EPF ADVOCACY TOOLKIT

on the revision of EU pharmaceutical legislation

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EPF European Patients Forum

A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE

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Summary of EPF position on the revision of the EU pharmaceutical legislation

Following the publication of the Commission's proposals for a new Directive and a new Regulation, which revise and replace the existing general pharmaceutical legislation, the European Patients' Forum (EPF) published its recommendations to make the EU regulatory framework for the authorisation of medicines **more patient-centred**, aiming for fair access to medicines.

Although the Commission's proposals contain some positive steps forward, more can be done to ensure that the legislation meets the needs of those who will use the approved medicines: the patients.

Below is a summary of the changes we are proposing to promote patient involvement in the regulatory process, improving access to safe, effective, and high-quality medicines, and developing new medicines that better address unmet medical needs.

Firstly, the legislative overhaul must lead to the **development of medicines that target patients' needs**. In this context, EPF is calling for a common EU-wide definition of **"added therapeutic value",** developed in partnership with patients. This is a concept that is currently insufficiently defined throughout the lifecycle of new medicines. Without systematic patient involvement, it is impossible to assess the "real" value and obtain a comprehensive, fully accurate picture of the benefit-risk balance of new products. This is why patient-relevant outcomes should be included in the marketing authorisation dossier to oblige pharmaceutical companies to genuinely involve patients from the very start of development and in the design of research. Similarly, the **definition of "unmet medical need"** included in the proposal fails to foster patient-centred innovation and ignores factors that are important to patients, such as impacts on quality of life. As discussed in our call on unmet medical needs, defining what constitutes an unmet medical need can only be done with meaningful patient involvement, including patient participation in decision-making, as well as consultation with patient representatives in each specific disease area.

Secondly, the review should also **create a fairer system of access to medicines.** There needs to be a **fair balance** between incentivising R&D of products that provide a real added value and ensuring access to new therapies. As the current system has shown its limitations, we support **modulated incentives** that encourage faster launch of new medicines across all EU member states, while supporting faster access to generics and biosimilars. The total duration of incentives in the Commission's proposal, if all the conditions are met, is similar to, or may be greater than, current levels, while encouraging earlier patient access. Member States must also play their role in ensuring the availability and access to medicines. In particular, they should respect the deadlines set out in the Transparency Directive for pricing and reimbursement decisions, which are 180 days for joint pricing and reimbursement procedures.

In the area of **antimicrobial resistance**, we are concerned about the effectiveness and costs for healthcare systems of the transferable exclusivity vouchers proposed by the Commission, as well as its impact on access to medicines for patients in other therapeutic areas. The regulatory framework should create the conditions for faster approval of new antimicrobials and promote incentives that de-link sales revenues from sales volumes.

While EPF supports the focus on **shortages** in the revision, we regret the lack of patient involvement in the management of shortages. Patients should be able to report shortages at the

national level. They should also be involved in identifying shortages and critical medicines that will feature on the two lists coordinating EU action in that area. In line with our call to action on shortages, their involvement in the development of policy solutions is key, not only to improve data collection and understanding of the societal impact of shortages, but also to ensure that policy responses meet patients' needs.

Thirdly, the revision of pharmaceutical legislation must lead to **a patient-centred regulatory process**. While we welcome the inclusion of patients in the Committee for Human Medicinal Products (CHMP), we call for the involvement of patients in the scientific working groups that will be set up by the CHMP. We also need to ensure that the expertise of the scientific committees that are set to disappear under the new proposal will be preserved. As highlighted in our call for a continued focus on paediatrics, we are concerned about the disappearance of the Paediatric Committee (PDCO). Without a dedicated committee, it is unclear how patients' and member states' expertise will be maintained and whether EMA will have the leverage and resources to push for specific studies in the most underserved populations, such as neonates.

