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# Open Public Consultation on the revision of EU rules on medicines for children and rare diseases

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## Introduction

The EU rules on medicines for rare diseases and medicines for children were adopted in 2000 and 2006, respectively. The rules were designed to improve the treatment options available to 30 million European patients affected by one of over 6000 rare diseases, as well as for 100 million European children affected by paediatric diseases. At the time, there were limited or no medicinal products available for treatment of both groups.

A recent evaluation of the rules showed that they have stimulated research and development of medicines to treat rare diseases and other conditions affecting children. However, the evaluation also revealed shortcomings in the current system. The rules have not been effective for stimulating the development of medicines in areas of unmet needs (e.g. 95% of rare diseases still have no treatment option), and they have not ensured that the medicines are accessible to all European patients across all Member States.

The rules provide incentives and rewards, and their design can influence business decisions on research and development for new medicines, as well as whether such investment can be focused in areas of the greatest need for patients. In addition, the system of incentives can impact market competition and indirectly influence the availability of and access to those medicines by EU patients.

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* Organisation name

*255 character(s) maximum*

European Federation of Allergy and Airways Diseases Patients' Associations (EFA)

* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

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## Questionnaire on the revision of EU rules for medicines for rare diseases and children

**Q1: The main problems identified in the evaluation of the legislation for medicines for rare diseases and for children were the following:**

- **Insufficient development in areas of the greatest needs for patients.**
- **Unequal availability, delayed access, and often unaffordable treatments for patients in the EU Member States.**
- **Inadequate measures to adopt scientific and technological developments in the areas of paediatric and rare diseases.**

**In your opinion, are there any other barriers to the development of treatments for rare diseases and children?**

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Lack of understanding of the underlying mechanisms in the development of diseases, particularly their development from early life impact: allergy and respiratory diseases, who rank as the most prevalent childhood diseases, are not single conditions, but rather a wide spectrum of systemic chronic inflammations affecting the lungs, the airways, the digestive system, and the skin. They encompass hundreds of disease subtypes i.e. numerous rare allergies such as to fruit such as grape, to insects such as mosquito, to foods such as rice, to human sperm, to almost every known drug or vaccine: hundreds of specific hypersensitivities for which the only current management is ‘avoidance’, or taking the risk.

Sub-type diagnosis for allergic and respiratory diseases is limited and leaves many allergic and respiratory disease patients underserved of management. Early and accurate biomarker-based diagnosis, that looks at disease subtypes, is paramount to demonstrate prevalence, conduct interventions (both preventive and therapeutic) and find solutions. Having accurate information about the needs is the baseline for the development of efficient and safe medicines.

Delay and lack of adaption from adult drugs to children and limited access to clinical trials: EU legislation should allow for a wider spectrum of studies to be used in the registration of medications for rare diseases. For example, double blinded, controlled, clinical trials can be challenging and inadequate for rare allergies; pragmatic trials, observational studies and registries can support more efficient access and increased patient enrollment.

Life-cycle of medicines could be improved to prioritise innovation: the medicine post-authorization process should improve drug development enabling more research studies, real-world evidence emanating from patients, and registries informing pharmacovigilance and effectiveness.

**Q2: In your opinion, and based on your experience, what has been the additional impact of COVID-19 on the main problems identified through the evaluation? Is there a 'lesson to be learned' from the pandemic that the EU could apply in relation to medicines for rare diseases and children?**

*2000 character(s) maximum*

The main ‘lesson’ from COVID is that epidemiology and clinical presentation of a respiratory infection can be radically different between ages, confirming that particular focus needs to be given to children, stratified to different age groups.

EFA welcomes the research focus into COVID-19, which is a respiratory infection with systemic consequences. However, it has halted non-COVID related research, delaying potential progress to rare disease medicines for those in planning stages, and moving away from the chronic disease epidemic, all this despite COVID-19 is deadliest among people with chronic conditions, such as COPD and severe asthma patients, who are also at risk of long-COVID effects.

EMA could have been designated to centralise EU level registries and evidence on 1) secondary allergic reactions, i.e. PEG- and egg- containing vaccines and on 2) labelling gaps in diagnostic tools, i.e. as latex-containing examination gloves and COVID swab testing kits.

