Looking back

As mentioned in the Inception Impact assessment, the revision aims to tackle the following problems:

- Unmet medical needs and market failures for medicines other than medicines for rare diseases andchildren;
- Unequal access to available and affordable medicines for patients across the EU;
- The current legislative framework may not be fully equipped to respond quickly to innovation;
- Inefficiency and administrative burden of regulatory procedures;
- Vulnerability of supply of medicines, shortages of medicines;
- Environmental challenges and sustainability;
- Any other issues, which might emerge from the evaluation.

Q1 In your opinion, are there any other issues that should be addressed inthis revision?

800 character(s) maximum **795 characters**

The scope of the revision as presented does not align with the European Commission's bid to promote the EU as a competitive global leader in biopharmaceutical R&D for the betterment of patients and the accessibility of medicines. Since the identification of biotechnology as a 'key enabling technology' in the 1990s, the EU's ability to retain or attract biotechnological development that translates to EU-first market launch medicines has dwindled. Little in this revision seeks to address the issues we face for next generation medicine development, and errs on the side of pinning EU affordability and access issues solely on industry when a plethora of issues lie outside industry and EU control: national pricing and reimbursement policies, MS health system organisation and administration.

Q2 How has the legislation performed in terms of the following elements?

	Very well	Well	Moderately	Poorly	Very poorly	Don't know
1. Fulfilling its public health protection mission for patients and society.		**X**				
2. Promoting the development of new medicines, especially for unmet medical needs.		**X**				
3. Enabling timely development of medicines at all times, including duringcrises.			X			
4. Enabling timely authorisation, including scientific evaluation, of medicines in normal times.			**X**			
5. Enabling timely authorisation, including scientific evaluation during crises.			X			
6. Adapting efficiently and effectively to technological and scientific advancements and innovation.			X			

7. Ensuring medicines are of high quality,safe and effective.	X					
8. Addressing the competitive functioningof the market to support affordability.		X				
9. Ensuring the availability of generic[3]and biosimilar[4] medicines. *[3] "Generic" is a copy of a medicine based on simple or chemical molecules.* *[4] "Biosimilar" is a copy of a medicine based on biological molecules.*		X				
10. Ensuring that new medicines are timely available to patients in all EU countries.			X			
11. Ensuring that medicines stay on the market at all times and that there are no shortages.		X				
12. Ensuring that authorised medicinesare manufactured, used and disposed ofin an environmentally friendly manner.			X			
13. Ensuring that the EU system for development, authorisation and monitoring of medicines, including its rules and procedures, is understandableand easy to navigate.			X			
14. Attracting global investment for medicine innovation in the EU.			X			

Is there any other aspect you would like to mention, including positive or unintended effects of the legislation, or would you like to justify your replies?

800 character(s) maximum **792 characters**

The performance of the pharmaceutical legislation must be evaluated in the full context of bringing medicines to market: some driving factors are in the remit of the EU and others remain MS competencies. The evaluation should focus on areas where the EU can be most impactful. The COVID-19 crisis has accelerated adoption of new technologies. Biological advances, computing bioinformatics, and AI are transforming medicine development. Faced with global challenges and accelerated science, the ambition of the pharmaceutical legislation review in the EU should be to look at how a strong research base can be more efficiently translated into breakthrough innovation to better address the health needs of European patients and to regain EU's global leadership in R&D and cutting-edge industry.

Looking forward

This section reflects on possible solutions to address the problems identified in the inception impact assessment mentioned in the previous section. Your contribution will help us in defining the way forward.

UNMET MEDICAL NEEDS

One of the aims of the strategy is to stimulate innovation and breakthrough therapies, especially in areas of'unmet medical need'.

Regulators, health technology assessment experts and representatives of bodies responsible for reimbursing or paying for medicines ('payers') are discussing a definition or a set of principles for 'unmetmedical needs'[5] in order to achieve the objectives of the general pharmaceutical legislation. The discussions reveal different perceptions of what is an 'unmet medical need'. Convergence on this key concept should facilitate the design of clinical trials, generation of evidence and its assessment, and thequick availability on the market of these products and ensuring that innovation matches the needs of patients and of the national health systems.