In terms of adapting to scientific progress, there is a need for a **flexible and adaptable regulatory framework** that supports innovation and remains fit for purpose, but any new regulatory approaches to emerging technologies must be guided by the principle of patient safety. The collection of real-world data (RWD) and the generation of real-world evidence (RWE) can play a critical role in adaptative pathways in enabling regulators to deepen their understanding of the benefit-risk balance of a medicine and assess its value to patients and healthcare systems. To realise the full potential of RWD/RWE, patients should be fully involved in future initiatives to provide guidance on, for example, the sources of RWD, the data elements they should include and data quality standards.

Finally, the revision should move towards more **objective, reliable, relevant and user-friendly information.** All patients have a fundamental and legitimate human right of access to information about their health, medical conditions, and the availability of treatments. In this sense, the legislation should not create new inequalities between patients. Paper leaflets should remain available, alongside electronic formats, for all patients who do not have access to the Internet or have limited digital literacy. In addition, patients must be involved in the drafting of all materials intended for them, such as the AMR Awareness Card, to ensure that they meet their needs.

EPF's analysis of the European Parliament reports on the revision of the EU pharmaceutical legislation

June 2024

On 10 April 2024, the European Parliament adopted the reports on the Directive and the Regulation, thus formalising the **Parliament's official position on the revision of the EU pharmaceutical legislation**. The reports of the European Parliament amend the proposals for a Directive and a Regulation of the European Commission published in April 2023.

Below is a summary of the main changes proposed by the Parliament that are relevant to the patient community[1].

Key points:

- Inclusion of **patient representatives in the ad hoc working groups** set up by the Committee for Medicinal Products for Human Use.
- Inclusion of a **patient organisation representative in the Coordination Group for Decentralised and Mutual Recognition Procedures.**
- **Reimbursement of patients' expenses** incurred in performing their duties as members or alternates of EMA's scientific committees.
- Consultation of patients in drawing up the Union's **list of critical shortages and critical medicines**.
- Establishment of a system for **patients to report shortages at national level**.
- **Consultation of patients** if a Member State decides to implement electronic patient information leaflets only.
- Inclusion of a **key information section** in the package leaflet reflecting the results of consultations with patient organisations.
- Allowing patient organisations to **submit data for new indications for any medicine**, beyond those addressing unmet medical needs.

The functioning of the European Medicines Agency

The European Parliament's reports maintain the **Commission's proposal to switch from a committee-based** to an expert-based structure for the European Medicines Agency (EMA), but significantly **strengthen patient involvement**.

Under the new EMA structure, which retains only two scientific committees, the Commission envisaged that the Committee for Medicinal Products for Human Use (CHMP) would set up ad hoc working groups without specifying their topics. The Parliament establishes **ad hoc working groups on paediatric, orphan**, and **advanced therapy medicines**.

In addition to increasing patient representation in the Pharmacovigilance Risk Assessment Committee (PRAC) and introducing patient representatives in the CHMP, as planned by the Commission, the Parliament specifies that **patients should also be represented in the CHMP ad hoc working groups**.

[1] The incentives for developing medicines targeting rare diseases are not covered in this report.

Representatives of patient organisations serving as members or alternates of scientific committees will also be entitled to reimbursement of expenses incurred in the performance of their duties.

Finally, the Parliament agreed on the inclusion of a representative of patient organisations in the **Coordination Group for Decentralised and Mutual Recognition Procedures**, where patients are not represented currently.

Incentives for the development and access of medicines

The European Parliament **revises the Commission's modulated incentive model** and **proposes another mechanism to improve access to medicines across the EU**.

The Commission proposal reduces the regulatory data protection period of new medicines to 8 years (6 years of data protection[2] and 2 years of market exclusivity[3]), with a possible extension to 12 years under specific conditions such as launch in all EU member states, comparative clinical trial data or targeting unmet medical needs. In contrast, the Parliament's proposal sets a baseline of 7.5 years for regulatory data protection, extendable by 1 year for addressing unmet medical needs, 6 months for comparative clinical trials, and an additional 6 months for significant EU-based research and development with public involvement. This could potentially bring total regulatory data protection to 8.5 years, plus 2 years of market exclusivity, which can be extended by a further year for new therapeutic indications. This means that the total protection period could reach up to 11.5 years, compared to the current 11 years.