Positively:
- The EU’s response has been unprecedented, with regulatory flexibility, procurement to match innovation (i.e. advanced purchase agreements), and massive investments
- New research scenarios have emerged, fostering collaboration rather than competition, giving ultra-speed of genetic coding of the virus, and into vaccine development. COVID also allowed the remote monitoring of patients, especially those in clinical trials, and enabled use of large volumes of data and AI
- It has proven personalised medicine is not just about innovation, but adaptation to patients’ choice and the environment (i.e. prescription of f-gas containing pMDI to avoid aerosols from nebulizers)
- It has shown the importance of research into novel therapies options (i.e. RNA technology) and why the EU should support disruptive science (i.e. phage therapy https://www.cureasthma.eu/about-us)
- We perceive a decrease in vaccine hesitancy, and an improvement in public health literacy, especially around prevention

**Q3: In your opinion, how adequate are the approaches listed below for better addressing the needs of rare disease patients?**

*at most 4 answered row(s)*

| | Very adequate | Moderately adequate | Not at all adequate |
|---|---|---|---|
| When considering whether a particular medicine is eligible for support, the rarity of the disease – the total number of cases of a disease at a specific time, currently less than 5 in 10 000 people – forms the main element of the EU rules on medicines for patients suffering from rare diseases. | ○ | ◉ | ○ |

| | | | |
|---|---|---|---|
| Some diseases occur frequently, but last for a relatively short period of time (for example, some rare cancers). These are covered by the EU rules on medicines for rare diseases and the principle of rarity. However, because many patients acquire such diseases during a specified, limited period of time, those diseases should not be considered as rare in the EU anymore. | ○ | ◉ | ○ |
| Amongst all medicines for rare diseases which become available to the EU patients, only those bringing a clear benefit to patients should be rewarded. Clear rules should apply to decide if one medicine brings a clear benefit to patients when compared to any other available treatment in the EU for a specific rare disease. | ○ | ◉ | ○ |
| Additional incentives and rewards should exist for medicines that have the potential to address the unmet needs of patients with rare diseases, for example in areas where no treatments exist. | ◉ | ○ | ○ |

Other (please suggest any other criteria/approaches you think might be relevant).

*2000 character(s) maximum*

We welcome the initiative of the European Commission to address patients' unmet needs and to define new mechanisms to better deliver on those needs. While we acknowledge the EU's main focus to encourage the development of therapeutic options for those rare disease patients who do not have access to any, we also recall that there are many chronic patients who are undertreated. We urge the European Commission to avoid working in silos and legislate for all children across disease areas, looking also at needs beyond the currently considered rare diseases. For example, there are but rare phenotypes of common conditions that require attention (i.e. severe neutrophilic asthma) or biomarker-based disease subtypes that do not have treatment solutions and where innovation is lagging. It is the case for some sub-types of low prevalence allergens. We would like that the future legislation defines some status for these unmet patient needs.

Regarding incentives, at EFA we would like to see strong support for medicine development that include academia and patient organisation consortia research. In our view, research into drugs for rare diseases should be done hand in hand with patient organisations.

**Q4: What factors are important to take into consideration when deciding if one medicine for a rare disease brings more benefits compared with other available treatments?**

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EFA calls on the European Commission to provide better clarity on what is meant by ‘greater efficacy’. In addition, our federation composed of 42 patient groups in 26 European countries has identified the following factors as decisive to evaluate benefits of rare diseases drugs:

- Higher accessibility and affordability
- Better alignment of requirements of regulatory, HTA and payers.
- Sustainability at social and environmental levels
- Disease endpoints - efficiency: increased capacities to cure, heal, treat, control and reduce disease and its symptoms among patients
- Personalised medicine: easier intake for children (adapted dosage, deviceless and “technique-less”, less medicalized intake) and patient choice (flavour),
- Collateral benefits: what are the effects resulting from the combination of drugs in the case of comorbidities. For example, children having simultaneously severe asthma and food allergy receiving biologicals for their asthma see a reduction on the severity of their food allergies. Those are breakthroughs that considerably improve quality of life.
- Efficacy ratio: the patients population percentage it serves, by age and sex
- Risk-gain benefits: measuring side effects on patients and understanding the impact of a long-term use of drugs (i.e. lung remodeling, use of oral steroids, immune-supressants, renal function decrease).
- Generation of evidence when patients are actually using a therapy (post authorisation), including impact on both mental and physical health and improvements in quality-of-life patient related outcome measures (PROMs).
- Transferability of the treatment to other rare diseases.
- Allergen free excipients in medicines: whether fragrances or food allergens, patients would like medicines with less allergens, accurate labelling, and minimized risk of adverse allergic reactions.

**Q5: What do you consider to be an unmet therapeutic need of rare disease patients and children?**

- [x] Authorised medicines for a particular rare disease or a disease affecting children are not available, and no other medical treatments are available (e.g. surgery).
- [x] Treatments are already available, but their efficacy and/or safety is not optimal. For example, it addresses only symptoms.
- [x] Treatments are available, but impose an elevated burden for patients. For example, frequent visits to the hospital to have the medicine administered.
- [x] Treatments are available, but not adapted to all subpopulations. For example, no adapted doses and/or formulations, like syrups or drops exist for children.