The purpose of this question is to identify elements that are important in defining what is unmet medicalneed and in which areas of unmet medical need innovation should be stimulated.*[5] Please note that a similar discussion is taking place in the context of medicines for rare diseases and for children. The concept of 'unmetneeds' in the context of rare diseases and children might be slightly differentiated compared to 'unmet needs' in the context of the general pharmaceutical legislation.*

Q3 How important are the following elements for defining 'unmet medical needs'?

	Very important	Important	Fairly important	Slightly important	Not important	Don't know
1. Seriousness of a disease.	**X**					
2. Absence of satisfactory treatment authorised in theEU.	**X**					
3. A new medicine hasmajor therapeutic advantage over existingtreatment(s).	X					
4. Lack of access for patients across the EU toan authorised treatment.					X	
5. Other (please specify).						

Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the outlined elements, or would you like to justify your replies?

800 character(s) maximum **794 characters**

The following should be considered to establish criteria for UMN: disease severity; absence of satisfactory treatments; quality of life; burden of disease; burden of available treatment; or a treatment with a major therapeutic advantage. UMN should be patient-centric and agreed in a multi-stakeholder forum of patients, caregivers, regulators, healthcare professionals, industry, HTA bodies, payers, etc. Due to evolution of treatments, science and disease understanding, there may be a need for life cycle approach which must be carefully balanced against the need for predictability and reliability for drug developers. Drug development is a lengthy process spanning over long periods of time. A narrow, prescriptive understanding of UMN would stifle innovation to the detriment of patients.

INCENTIVES FOR INNOVATION

The general pharmaceutical legislation guarantees the pharmaceutical innovator, typically a company, regulatory data and market protection for its new medicinal product. This data protection makes sure that another pharmaceutical company cannot re-use the proprietary data of the innovator for 8 years. Market protection makes sure that a generic or biosimilar medicine cannot be marketed until 10 years after authorisation. This dual protection shields a pharmaceutical innovator from generics or biosimilars on the market for 10 years. This protection is part of the EU system of incentives for innovation. The EU regime of intellectual property protection provides an additional protection coverage but is beyond the scope of this questionnaire and the revision of the general pharmaceutical legislation.

Q4 What do you think of the following measures to support innovation,including for 'unmet medical needs'?

	Very important	Important	Fairly important	Slightly important	Not important	Don't know
1. The current data and market protection periods for innovative medicines: 10years of market protection, and 8 years of data protection.	**X**					
2. Provide different data and market protection periods depending on thepurpose of the medicine (i. e. longer period of protection in areas of unmetmedical need).					**X**	
3. Reduce the data and market protection periods toallow earlier access for generic and biosimilar medicines to the market.					**X**	
4. Introduce new types of incentives[6] on top of the existing data and market protection for medicines addressing an 'unmet medical need'.	**X**					

[6] Examples of new incentives are a transferable exclusivity voucher or a priority review voucher. A transferable exclusivityvoucher would give the legal right to extend the protection time period of any other patented medicinal product, in exchange forthe successful regulatory approvalof a specified medicine for unmet medical need (e.g. an antibiotic). The voucher would be transferable or saleable, and may impact the turnover and profitability levels of other products in a developer's portfolio.A priority review voucher gives priority to the assessment of the application of the medicine in question or another medicine in the applicant's portfolio.						
5. Early scientific supportand faster review /authorisation of a new promising medicine for anunmet medical need.	**X**					
6. Public listing of priority therapeutic areas of high unmet medical need to support product development by providing incentives.				**X**		
7. Require transparent reporting from companiesabout their research and development costs and public funding as a condition to obtain certain incentives.					**X**	
8. Other (please specify)						

Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

800 character(s) maximum **792 characters**

Development of novel biotechnology derived treatments requires a supportive and predictable framework of incentives to underpin high-risk-failure R&D. Targeting areas of UMN where potential commercialisation is uncertain requires both research push-solutions from basic scientific research to understand disease pathology, to late-stage clinical translational research, and market pull factors that cover the entire R&D lifecycle. Transparency of R&D costs should not be a precondition to funding, this only serves to disincentivise global investment in the EU as a place to develop medical-IP. As other jurisdictions develop new incentives to entice R&D the EU should follow suit. Creating additional hurdles to access EU incentives, particularly in areas of UMN, would be counterproductive.

