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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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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?

2000 character(s) maximum

It is misleading to speak of 'insufficient development in areas of greatest need'; the fact that there are no treatments for 95% of diseases cannot be used to justify such a claim. Some 84% of rare diseases impact single patients or single families and have a prevalence rate of below 1 in a million (Nguengang Wakap, S. et al. Estimating cumulative point prevalence of rare diseases: analysis of the Orphanet database, Eur J Hum Genet 28, 165–173 (2020)). This epidemiological distribution is a major barrier to creating a Regulation that would sufficiently incentivise development of medicines in such extremely rare diseases.

It is also incorrect to suggest a direct link between the Regulation and the "unequal availability, delayed access and often unaffordable treatments". In fact, the Commission study makes clear that "the observed [availability and access] problem can only be addressed by an EU Regulation to a very limited extent, as a substantial part of the observed unevenness stems from national policies and decision-making processes". (Technopolis study, 148)

Finally, it should not be neglected that the US—through a willingness to reward innovation—fund most of the worldwide drug development, including in orphans. If Europe were to be on par (i.e. by increasing their willingness to pay by 20%), this could result in substantially more drug discovery worldwide (Goldman and Lakdawalla, The Global Burden of Medical Innovation, USC-Brookings Initiative for Health Policy (2018)). According to the Technopolis study, almost 50% of all orphans have a yearly turnover of €10m or less; one can conclude that a major barrier to the development of treatments is the lack of pull mechanisms through willingness to pay by European healthcare systems (Technopolis study, 150). Further, some evidence requirements by HTA bodies and payers render the environment unpredictable and often unattractive for companies.

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 pharmaceutical industry has played a fundamental role in addressing the pandemic, in attending to patients' increasing non-COVID healthcare needs and in addressing the backlog of unmet need built up during the crisis. In a general sense, future policy reforms should reflect this role and the industry's contribution to healthcare systems resilience.

More specifically, the pandemic has provided evidence for the following items that are universally applicable in drug discovery and development:
1) It is imperative to understand the biology of the disease and of potential technologies where there are no sufficient treatment options: basic science is essential;
2) Multinational and decentralised trials allow for faster product development and can offer better access to trials and lower patient burden for participation (especially in rare and pediatric disease), showing it is essential the EU works with and does not diverge too far from other regions in the world;
3) Quick regulatory approvals and rolling reviews allow for earlier access to innovation;
4) Without strong and clear IP rules, there would be neither cooperation nor the possibility to transform basic science into a concrete medicine;
5) Digital technologies and the collection of real-world evidence have proven crucial to crisis management and rapid authorisation of vaccines and therapies – this should inform future reforms.

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

The current orphan drug designation (ODD) prevalence criteria is predictable and has been effective in encouraging the development of products for RD. Lowering the prevalence criterion is a risk, as is a cumulative prevalence criterion for products with more than one orphan designation.

We urge caution towards changing current eligibility criteria for ODD as there are challenges and possibly unintended consequences in using the incidence criterion, not to mention the lack of reliable EU-level data. These might defy the very purpose the provision would aim to address.

It will prove incredibly cumbersome to set the threshold of awarding ODD on the basis of incidence, as the number of patients will have to be monitored every year. This is a moving target in rare diseases, where tracking all patients at all times is extremely difficult and also evolving diagnostic techniques and practices have an impact on reported incidence. The incidence criterion might also be providing an inaccurate picture of unmet needs for diseases with high mortality rate which might fall ‘’out’’ of the designation criterion, as also noted by some patient groups. For example, the proposal to add an incidence criterion for oncology products is concerning, as rare cancers are rare diseases in their own right and it is very difficult to find relevant scientific literature to support findings on incidence. This proposal also seems to discriminate against the deadliest diseases by disincentivizing investment in diseases that have rapid fatal consequences. This uncertainty would make it challenging for industry to invest in these areas without a clearer understanding of the incentives and rewards that might be available.