Other (please specify).

*2000 character(s) maximum*

All conditions have unmet clinical need, but we note important ones for allergy and respiratory rare and pediatric diseases.

EFA encourages legislation allowing the conduct of so-called “pragmatic trials” to address underserved chronic disease subtypes.

There is a lack of patient related outcome measures (PROMS) and disease-progression biomarkers: there is a pressing need to for real world data and evidence to understand steroid responsiveness and adherence considering the impact of sex hormones both in retrospective and prospective timeframe, non-T2 asthma and atopic dermatitis. EFA demands more information on newly authorized medicinal products in children (i. e. the use of biomarkers and therapeutic targets to cross generational patients), with provisions for treatment follow up and cross-examination procedures, enabling patients to be well prepared and informed up-front on any modality.

On the efficacy and safety, we cannot say loud enough that any new medicine should avoid use of common allergens in its excipients’ formulation to reduce the risk of adverse allergic reactions. There is presence of eggs and PEG in vaccines, lactose in inhalers and tablets, soya and peanuts in pediatric anesthesia gases, and latex in examination gloves. We demand common allergen-free drug development and accurate allergen labelling (i.e. using “non-protein soya” versus simply “soya”). Finally, anaphylaxis should be reported globally during the trial process, and be a central part of a post market authorization, we therefore demand the creation and support of patient registries.

A long-lasting unmet meet need for patients are the ineffective and difficult to use Drug – Device Combinations, who fall into an EU regulatory limbo. We need legislation to ensure both drug and device are conceived, authorized, and monitored simultaneously due to their nature and interoperability. (i.e. life-saving emergency medications such as Adrenaline Auto Injectors).

**Q6: Which of the following measures, in your view, would be most effective for boosting the development of medicines addressing unmet therapeutic need of patients suffering from a rare disease and/or for children? (1 being the least effective, 10 being the most effective)**

*at most 4 answered row(s)*

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Assistance with Research & Development (R&D), where medicines under the development can benefit from national and/or EU funding | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ◉ |
| Additional scientific support for the development of medicines from the European Medicines Agency | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ◉ | ○ | ○ |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Assistance with authorisation procedures, such as priority review of the application from the European Medicines Agency and/or expedited approval from the European Commission | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ◉ | ○ |
| Additional post-authorisation incentives that complement or replace the current incentives and rewards | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ◉ | ○ | ○ |

Do you have other suggestions that would allow the EU to boost the development of specific medicinal products?

*2000 character(s) maximum*

While most of current innovation is achieved through partnership between academia and private sponsorship, it is the economic interest that paves the way. Future legislation should encourage publicly backed-up laboratories and joint initiatives to reduce barriers for public funded organizations and public-private partnerships to develop medicines that result more accessible to patients. In fact, EFA would like to see assistance, scientific support and incentives that prioritise consortia inclusive of academic and patient organsations as close research partnership with them can lead to better use of Real-time data, evidence-based effectiveness of drugs, improvement on patient data generation, development of tracking and monitoring links to patients' behavioral patterns, and understanding the outcomes of a treatment with new products. The latter can be supported and linked with the general digital health initiatives of the European Commission (setup of the European Health Data Space, implementation of the Health Technology Assessment Regulations, increase of cross border healthcare cooperation).

On the procedural side, we note the following as potential boosters of drug development:

- Fiscal incentives
- A continuum of comparative evidence generation throughout the patient journey and product /technology lifecycle collected in disease registries, supported by a European fund.
- Strengthen early dialogue on HTA / payers
- Streamlined work post authorisation / scientific assessment / joint negotiation / joint procurement + streamlined cross border healthcare

Do you see any drawbacks with the approaches above? Please describe.

*2000 character(s) maximum*

- Potential additional administrative burden
- Innovation follows science. The scientific, data and innovation barrier can only be addressed by scientific progress – we need to be mindful that no amount of incentive will completely address the issue

**Q7: Which of the following options, in your view, could help all EU patients (irrespective of where they live within the EU) to provide them with better access to medicines and treatments for rare diseases or children?**

- [x] Greater availability of alternative treatment options. For instance, by allowing a generic or biosimilar product to enter the market faster.
- [x] Allowing companies that lose commercial interest in a rare disease or children medicine product to transfer its product to another company, encouraging further development and market continuity.
- [x] For companies to benefit from full support and incentives, products need to be placed timely on the market within all Member States in need as soon as they received a marketing authorisation.

Other (please suggest any other solution you think might be relevant).