ANTIMICROBIAL RESISTANCE[7]

Antimicrobial resistance (AMR) is the ability of microorganisms (such as bacteria, viruses, fungi or parasites) to survive and grow over time and no longer respond to medicines making infections harder to treat and increasing the risk of infections, severe illness and death. Antimicrobials include antibiotics, whichare substances that fight bacterial infections. Overprescribing, overuse and inappropriate use of antibiotics are key drivers of AMR, leading to harmful health outcomes. The question below is intended to collect opinions on both the incentives for the development of new antimicrobials as well as possible option on their prudent use.

[7] amr_2017_action-plan.pdf (europa.eu).

Q5 Should there be specific regulatory incentives for the development of newantimicrobials while taking into account the need for more prudent use and ifso what should they be?

1000 character(s) maximum **999 characters**

AMR is a longstanding issue and should be a priority. HERA can play a key role. Fighting AMR needs the right incentives to encourage further research and innovation and implementation of a strong Public Private Partnership to create market conditions that today do not exist. It is important to have an EU-list of priority pathogens that guide developers to target the right unmet needs, as well as an alignment on the value demonstration amongst all concerned stakeholders (regulators, HTAs, payers). Economic models that apply to conventional treatments do not apply to new antimicrobials as they must be reserved in last resort. Innovative approaches to incentivise R&D in conditions which do not meet the traditional volume-based business model are required to reverse the market failure. For stewardship of existing antibiotics, effective use should be widely promoted and aimed at both healthcare professionals and citizens to address general health threats and to reduce environmental impact.

FUTURE PROOFING: ADAPTED, AGILE AND PREDICTABLE REGULATORY FRAMEWORK FOR NOVEL PRODUCTS

Novel products and innovative solutions continue to challenge the understanding of a “medicinal product” with low volume, and cutting-edge products (e.g. medicines combined with self-learning artificial intelligence) becoming a new reality. ‘Bedside’ manufacture of more individualised medicines changes the way medicines are produced. There are classification and interplay challenges with other medical products,such as medical devices and substances of human origin, or related to the combination of clinical trials within vitro diagnostics/medical devices and medicines. In

addition, certain cell-based advanced therapy medicines[8] are offered in hospital settings and are exempted from aspects of the pharmaceutical legislation. These developments offer possibilities for novel promising treatments and new ways of authorising and monitoring medicines but they are also testing the limits of the current regulatory system. They need to be addressed to unfold their potential while safeguarding the principles of high quality, safetyand efficacy of medicines.

Digital transformation is affecting the discovery, development, manufacture, evidence generation, assessment, supply and use of medicines. Medicines, medical technologies and digital health are becoming increasingly integral to overarching therapeutic options. These include systems based on artificial intelligence for prevention, diagnosis, better treatment, therapeutic monitoring and data forpersonalised medicines and other healthcare applications.

[8] Advanced therapy medicinal products (ATMPs) are medicines for human use that are based on genes, tissues or cells. They offer ground-breaking new opportunities for the treatment of disease and injury.

6 How would you assess the following measures to create an adapted, agileand predictable regulatory framework for novel products?

