new therapeutic indication. We also support establishing a more harmonised scheme on hospital exemptions[24] with guarantees on quality, safety, and efficacy, and the provision of specific regulatory support by EMA to non-profits. The co-legislators should not weaken the proposed measures.

Recommendation 25:

Ensure that the future pharmaceutical legislation contributes to enhance the role of non-profits in the development of safe, effective, and affordable medicines.

Changes in the legislation should go hand in hand with adequate public funding for non-profits from the EU Framework Programme on Research and Innovation, and similar national schemes.

END

[24] See the recommendations from Salud por Derecho on how to strengthen even more the Commission's proposal on Hospital Exemptions: 'The hospital exemption: Increasing access to innovation and local production', 2023.

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