The Parliament **keeps the Commission's definition of "unmet medical need[4]"**, linked to mortality and morbidity, but clarifies in a recital that morbidity includes the patient's quality of life, disease and treatment burden, inability to perform daily activities, and relevant patient experience data in the assessment. Patients should also be consulted in developing scientific guidelines on unmet medical needs.

Of note, the Parliament **rejected the Commission's proposal** to make 2 years of regulatory data protection conditional on companies launching new products in all Member States. Instead, Member States will have 1 year to request the launch of the product in their national market, which will oblige **companies to apply for pricing and reimbursement** within 1 year (or 2 years for small and medium-sized companies). If Member States and companies comply with the Parliament's deadlines and the Transparency Directive, medicines could be on the market across all requesting EU countries in less than 2.5 years.

Finally, the Parliament calls on the Commission and Member States to **develop indicators to measure access to medicines in the EU**. It proposes the creation of a dedicated public website to provide transparent information on access indicators and availability of medicines across the EU.

[2] Period during which generic or biosimilar applicants are not allowed to rely on originator data to obtain approval for their products through an "abridged" application.

[3] Period during which a generic or biosimilar cannot be placed on the market. However, a generic or biosimilar manufacturer may rely on the full data set to prepare its own marketing authorisation dossier.

[4] A medicine is considered to meet an unmet medical need if it treats a life-threatening or seriously debilitating condition and addresses the following conditions: (a) there is no approved medicine for the condition, or there is an approved medicine, but it is associated with high mortality and morbidity; (b) the medicine reduces morbidity or mortality in the relevant patient population.

Measures to tackle antimicrobial resistance

The Parliament introduces **milestone payment** and **market entry reward schemes** for 'priority' antimicrobials[5]. These schemes provide early-stage financial support for the achievement of specific research & development milestones before market authorisation. They are complemented by a voluntary **joint procurement scheme** based on a subscription model to encourage investment in antimicrobial development.

For companies not eligible for milestone payments, the Parliament maintains the **Transferable Exclusivity Vouchers** (TEVs) granted to companies developing a new antimicrobial, but adds more requirements. The voucher's regulatory data protection reward will now depend on the type of antimicrobial: 12 months for 'critical' antimicrobials, 9 months for 'high' priority antimicrobials and 6 months for 'medium' priority antimicrobials, as defined by the European Commission in subsequent implementing legislation. It remains transferrable once, which means that a company can sell the voucher to another company. That company will be able to use it on any product that has not already benefited from the maximum regulatory data protection period, within its first 4 years of regulatory data protection.

To promote the prudent use of antimicrobials, MEPs call for more stringent measures such as limiting prescriptions and dispensations to necessary treatment quantities and limiting prescription duration.

Medicine shortages

Beyond the measures proposed by the Commission, including earlier notification of shortages and withdrawals, a requirement for manufacturers' shortage prevention plans for all medicines, and stronger EU coordination mechanisms, the Parliament introduces additional provisions to tackle shortages. These include the institutionalisation of a **Voluntary Solidarity Mechanism**, which allows Member States to redistribute medicines to other Member States experiencing shortages. The Parliament also calls for Commission guidance to support **public procurement practices** that include criteria other than price.

Importantly, the Parliament significantly **enhances patient involvement in the management of shortages**. At the EU level, the EMA's Patients and Consumers Working Party (PCWP) would be consulted on future EMA guidelines on shortage prevention plans and on the Union's lists of critical shortages and critical medicines. At national level, patient organisations must be consulted on the identification of critical medicines within Member States. National authorities are also required to set up **a system for patients to report shortages**.

Changes to shortage information have also been introduced. All relevant information, including available alternatives, must be **actively communicated to healthcare professionals and patients** by the competent national authorities in a publicly accessible and user-friendly manner. In addition to national databases, the EMA should include information from other pertinent sources and databases wherever possible.