*2000 character(s) maximum*

Some remarks on our choices:

- On availability, we have selected the option, but we keep note that instead of facilitating biosimilars, better pricing regulations may be preferable. HCPs and patients still perceive generics and biosimilar as less effective.
- On incentives and placement, while we consider that the liability to produce could improve access, obligations should not apply for all types of pharmaceutical companies as there are certain types of companies, usually the smaller ones, that may not have the means of achieving placement in a certain timeframe, even with incentives.

**Q8: Most of the medicines for rare diseases are innovative medicines. However, in some cases, an older, well-known medicine for a common disease can be repurposed (i.e., using existing licensed medicines for new medical uses) to treat a rare disease. In your view, what would be the appropriate way to award innovative medicines in cases where other treatments are available:**

- (●) Both new, innovative medicines and well-known medicines repurposed to treat a rare disease should receive the same reward
- ( ) New, innovative medicines to treat a rare disease should receive an enhanced reward
- ( ) Do not know/cannot answer

**Q9: Despite the presence of a dedicated procedure (the Paediatric Use Marketing Authorisation, PUMA) in the Paediatric Regulation, many older medicines that are currently used to treat children have only been studied for use within adult populations, and therefore lack the appropriate dosage or formulation suitable for use in younger patients. However, the development of medicines that have been adapted for use in children could also result in a product being more expensive than its adult-focused counterpart. In your view:**

Should the development of appropriate dosage or formulation suitable for children of such older medicines be stimulated even if their price will be higher than that of the available alternatives?

- (●) Yes
- ( ) No
- ( ) Do not know/cannot answer

Please explain your answer.

*2000 character(s) maximum*

With the slow speed of treatments for many paediatric respiratory conditions being made available, this formulation testing on approved adult treatments (if found to be successful) will have a positive impact on disease burden and/or be lifesaving, which may potentially preserve developmental stages for these paediatric patients, relieve iatrogenic symptoms/treatments of current regimes, and improve quality of life. However, it is important to state that dosage or formulation suitable for children should be done through cost-effective real-life approaches and not through clinical trials that have a huge cost. EFA stresses that in no case price for children drugs should be higher than the price for the same drug for adults.

How would you suggest stimulating further development of appropriate dosage or formulation suitable for children of such older medicines?

*2000 character(s) maximum*

Generally, we think creating a task force team dedicated to this type of research to identify potential treatments and help support these initiatives could serve development for example by setting the threshold criteria: to create pharmaceutical products tailored to children needs and dosage, we need to identify issues that currently rise from the actual products guidelines. When a new product is being tested, the criteria should include the age and region where they live to create accurate guidelines for regular and correct dosing of the medicine intake.

Enhance collaboration (PPP/Academia-pharma) by incentivising pharma for taking up the academic research and developing the product– as tax incentives, vouchers, regulatory exemptions fees, etc – all this including also patient groups into the research.

Medicines for children are also those taken during pregnancy and breastfeeding, which are areas where the knowledge is still limited and remain an unexplored but fruitful field.

How can it be ensured that such developed products are reasonably profitable for companies and also reach patients?

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It cannot be ensured if there is a ‘for-profit’ mentality. Therefore, a few suggestions include:

1. EU-based subsidy or tax incentive breaks for supporting rare diseases
2. Development of a rare disease EU-based charitable fund for companies to utilise (potentially use this to claim expenses and/or losses)
3. Development of a rare-disease philanthropic fund targeting wealthy individuals/corporations for a hybrid-approach of using interested academic or smaller not-for-profit institutions to conduct this type of

research but pharmaceutical companies to deal with packaging and distribution

4. List of essential drugs to be reimbursed (like covid19 vaccines)

5. The company has to develop the medicinal product with the patient's organizations help. This way the company can be sure the product will reach the patients, and the patients are going to like it and use it (they have helped in the design of the medicinal product). If the product is already developed and is a good medicinal product (delays the disease degeneration/ ameliorates the patient's symptoms) the patients will know – might get higher chances for the reimbursement too

ACKNOWLEDGMENTS

The European Federation of Allergies and Airways Diseases Patients' Associations (EFA) is the voice of over 200 million people in Europe living with allergy, asthma and chronic obstructive pulmonary disease (COPD).

The response to this consultation has been prepared in close discussion with our membership of 42 organisations in 26 countries, our Allergy & Asthma, COPD, Atopic Eczema and Food Allergy working groups and with the Members of the European Youth Parliament on Allergy and Asthma. Our response is also the result of collaboration with the European-level respiratory patient groups and medical society participating in the European Lung Health Group (ELHG). Finally, our responses are formally endorsed by the European Academy of Allergy and Clinical Immunology (EAACI), who we thank for their precious input.

## Contact

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