	Very important	Important	Fairly important	Slightly important	Not important	Don't know
1. Maintain the current rules.		x				
2. Create a central mechanism in close coordination with other concerned authorities (e.g. those responsible for medical devices, substances of human origins) to provide non- binding scientific advice on whether a treatment/product should be classified as a medicine or not.			x			
3. Make use of the possibility for 'regulatory sandboxes'[9] in legislation to pilot certain categories of novel products/technologies. *[9] Some very innovative solutionsfail to see the light of day becauseof regulations which might be outdated or poorly adapted for fastevolving technologies. One way toaddress this is through regulatory sandboxes. This enables*						

innovative solutions not already foreseen in regulations or guidelines to be live-tested with supervisors and regulators, provided that the appropriate conditions are in place, for example to ensure equal treatment. Regulatory sandboxes provide up-to-date information to regulators and supervisors on, and experience with, new technology, while enabling policy experimentation. See COM(2020) 103 final.	X					
4. Create adaptive regulatory frameworks (e.g.adapted requirements for authorisation and monitoring with possibility toadjust easily to scientific progress) for certain novel types of medicines or low volume products (hospital preparations) in coherence with other legal frameworks (e.g. medical devices and substances of human origin [10]) and respecting the principles of quality, safety and efficacy. *[10] Substances that are donatedby humans such as blood, plasma, cells, gametes, tissues* *and organs and are applied as therapy. Some substances of human origin can also become starting materials to manufacture medicines.*	X					

5. Introduce an EU-wide centrally coordinated process for early dialogue and more coordination among clinical trial, marketing authorisation, health technology assessment bodies, pricingand reimbursement authorities and payers for integrated medicines development and post- authorisation monitoring.		X				
6. Other (please specify)						

Is there any other aspect you would like to mention, for example on the potentialeconomic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

800 character(s) maximum **797 characters**

The EU network needs a streamlined, flexible and coherent regulatory system improving coordination between EMA and MSs to support new advances in health innovation and accelerate patient access. Alignment of standards and methodologies internationally and between EU stakeholders will avoid duplicative work, increasing efficiency. Access to assessors to guide companies through the regulatory process should be strengthened. The EU system should fully collaborate with other global agencies; this requires a competitive assessment timeline and iterative scientific advice in particular for SMEs. Adequate resourcing is necessary to keep pace with evolving regulatory approaches globally such as the use of RWE. For broad and fast access to medicines an efficient P&R system at MS-level is needed.

Q7. Do you think that certain definitions and the scope of the legislation need to be updated to reflect scientific and technological developments in the sector (e.g. personalised medicines, bedside manufacturing, artificial intelligence) and if so what would you propose to change?

1000 character(s) maximum **948 characters**

Healthcare is experiencing a major paradigm shift, from traditional one-size-fits-all medical care to personalised medicine tailored to the genomic, molecular, and lifestyle characteristics of individual patients; the need for accessible data, within transparent governance frameworks, to support drug development and regulatory assessment is clear. Create conditions for better use of RWE with the right regulatory framework. Harmonised regulatory definitions for AI and risk classifications should be supported and AI driven software should be aligned with the IVDR/MDR regulations. Elements of the ATMP hospital exemption, Art. 28(2) of Regulation (EC) 1394/2007, require clarification or standard definitions to ensure harmonisation across all MSs. Based on the lessons from COVID-19 (rapid scientific advice, rolling reviews, labelling and other regulatory flexibilities, GMO exemptions etc.) accelerated regulatory pathways should be defined.

REWARDS AND OBLIGATIONS RELATED TO IMPROVED ACCESS TO MEDICINES

Some medicines and therapies do not always reach patients in all EU countries, so patients in the EU still have different levels of access to medicines, depending on where they live. Even if a medicine received an EU-wide authorisation, companies are currently not obliged to market it in all EU countries. A company maydecide not to market its medicines in, or decide to withdraw them from, one or more countries. This can be due to various factors, such as national pricing and reimbursement policies, size of the population and levelof wealth, the organisation of health systems and national administrative procedures. Smaller markets in particular face challenges for availability and supplies of medicines.

Q8 How would you assess the following measures to improve patient accessto medicines across the EU?