The ‘Significant Benefit’ criteria already included in the Regulation provides guidance on the benefits of a medicine and should be maintained. Additional criteria would increase complexities in evidence generation, create confusion and delay development and patient access.

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?

2000 character(s) maximum

The key factors that have most influence on assessing the benefit of a medicine to patients will be improvements to quality of life and whether a medicine reduces the risk of dying from a disease when compared to the existing authorised treatments, preventions or diagnostics. Factors listed under Commission notice 2016/C 424/03, clarifying the concept of significant benefit (Article 3(2) of Regulation (EC) No 847/2000) remain valid.

Particularly when compared with the US, there are already very strict criteria in place to evaluate whether one medicine for a rare disease brings more benefits compared with other available treatments. There is a strict (which has become even stricter with the evolution of the latest EU case law) significant benefit test at the time of marketing authorisation at EU level (which due to the late time point can result in poorly justified, last minute decisions), while at national level, a health technology assessment will very often compare the product in question with the available standard of care.

Taking inspiration from the FDA, a broader list of criteria could be envisaged, including:

• No treatment currently exists;
• The new treatment has greater efficacy with regard to a serious outcome of the disease;
• The new treatment avoids toxicity that is serious or often leads to treatment discontinuation;
• The new treatment has a documented benefit, such as improved compliance, that is expected to improve serious outcomes;
• The new treatment can be used effectively with other critical agents that cannot be combined with available therapies;
• The new treatment addresses an emerging or anticipated public health need.

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 of the situations described above are unmet therapeutic needs. However, none of them constitute a sufficient definition of a term which is almost entirely subjective. It is challenging to produce a single definition, an unmet need exists if a patient's mortality or morbidity is negatively impacted by the disease despite the current treatments (e.g., where symptoms are alleviated but the disease remains lethal), or if the current treatment is negatively affecting a patient's quality of life (e.g. strong side effects).

AmCham EU disagrees with a restrictive approach defining unmet medical needs as those conditions with no treatment approved. In fact, in the OMP context, unmet needs do not only exist where there is no authorised treatment for rare diseases, but depending on disease severity, burden of the illness and impact on patient quality of life, the absence of transformative and curative treatments also qualifies as an unmet need. It is also crucial to define elements to be considered for decisions if one medicine for a rare disease brings more benefits compared with other available treatments (see answer to Q4).

Therefore, rather than a rigid definition/legal framework, we support establishing an UMN principle-based (criteria) approach, that can be applied as appropriate to OMP, Paediatric medicines and beyond. We call on the Commission to convene a multi-stakeholder initiative including clinicians, patient advocacy groups, manufacturers, academic researchers to ensure the definition of unmet need takes into account the views of relevant stakeholders.

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

As several factors influence decisions to research, develop and commercialise medicinal products and the challenges to development in rare and paediatric diseases are multifactorial, a package or toolbox of measures will be needed to further stimulate development in currently underserved areas.

In some instances, basic science and disease understanding is missing. Investments across the whole R&D ecosystem, clarity on research priorities in basic research funding, dedicated research funding and incentives for academia and SMEs would all be important tools to foster collaboration and bring about better knowledge about a given disease.

In some instances, the current incentives are insufficient to attract investment as the economic outlook of a successful product would not be positive, for instance when the patient number is extremely low. A 'transferable exclusivity extension' (TEE), which would allow to get an additional exclusivity period that can be transferred to another product, could help overcome this. By transferring the exclusivity, it allows investment in a product that has no commercial viability on its own. Any new incentive should be complementary to established incentives that have proven their worth in bringing about new innovation.

Another issue is a lack of 'pull incentives' and lack of ability to achieve an adequate price acceptable for both payers and industry: as mentioned previously, and in contrast to anecdotal high-priced products, most orphan medicines will have a very low turnover (close to 50% with less than €10m p.a.; Technopolis study, 150). Market access incentives such as the ones in place in Germany or Italy are key to stimulate innovation. They should also include greater predictability for industry, through flexibility of methodologies/evidence requirements from HTA bodies and alignment with regulatory bodies and payers.