[5] An antimicrobial is considered a 'priority antimicrobial' if it helps fight antimicrobial resistance and has one of the following characteristics: (a) it is a new type of antimicrobial; (b) it works differently to other authorised antimicrobials; (c) it contains an active substance not previously authorised that addresses a multi-drug resistant organism and serious or life-threatening infection.

Information to patients

The Parliament's proposal **eliminates the option to provide package leaflets only in electronic form**. It is now up to Member States to decide whether package leaflets should be available only in paper form, only in electronic form, or in both forms for certain products, categories or all products. If a Member State chooses electronic-only availability, it must first consult patients, carers and relevant stakeholders. In the absence of specific national requirements, package leaflets should be available in both electronic and paper formats.

Patients retain the **right to request a paper copy** if the leaflet is only available electronically, and the Parliament specifies that patients should be informed of this right. In addition, companies may choose to provide a paper version on a voluntary basis. Whether electronic or paper, **a key information section** should be included, reflecting the results of consultations with patient organisations, to ensure that the leaflet is legible, clear, and easy to use.

Of note, medicines that are dispensed and administered by a qualified healthcare professional, rather than for self-administration, may have electronic-only leaflets.

Finally, the **antimicrobial resistance (AMR) awareness card** may be made available in paper format or both paper and electronic formats.

Updates to the marketing authorisation processes

The Parliament introduces a new provision for granting marketing authorisation on the basis of **a platform technology master file**. This means that once the relevant information has been reviewed and approved by a competent authority, it can be referenced in future submissions without having to be resubmitted. The details of the information to be included in this file will be determined by the EMA.

In addition, the Parliament **extends transparency requirements** beyond the Commission's proposal. It requires disclosure of all direct funding from public authorities or publicly funded bodies for the development of a new product, including philanthropic or non-profit organisations worldwide, as well as indirect financial support from EU public authorities or publicly funded bodies. Companies must also disclose any licensing agreements or acquisitions related to the medicine in earlier stages of development, specifying the stage of research and development.

In addition, **environmental risk assessments** for medicines will now assess the entire life cycle of the medicine, including manufacturing processes, and this information must be made publicly available.

Regulatory procedures and additional support for medicine development

The Parliament imposes stricter measures for non-compliance with conditional marketing authorisations' (CMA) requirements, including mandatory post-authorisation studies and the creation of a CMA database by the EMA. In addition, companies must now justify withdrawals or suspensions of marketing of medicines for commercial reasons.

The Parliament also includes several measures to promote patient safety. The Eudravigilance database, the system for managing and analysing information on suspected adverse reactions to medicines authorised or undergoing clinical trials, will now include data on medication errors. Member States should also develop and implement plans for the safe administration and handling of medicines, which may include the use of digital medication safety systems in hospitals and outpatient care settings.

In addition, the possibility for not-for-profit organisations, including patient organisations, to **submit data for a new indication** of an approved product is extended to all medicinal products, beyond those that

address an unmet medical need. Based on these data, including any additional evidence submitted by the marketing authorisation holder of the product in question, the EMA may assess the risk-benefit balance of the new therapeutic indication.

Compassionate use, which allows the use of unauthorised medicines outside a clinical study, now covers patients with treatment-resistant diseases, diseases causing psychological distress or in palliative care. **The Parliament also expands the proposed scope of PRIME**, an EMA scheme that supports the development of promising medicines targeting an unmet medical need. Medicines that address an unmet medical need, have orphan status ***or*** are of major public health importance will be eligible for PRIME.

Finally, the Parliament maintains but tightens the Commission's proposal for **regulatory sandboxes.** When faced with new innovative products that do not "fit" into the "traditional" regulatory framework, the Commission can set up an environment with the EMA, developers and other relevant stakeholders to test adapted, derogatory or deferred requirements for a product or category of products that offer major benefits to patients and cannot be developed in full compliance with the current rules (e.g. software-dependent implants). Sandboxes will only be possible on a case-by-case basis and must lead to an adapted regulatory framework when completed. The EMA will consult patients where appropriate.