	Very important	Important	Fairly important	Slightly important	Not important	Don't know
1. Maintain the current rules which provide no obligationto market medicines in all EU countries.	**X**					
2. Require companies to notify their market launch intentions to regulators at the time of the authorisationof the medicine.					**X**	
3. Introduce incentives for swift market launch across the EU.				**X**		
4. Allow early introduction of generics in case of delayed market launch of medicines across the EU, while respecting intellectual property rights.					**X**	
5. Require companies to place – within a certain period after authorisation –a medicine on the market ofthe majority of Member States, that includes small markets.					**X**	
6. Require companies withdrawing a medicine from the market to offer another company to takerover the medicine.				**X**		

7. Introduce rules on electronic product information to replace thepaper package leaflet.	X					
8. Introduce harmonisedrules for multi-country packages of medicines.	X					
9. Other (please specify).						

Is there any other aspect you would like to mention, for example on the potentialeconomic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

800 character(s) maximum **798 characters**

Biotechnology companies seek to make their medicines available to as many patients, in as many countries as early as possible. For those biotech-derived cell and gene therapies that require highly specialised physicians and treatment centres, commitment to equal EU-patient access through existing mechanisms such as the Cross-Border Healthcare Directive are more useful than implementing new administratively burdensome and unrealistic product launch obligations. Key factors such as national pricing and reimbursement policies, limited number of patients, MS health systems organisation, health expenditure levels and companies' (SMEs) resources are outside EU-policy control. Real incentivisation for industry to launch lies in simplified, clear and coherent procedures and respect of IP rights.

ENHANCE THE COMPETITIVE FUNCTIONING OF THE MARKET TO ENSURE AFFORDABLEMEDICINES

The affordability of medicines has implications for both public and household finances. It poses a growing challenge to pay for medicines in the majority of Member States. Often, innovative medicines have higher prices, while there are growing concerns among stakeholders about the real-life effectiveness of some medicines and related overall costs. This puts the budgetary sustainability of health systems at risk, and reduces the possibilities for patients to have access to these medicines. Generics and biosimilars[11] of medicines which no longer benefit from intellectual property protection (off-patent medicines) may provide accessible and affordable treatments. They also increase the availability of alternative treatment options for patients. They may also increase competition between available medicines. However, experience showsthat there are still barriers for medicines entering the EU market, including for generics or biosimilars.

[11] "Generics" are copies of medicines based on simple or chemical molecules; "biosimilars" are copies of medicines based on biologicalmolecules.

Q9 In your view, to what extent would the following measures support accessto affordable medicines?

	To a great extent	To a certain extent	No change	Very little	Not at all	Don't know

1. Maintain the current rules.		X				
2. Stimulate earlier market entry through a broader possibility to authorise generics /biosimilars despite ongoing patentprotection ('Bolar exemption')[12]. *[12] The Bolar exemption allows companies to conduct research on patent protected medicines under the condition that it is with a view to apply for a marketing authorisation for a generic.*			X			
3. Create a specific (regulatory) incentive fora limited number of biosimilars that come to the market first.					X	
4. Introduce an EU-wide scientific recommendation on interchangeability forspecific biosimilars.					X	
5. Introduce other, non-legislative measures,such as joint procurement to reinforce competition while addressing security of supply and environmental challenges.					X	
6. Other (please specify).	X					

Is there any other aspect you would like to mention, for example on the potentialeconomic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

800 character(s) maximum **799 characters**

The 'Most Economically Advantageous Tender' (MEAT) criterion can place more emphasis on qualitative aspects (technical merit, functional characteristics, accessibility etc.) environmental consideration, social aspects, service and assistance and delivery conditions that go far beyond price only considerations. Novel treatments offer vast improvements to lives of patients and to the long-term financial sustainability of healthcare systems, better value for money could be achieved by considering these broader societal goals. While off-patent pharmaceutical/biologics have the potential to contribute to the sustainability of health systems and increase accessibility of certain medicines, these do not offer medical innovation to patients which is increasingly available faster in other regions.