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

2000 character(s) maximum

Priority review vouchers, as mentioned in the Commission's IIA, need to be linked to faster access at national level, as otherwise the time gained at a regulatory level may be lost again at market access point, thereby eroding the benefits. This is very different from the US environment where a marketing authorisation leads to immediate market access.

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

None of the measures above are based on an analysis of root causes of differences in access, nor do they provide a viable route forward to increase access.

Access to medicines is a responsibility shared by companies and national public authorities. Access discussions are based on procedures set out by governments, which often differ based on jurisdiction: the level of regulatory requirements, differences in medical practices, speed of pricing and reimbursement negotiations, ability to achieve an adequate price acceptable for both payers and industry, level of health expenditures (and general wealth), multiple layers of decision making (e.g. in the case of regionalized healthcare). Additionally, measures enacted by European countries, such as price control mechanisms, have unintended consequences that should be included among the root causes in differences to access. Next to reducing the amount of innovation available (see Q1), measures such as international reference pricing disincentivise companies to prioritise countries with lower GDPs, where countries compare prices across borders without accounting for different GDP levels. There is wide variation in the amount of resources devoted to healthcare by EU Member States, even as a share of GPD.
To address existing access issues, it is critical to first disentangle the root causes to avoid unintended consequences and unhelpful narratives. For instance, rare disease and pediatric incentives are akin to other incentives such as patents or regulatory data protection as they are built to support innovation. Global IP standards, including the Paris Convention and the WTO TRIPS Agreement, do not allow conditioning the grant or enjoyment of such incentives in certain markets based on launch or lack thereof and certainly not based on launch in different markets. There is a risk that by pursuing some of the options laid out that the EU would not solve access issues while also becoming out-of-step with global IP and trade

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

To appropriately dose or formulate a medicine for use in children is no small endeavour, as children are not simply smaller-sized adults. The development of a formulation suitable for use in children can be very challenging: for example, tablets or capsules may not be suitable for very young children, so liquid oral or smaller volume injectable dosage forms may need to be developed. A tailored approach is required in order to meet quality, safety and efficacy standards. Often this requires sustained investment and full pharmaceutical and clinical development (ie. clinical trial data must be regenerated for submission and approval, necessitating the conduct of a new trial).

As such this investment should be incentivised and appropriately rewarded. Furthermore, such innovation should not be foregone on account of potential public budget impact; to do so is a poor reflection on the necessity to ensure the safety of medicines in populations who are often restricted from clinical trials despite their equal right to safe and efficacious care.

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

2000 character(s) maximum

Initiatives such as FAIR/Accelerate, which recognise the need for inclusion of children and adolescents in cancer care research, should be further supported. Where there is limited inclusion in clinical trials due to regulatory or ethical concerns, such initiative – developed in collaboration with industry stakeholders – provide solutions to speed up dosage and formulation processes.

A mix of “push” and “pull” incentives should also be studied. Public investment may support the adaptation to children of older compounds with known efficacy. For the industry to take on this role, financial rewards could take the form of market exclusivity for the paediatric formulation, or novel incentives such as a transferrable exclusivity voucher sellable or applicable to other products. Regulatory facilitations also prove helpful.

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

2000 character(s) maximum

This innovation should not be foregone on account of potential budget impact – pricing and reimbursement is established down the road at national or sub-national levels based on a range of factors including value and ability to pay. As demonstrated by EFPIA’s 2020 analysis of “The Root Causes of Unavailability and Delay to Innovative Medicines”, access hurdles are complex and numerous. Streamlining procedures, aligning evidence requirements and removing barriers to differential pricing would all facilitate access to such developed products. The concept of overcompensation is not established: the staff working document (SWD) showed that only 14% of OMPs have yearly turnover of >€100 million. The focus should continue to be on looking at the value products bring and making sure that health systems then reward that value.

Contact

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