Next steps

The dossier is now in the hands of the Council of the European Union, which started negotiations on provisions related to shortages and incentives under the Belgian Presidency (January-June 2024). Negotiations are expected to continue for several months to come. Once the Council has adopted its negotiating position, the trilogue will begin, involving inter-institutional negotiations between representatives of the European Parliament, the Council, and the European Commission.

Throughout this process, EPF will continue advocating for a revision that meets patients' needs and puts patients at the heart of the regulatory system for medicines in the EU.

Key messages on the revision of the EU pharmaceutical legislation

1

Medicines are an essential aspect of treatment for many patients living with chronic diseases, but they are only useful if patients who need them **have access to them.** EPF defines access according to five principles: availability, affordability, adequacy, appropriateness, and accessibility.

2

The revision should foster the development of medicines that meet patients' needs, as defined by patients:

- **Only patients know what added value means for them and their condition.** A common EU-wide definition of "added therapeutic value", developed in partnership with patients, is needed.

- **The legislative overhaul must stimulate research and development of medicines in areas of unmet medical need (UMN)**. A definition of UMN should be inclusive and include important life-changing indicators from a patient perspective, such as the appropriateness of existing treatments or impacts on quality of life. Patients must be involved in the development of a definition.

3

The revision should improve patient access to medicines and create a fairer system of access across Member States:

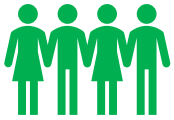
- The legislation must strike the **right balance between incentivising R&D of new products with real added value and ensuring access to new therapies for all patients across the EU**. Greater conditionality of incentives or sanctions can help address some of the inequalities in access to medicines across the EU but must be accompanied by obligations for Member States to comply with EU rules for the transparency and timeliness of pricing and reimbursement decisions.

- The regulatory framework should create the conditions for faster approval of new antimicrobials as well as promote **proportionate incentives that de-link sales revenues from sales volumes** and do not negatively affect patients' access to other medicines.
- The revision must allow **proportionate regulatory flexibilities** to adapt to scientific progress and speed up access to life-saving products **without compromising patient safety.**
- The **involvement of patients and their representatives in the management of shortages** is essential, not only to improve data collection and understanding of the societal impact of shortages, but also to ensure that policy responses meet patients' needs.

4

The legislative overhaul should lead to greater involvement of patients in the regulatory process, which will result in better regulatory outcomes:

- **Patient involvement should be streamlined** at all stages of the regulatory process. In particular, the revision should include a definition of "patient organisations" and patients should be represented on the scientific working groups to be set up by the Committee for Medicinal Products for Human Use (CHMP).



- Greater involvement of patients in the regulatory process should go hand in hand with **reasonable compensation from the EU budget** for the time and effort spent.

- **The expertise of the scientific committees that are set to disappear under the new proposal needs to be preserved**. Without a dedicated committee on paediatric medicines, it is unclear how patients' and member states' expertise will be maintained and whether EMA will have the leverage and resources to push for specific studies in the most underserved populations, such as neonates.

The revision should move towards more objective, reliable, relevant and user-friendly information on medicines:

- **Paper leaflets should remain available**, alongside electronic formats, as not all patients have access to the Internet or are digitally literate.

- **Information on medicines should be better tailored to the needs of patients** and include a key information section in the package leaflet, information on how to dispose of the product and, where possible, its environmental footprint to support choice of less polluting alternatives.

- The **involvement of patients in the drafting of materials intended for them** is crucial to ensure that these meet their needs.

"HOW TO" GUIDE!

Outreach strategy

Our messages on the revision of EU pharmaceutical legislation can be disseminated through various channels. Here are four impactful strategies to amplify the patient's voice.

Contact your focal point/contact at the Ministry of Health

Reaching out to the Ministry of Health has an impact on discussions at the EU level, influencing the stance taken by your government's representatives at the Council of the EU. The Ministry of Health plays a pivotal role in formulating and conveying the national position to the Member State's Permanent Representation. National ambassadors and health attachés from the Permanent Representations then defend their country's position on the revision at the Council of the EU.

