

Survey on the Pharmaceutical Strategy - Timely patient access to affordable medicines

Fields marked with * are mandatory.

Introduction

The EU strives to be a frontrunner in ensuring universal health coverage. In addition, it is a global leader in healthcare research and development and a major trading partner in pharmaceuticals and medical technologies. People across the EU expect to benefit from equal access to safe, state-of-the-art and affordable new and established therapies. Medicines play an important role in this regard, as they offer therapeutic options for diagnosis, treatment and prevention of diseases.

The unprecedented coronavirus pandemic (COVID-19) clearly demonstrates the need to modernise the way the EU ensures that its citizens get the medicines they need. Although this has been thrown into sharp relief by the coronavirus pandemic, it is not a new problem: even prior to the pandemic we witnessed shortages of essential medicines, such as cancer treatments, vaccines and antimicrobials. This calls for a thorough examination of how the supply chain - from the importing of active ingredients, raw materials, and medicines from third countries to internal EU production and distribution – can be made more secure and reliable.

Securing the supply of medicines is not only about existing therapies. There is also a need to ensure that the European pharmaceutical industry remains an innovator and world leader. Innovative technologies such as artificial intelligence as well as data collected from clinical experience (“real world data”) have the potential to transform therapeutic approaches and the way medicines are developed, produced, authorised and placed on the market and used. Innovation needs to be focused on areas of most need.

At the same time, more must be done to ensure that innovative and promising therapies reach all patients who need them: at present, this is not the case, with patients in smaller markets being particularly affected. Health systems, which are also seeking to ensure their financial and fiscal sustainability, need new therapies that are clinically better than existing alternatives as well as cost effective.

Finally, we are more aware than ever of the need to reduce the environmental footprint of medicines.

All these challenges will be addressed in the forthcoming EU Pharmaceutical Strategy, which should cover the whole life-cycle of pharmaceutical products from scientific discovery to authorisation and patient access.

More information on the context of the initiative, on the challenges identified so far and on the objectives can be found in the roadmap (<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines>). Whether you are a concerned citizen or a professional in the area of medicines we would like you to let us know if you share our

objectives, what actions we should focus on and whether there are any additional aspects that we should cover.

After some introductory questions about yourself, the questionnaire continues with questions on the Pharmaceutical strategy.

When replying, please keep in mind that the questions in this survey were developed to address the long-standing issues identified in the EU pharmaceuticals system. These may be related to the problems arising from the coronavirus pandemic but are broader than that. The end of the survey includes dedicated questions on coronavirus related issues.

Please note that in this questionnaire, we do not intend to obtain data relating to identifiable persons. Therefore, in case you will describe a particular experience or situation, please do it in a way that will not allow linking to a particular individual, whether it is you or somebody else.

We thank you in advance for your time and input.

About you

* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- Gaelic
- German
- Greek
- Hungarian
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese

- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

* Organisation name

255 character(s) maximum

EuropaBio - The European Association for Bioindustries

* Organisation size

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

Transparency register number

255 character(s) maximum

Check if your organisation is on the [transparency register](#). It's a voluntary database for organisations seeking to influence EU decision-making.

1298286943-59

* Which stakeholder group do you represent?

- Individual member of the public
- Patient or consumer organisation
- Healthcare professional
- Healthcare provider organisation (incl. Hospitals, pharmacies)
- Healthcare pricing & reimbursement body and/or final payer
- Centralised health goods procurement body
- Health technology assessment body
- Academic researcher
- Research funder
- Learned society
- European research infrastructure
- Other scientific organisation
- Environmental organisation
- Pharmaceuticals industry
- Chemicals industry
- Pharmaceuticals traders/wholesalers
- Medical devices industry
- Public authority (e.g. national ministries of health)
- EU regulatory partner / EU institution
- Non-EU regulator / non-EU body
- Other (please specify)

Please specify: is the organisation you represent an active pharmaceutical ingredients producer/importer?

- Yes
- No

Are you responding on behalf of a Small or Medium Sized Enterprise?

- Yes
- No

* First name

Violeta

* Surname

* Email (this won't be published)

v.georgieva@europabio.org

* Country of origin

Please add your country of origin, or that of your organisation.