REPURPOSING OF MEDICINES

Repurposing is the process of identifying a new use for an established medicine in a disease or conditionother than that it is currently authorised for. Repurposing of older (off-patent) medicines constitutes an emerging and dynamic field of medicines development, often led by academic units and medical researchcharities, with the potential for faster development times and reduced costs as well as lower risks for companies. This is because repurposing commonly starts with substances that have already been tested and many have demonstrated an acceptable level of safety and tolerability. The objective is to identify theopportunities and address any regulatory burdens to facilitate repurposing of off-patent, affordable medicines.

Q10 What measures could stimulate the repurposing of off-patent medicinesand provide additional uses of the medicine against new diseases and medical conditions? Please justify your answers.

1000 character(s) maximum **993 characters**

Stimulating repurposing of off-patent medicines can clearly offer new opportunities of treatment to patients in the EU. To make significant progress, focus efforts on the current development barriers existing for SMEs, academic research centres or non-profit organisations: addressing the costs incurred by SMEs to develop new clinical trials, and creating the necessary infrastructure; help to develop the expertise and resources required to convert ideas into treatment solutions; and providing financial support to underpin clinical development periods that can be much longer than anticipated. Providing these additional incentives along the development cycle would boost research and in turn make more treatment options available for patients. To make drug development outside their current label more attractive to investors the EC should consider simplifying regulatory pathways to accelerate development and seek alignment from MSs on indication pricing and new sustainable P&R models.

SECURITY OF SUPPLY OF MEDICINES

Shortages of medicines and the vulnerabilities in the pharmaceutical supply chain continue to be concernsin the EU. Shortages of medicines can have serious impacts on patient care. Under the current pharmaceutical legislation, pharmaceutical companies and wholesalers must, within the limits of their responsibilities, ensure a continued supply of medicines once they are placed on the market in the EU. Companies must also notify national authorities at least two months before an expected shortage or planned market withdrawal.

Q11 What is your view on the following measures to ensure security ofsupply of medicines in the EU?

	Very important	Important	Fairly important	Slightly important	Not important	Don't know
1. Maintain the current rules.		X				
2. Earlier reporting of shortages and market withdrawals to national authorities in a common format.		X				
3. Companies to have shortage prevention plans.	X					
4. Companies to have safety stocks.			X			
5. Monitoring of supply and demand at national level.		X				
6. Introduce a shortage monitoring system at EUlevel.		X				

7. Require companies to diversify their supply chains,in particular the number of key suppliers of medicines and components.					X	
8. Companies to providemore information to regulators on their supplychain.					X	
9. Introduce penalties for non-compliance by companies with proposed new obligations.					X	
10. EU coordination to help identify areas where consolidation in the supply chain has reduced the number of suppliers.					X	
11. Other (please specify)						

Is there any other aspect you would like to mention, for example on the potentialeconomic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

800 character(s) maximum **776 characters**

It is global supply chains that have assured continuity of supply of innovative treatments when the COVID-19 crisis emerged, most of above listed measures could be counterproductive. There are three critical areas for policy support to consider: 1) the need to build strong resilient supply chains (through international cooperation on regulatory approaches and oversight); 2) the creation of adequate demand forecasts for critical medicines (with transparent supply and demand information from authorities and supply chain stakeholders); 3) the implementation of quick supply response/planning processes based on true patient needs, the ability to move stocks to respond to needs and to identify stockpiling requirements not justified and not coordinated across EU countries.

QUALITY AND MANUFACTURING

Medicines manufactured for the EU market must comply with the principles and guidelines of good manufacturing practice (GMP). GMP describes the minimum standard that a medicines manufacturer mustmeet in their production processes. GMP requires that medicines are of consistent high quality, are appropriate for their intended use and meet the requirements of the marketing authorisation or clinical trial authorisation.

Q12 What is your opinion of the following measures to ensure manufacturingand distribution of high quality products?