Contact the MEPs in your country working on health issues

Engaging with Members of the European Parliament (MEPs) from your country who focus on health issues influences the ongoing negotiations on the revision of EU pharmaceutical legislation. Even those who are not specifically assigned to the revision can still influence it, especially in their political group debates, where specific issues often come to the forefront.

Create a coalition with like-minded organisations

Other patient organisations, healthcare professional organisations, or healthcare NGOs may share the same concerns about the revision of the EU pharmaceutical legislation. By identifying issues of common interest and joining forces, whether through joint statements or joint meetings, you will amplify your voice and have a better chance of getting your messages heard.

Spread the word on (social) media

Social media plays a big role in the way we disseminate our messages. Platforms like Facebook, Twitter, LinkedIn and Instagram are used to amplify our messages, reach diverse audiences and create a community. You can use our infographics and social media posts to raise awareness of key messages and gather support. Op-eds or articles in relevant news outlets can also help reach your targeted audience.

Organise a policy event

Policy events, such as roundtables or panel discussions, bring together stakeholders including policymakers, healthcare professionals, researchers and other patient organisations. These events provide a forum to share evidence-based arguments and real-life stories and to educate policymakers about the specific needs of the patient community.

List of MEPs active in the field of health*

MEP name	Relevant parliamentary committees	Political Group	Country
Ignazio Roberto MARINO	SANT Full Member	**Greens/EFA**	Italy
Tilly METZ	SANT Full Member	**Greens/EFA**	Luxembourg
Marie TOUSSAINT	SANT Substitute	**Greens/EFA**	France
Majdouline SBAI	SANT Substitute	**Greens/EFA**	France
Jutta PAULUS	ENVI Full Member	**Greens/EFA**	Germany
Stine BOSSE	SANT Full Member	**Renew Europe**	Denmark
Olivier CHASTEL	SANT Full Member	**Renew Europe**	Belgium
Vlad VASILE-VOICULESCU	SANT Full Member	**Renew Europe**	Romania
Andreas GLÜCK	SANT Substitute	**Renew Europe**	Germany
Billy KELLEHER	SANT Substitute	**Renew Europe**	Ireland
Irena JOVEVA	SANT Substitute	**Renew Europe**	Slovenia
Vytenis Povilas ANDRIUKAITIS	SANT Full Member	**S&D**	Lithuania
Christophe CLERGEAU	SANT Full Member	**S&D**	France
Nicolás GONZÁLEZ CASARES	SANT Full Member	**S&D**	Spain
Romana JERKOVIĆ	SANT Full Member	**S&D**	Croatia
Victor NEGRESCU	SANT Full Member	**S&D**	Romania
Tiemo WÖLKEN	SANT Full Member	**S&D**	Germany
Estelle CEULEMANS	SANT Substitute	**S&D**	Belgium
Pierre JOUVET	SANT Substitute	**S&D**	France
Alessandra MORETTI	SANT Substitute	**S&D**	Italy
Leire PAJÍN	SANT Substitute	**S&D**	Spain
Marta TEMIDO	SANT Substitute	**S&D**	Portugal
Raffaele TOPO	SANT Substitute	**S&D**	Italy
Romana JERKOVIĆ	SANT Full Member	**S&D**	Croatia
Radan KANEV	SANT Substitute	**EPP**	Bulgaria