- | | | | |
|---|--|--|--|
| <input type="radio"/> Afghanistan | <input type="radio"/> Djibouti | <input type="radio"/> Libya | <input type="radio"/> Saint Martin |
| <input type="radio"/> Åland Islands | <input type="radio"/> Dominica | <input type="radio"/> Liechtenstein | <input type="radio"/> Saint Pierre and Miquelon |
| <input type="radio"/> Albania | <input type="radio"/> Dominican Republic | <input type="radio"/> Lithuania | <input type="radio"/> Saint Vincent and the Grenadines |
| <input type="radio"/> Algeria | <input type="radio"/> Ecuador | <input type="radio"/> Luxembourg | <input type="radio"/> Samoa |
| <input type="radio"/> American Samoa | <input type="radio"/> Egypt | <input type="radio"/> Macau | <input type="radio"/> San Marino |
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- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago

- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen

- Czechia
- Lebanon
- Saint Helena
Ascension and
Tristan da
Cunha
- Zambia
- Democratic
Republic of the
Congo
- Lesotho
- Saint Kitts and
Nevis
- Zimbabwe
- Denmark
- Liberia
- Saint Lucia

* Publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

Anonymous

Only your type of respondent, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.

Public

Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

I agree with the [personal data protection provisions](#)

International dependency and manufacturing

The EU is increasingly dependent on active ingredients originating from outside the EU. This has implications, including as regards increasing the risk of quality issues and shortages of medicines. The recent outbreak of COVID-19 shows that a disruption in the pharmaceutical products supply chain originating from outside the EU could present a major health security issue.

1. What type of EU action or initiative do you consider helpful to incentivise the production of active pharmaceutical ingredients for essential medicines (e.g. antibiotics, oncology medicines) in the EU?

800 character(s) maximum

EuropaBio's members produce innovative biotechnology-derived treatments. These require specialised, capital-intensive manufacturing sites with new treatment channels linked to centres of excellence where few sites can ensure treatment for many patients beyond national borders. Given that R&D and manufacturing are linked, a strategic approach to support innovative manufacturing is required to ensure reliable supply and high-skilled manufacturing jobs for the future.

EuropaBio recommends expanding advanced manufacturing capabilities and capacity in the EU by 1) Increasing and prioritizing EU funding; 2) more agile regulatory framework; 3) developing comprehensive talents, training and skills in biosciences; 4) tax , economic and trade policy measures to support investment.

2. What action do you consider most effective in enhancing the high quality of medicines in the EU?

between 1 and 1 choices

- Stronger enforcement of the marketing authorisation holder responsibilities
- Increased official controls in the manufacturing and distribution chain
- Other (please specify)
- I don't know

Please elaborate your reply.

500 character(s) maximum

EuropaBio believe that the development, product licencing, manufacturing, and distribution of APIs and medicinal products must be conducted in compliance with relevant International Codes and Standards, Good Laboratory Practice/General Laboratory Standard, Good Clinical Practice, Good Manufacturing/Distribution Practice and Good Regulatory Practice. Local regulatory requirements, as well as the requirements of the countries to which products or data are supplied, must be satisfied.

Access to affordable medicines

A shortage of a medicine occurs when there are not enough medicines in a country to treat every patient with a given condition. Shortages can have a big impact on patients if their treatment is delayed because there is no alternative, or the alternative is not suited to their needs.

3. Are you concerned about medicines shortages in the EU?

- I am concerned
- I am not concerned
- I have no particular opinion

If you wish, please elaborate your reply.

500 character(s) maximum

Shortages primarily related to generic products have not affected availability of innovative products from biotech companies. Distribution channels guarantee continuous access to innovative treatments. Despite the pandemic, the EU has not yet experienced wide-scale issues in supplying such treatments. Weaknesses identified like border controls, lack of coordination between Member States on demands or lack of overall safety stocks and data availability by country should be addressed in the future.

4. Which actions do you think would have the biggest impact on reducing shortages in the EU?

at most 3 choice(s)

- Stronger obligations on medicines producers, and other players in the supply chain to ensure medicines are available
- Transparent information exchange among authorities on medicine stocks available in each country
- Increased cooperation among public authorities/national governments on shortages
- Multi-lingual packaging and electronic product information leaflets facilitating purchasing in different countries
- Providing incentives to companies to increase the production of medicines in the EU
- Inform on and make available to patients suitable substitutes for medicines that are at risk of shortage
- Other (please specify).