	Very adequate	Adequate	Neutral	Less adequate	Not adequate	Don't know
1. Maintain the current rules.	X					
2. Strengthen manufacturingand oversight rules.			X			
3. Adapt manufacturing rules to reflect new manufacturing methods.		X				
4. Include selected environmental requirements for manufacturing of medicines in line with the onehealth approach on antimicrobial resistance[13]. *[13] The one-health approach is a holistic and multi-sectorial approachto addressing antimicrobial resistance since antimicrobials usedto treat infectious diseases in animals may be the same or be similar to those used in humans.*						X
5. Increase Member State cooperation and surveillanceof the supply chain in the EUand third countries.			X			
6. Strengthen and clarify responsibilities of business operators over the entire supply chain on sharing information on quality, safetyand efficacy.		X				
7. Other (please specify).	X					

Is there any other aspect you would like to mention, for example on the potentialeconomic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

800 character(s) maximum **789 characters**

The EU should recognise "bio-production" as a strategic sector to produce advanced therapy and biological products establishing the EU as a leader for breakthrough technologies that can compete at a global level. In general current manufacturing and oversight are appropriate but it is critical that those rules continue to converge with international regulations. Implement flexibilities agreed during COVID19, and enhance

the use of platform knowledge, MRAs, PIC/S. Changes to adapt to new manufacturing methodologies should ensure predictability and fair competition of the EU with other regions. Advanced biological therapies and manufacturing bring significant advantages to advance the EU's digital and green agenda, create high-skilled jobs and establish greater security of supply.

ENVIRONMENTAL CHALLENGES

While access to pharmaceuticals is a priority, it is also important that the environmental impacts of those pharmaceuticals are as low as possible. The environmental risk assessments (ERAs) is currently not takeninto account in the overall benefit/risk analysis which influences the delivery of a marketing authorisation (MA) of a medicine. ERA can influence risk management measures. Yet, ERA results are not decisive in the MA process.

Q13 How would you assess the following measures to ensure that the environmental challenges emerging from human medicines are addressed?

	Very important	Important	Fairly important	Slightly important	Not important	Don't know
1. Maintain the current rules.		**X**				
2. Strengthen the environmental risk assessment during authorisation of a medicine, including risk mitigation measures, where appropriate.			**X**			
3. Harmonize environmentalrisk assessment by national regulators, including risk mitigation measures.	**X**					
4. Increase information tothe health care professionals and the general public about the assessment of environmental risks of medicines.			**X**			
5. Allow companies to use existing data about environmental risks for authorisations of a new medicine to avoid duplicating tests.	**X**					
6. Other (please specify).						

Is there any other aspect you would like to mention, for example on the potentialeconomic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

800 character(s) maximum **796 characters**

ATMPs consisting of or containing GMOs are subject to a patchwork of different interpretations of the Deliberate Release and Contained Use Directive and subsequent ERA requirements by Member States. These requirements should be reconsidered. The Clinical Trial Regulation will implement a centralised administration of clinical trials across Europe, ATMPs will not likely reap the benefits given the need to conduct GMO authorisations at MS level, and given that such authorisations do not form part of the centralised clinical trial process. An effective, future-proof solution can be best achieved by legislative means; Regulation (EU) 2020/1043 has demonstrated the feasibility of an exemption on GMO requirements that we advocate should be adopted for clinical trials of GMO-containing ATMPs.

Q14 Is there anything else you would like to add that has not been covered inthis consultation?

900 character(s) maximum **897 characters**

EuropaBio firmly believes capturing the full potential of biotechnology is fundamental to finding new solutions to the challenges that Europe is facing, from health, ageing, through climate change, to sustainable economic, environmental and societal development. We outline eight key pillars for how biotechnology will help achieve a healthier and more sustainable Europe that attracts innovation and clinical development and delivers to its citizens: Capital and financing for fostering cutting-edge innovation by start-ups and SMEs; Skills and labor for a knowledge-based economy; R&D incentives for competitive innovation; Intellectual Property for sustainable biotech business model; Advanced manufacturing for sustainable production; Digitalisation to accelerate research and innovation; Regional development for jobs & growth creation; Global competitiveness for recovery and sustainability.

Q15 In case you would like to share a document that substantiates yourreplies, please upload it below (optional).

EuropaBio Life sciences and Biotechnology strategy