MEP Name	Relevant parliamentary committees	Political Group	Country
Laurent CASTILLO	SANT Full Member	**EPP**	France
Peter LIESE	SANT Full Member	**EPP**	Germany
Oliver SCHENK	SANT Full Member	**EPP**	Germany
András Tivadar KULJA	SANT Full Member	**EPP**	Hungary
Bartosz ARŁUKOWICZ	SANT Full Member	**EPP**	Poland
Adam JARUBAS	SANT Full Member	**EPP**	Poland
Dolors MONTSERRAT	SANT Full Member	**EPP**	Spain
Jessica POLFJÄRD	SANT Full Member	**EPP**	Sweden
Tomislav SOKOL	SANT Substitute	**EPP**	Croatia
Luděk NIEDERMAYER	SANT Substitute	**EPP**	Czechia
Manuela RIPA	SANT Substitute	**EPP**	Germany
Letizia MORATTI	SANT Substitute	**EPP**	Italy
Ingeborg TER LAAK	SANT Substitute	**EPP**	Netherlands
Ewa KOPACZ	SANT Substitute	**EPP**	Poland
Elena NEVADO DEL CAMPO	SANT Substitute	**EPP**	Spain
Valentina PALMISANO	SANT Substitute	**The Left**	Italy
Giorgos GEORGIOU	SANT Substitute	**The Left**	Cyprus
Anja HAZEKAMP	SANT Full Member	**The Left**	Netherlands
Catarina MARTINS	SANT Full Member	**The Left**	Portugal
Monika BEŇOVÁ	SANT Full Member	**Non-attached Members**	Slovakia
Kateřina KONEČNÁ	SANT Substitute	**Non-attached members**	Czechia

*This data is publicly available on the European Parliament's website.

[DATE]

[ADDRESS OF YOUR ORGANISATION]

TO:

[NAME OF THE MEP or MINISTRY OF HEALTH OFFICIAL]

Subject: the revision of the EU pharmaceutical legislation should meet the needs of patients

Dear [NAME of the MEP or REPRESENTATIVE OF THE MINISTRY OF HEALTH]

On behalf of [NAME OF YOUR ORGANISATION] and its member organisations representing patients [CONDITION/COUNTRY], I am writing to you to request your support for a patient-centred revision of the EU pharmaceutical legislation.

The revision of the EU pharmaceutical legislation will have a great impact on patients' health outcomes and daily lives, as medicines are often an essential part of their treatment. It is of utmost importance to ensure that the new rules meet the needs of those who will use the approved medicines: the patients. In this context, there are three priorities we would like to highlight:

- We call for **patients' involvement throughout the lifecycle of medicines**, from clinical research to post-market surveillance and reporting of shortages. In particular, patient representatives, remunerated through the EU budget, should be involved across EMA scientific working groups as well as in the development of key definitions that will drive patients' access to new medicines, such as unmet medical need. The new legislation should retain dedicated scientific working groups where needed (e.g. paediatric medicines) and encourage the inclusion of patient experience data in the marketing authorisation of new medicines.
- We see this review as a unique opportunity **to improve patients' access to the medicines they need across the EU**. Unacceptable inequalities persist, as new medicines become available with significant delay in some member states compared to others. While many issues can only be resolved at national level, the EU pharmaceutical legislation should include specific measures to promote faster availability of medicines for all patients, through increased conditionality of incentives and strict obligations.
- We support **adaptive pathways because they allow faster access to potentially life-saving medicines and treatments**, especially in areas where there are no or very suboptimal alternatives. In particular, regulatory sandboxes are needed to provide the European Medicines Agency (EMA) with the right tools and flexibility to ensure that new and emerging products are safe and effective for patients, while guaranteeing patient safety and close monitoring by the EMA.

Please find attached our position paper which provides more details on these points and on our priorities for this review. We would be happy to discuss it with you during an online or in-person meeting. Please do not hesitate to provide some suggested availabilities in the coming weeks if such a meeting could be scheduled.

Please do not hesitate to let us know if you have any questions.

Sincerely,

[NAME]

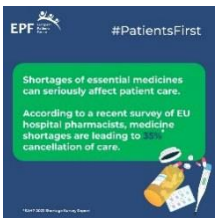
Social media content for Twitter/X and LinkedIn

1. Click on this link to access the infographics and visuals

The file contains:

- 2 infographics on shortages and access to medicines.
- 3 visuals on the issues of antimicrobial resistance, unmet medical needs and shortages.

2. Use them on your social media to spread the word about the patient community's priorities for the review



You can tag us @European Patients' Forum on LinkedIn and @eupatientsforum on Twitter.