Please elaborate your reply.

500 character(s) maximum

Parallel traders should have greater accountability. They should provide appropriate notification to the MAH when they anticipate shortages or reductions of their normal supply levels.
Regulatory adaptations should be envisaged to facilitate cross-border distribution of medicines when required.
Shortage should be defined to exclude artificial stockpiling. EU database for shortages by country
For high-quality medicines, include environmental sustainability requirements in procurement procedure

Innovative medicines have to undergo a centralised EU-wide marketing authorisation. Companies often initially market them in a limited number of EU countries. It can take several years before patients in the other EU countries have access to those products.

5. Do you think that companies that apply for and receive an EU-wide marketing authorisation should be required to make that product available in all EU countries?

- I agree
- I neither agree or disagree

- I disagree
- I don't know

If you wish, please elaborate your reply.

500 character(s) maximum

It is in innovative companies' interest to make products available to as many patients, in as many countries and as early as possible. Significant burdens for manufacturers are varying national dossier requirements, timelines for pricing and reimbursement processes, international reference pricing mechanisms. Misalignment of processes indirectly forces some companies to prioritise certain markets. These variations make it particularly challenging for SMEs.

In recent years, there has been an [increase](#) in the number of medicines withdrawn from the market upon decisions by the manufacturers.

6. Do you have an opinion on the reasons for these market withdrawals?

- Yes
- No

If yes, please elaborate.

500 character(s) maximum

There are several reasons why a medicine is removed from the market - market size reduction, improved products alternatives, lack of profitability while other alternatives exist etc. Removal does not necessarily correlate to reduced access authorisation of AMTPs and OMPs have increased in the past two years according to the EMA, alongside numerous new treatments. If treatments experience bottlenecks at country level because of pricing/reimbursement/uptake/ERP, this too can result in removals.

7. Are you aware of patients not receiving the medicine they need because of its price?

- Yes
- No

If you wish, please elaborate your reply.

500 character(s) maximum

Sometimes companies do not obtain a P&R decision for innovative treatments in all Member States. Even if a decision is reached, only a limited number of patients is treated which may lead to some patients not receiving treatment. This could be due to a variety of reasons, such as lack of budget allocation or patient eligibility to the treatment based on national payers' decision at hospital or regional level or opting for cheaper medicines without considering patients' long-term life benefit.

8. Do you think that medicine prices are justified, taking into consideration the costs associated to their development and manufacturing?

- Yes
- No
- I don't know

If you wish, please elaborate your reply.

500 character(s) maximum

The price of medicines should be set based on the value to patients, healthcare system and society. R&D costs are difficult to predict and allocate to one single product and cannot be the base for evaluating the price. Cost-plus pricing rewards high-cost manufacturing, not high-value products. A model considering only development and production inputs indirectly encourages inefficiency and creates perverse incentives where medicines with higher development costs are granted higher prices.

High prices for new medicines put pressure on public health spending. The costs for research and development are not publically disclosed and there is no agreement on how to calculate such costs. In certain cases, some EU countries join forces to increase their negotiating power when discussing prices with pharmaceutical companies. Individual pricing decisions in some EU countries may affect others. As an example, some EU countries limit the prices of medicines by linking that price to average prices in other EU countries (we call this "external reference pricing"- ERP). Because of ERP, a pricing decision in one EU country can inadvertently affect the prices in others. Once patents and other forms of market protection expire, generic and [biosimilar](#) medicines can enter the market and compete with the existing ones, this also typically brings down prices. Finally, there are plans to strengthen support to EU countries to work with each other on the clinical effectiveness of new medicines compared to existing alternatives, simply put how much better a medicine works compared to another one. This is part of the so called "health technology assessment" process.

9. What are the most effective ways the EU can help improve affordability of medicines for health systems?

at most 3 choice(s)

- Support the EU countries in better assessing and/or evaluating the value of medicines, meaning the effectiveness of a (new) medicine compared with existing ones
- Help EU countries share experiences and pool expertise on pricing and procurement methods
- Better coordination among EU countries to ensure that pricing decisions taken by one EU country do not lead to negative impacts on patient access in another EU country
- Facilitate, market entry and a healthy market functioning for generics and biosimilars
- More transparency on how the cost of a medicine relates to the cost of its research and development

- There should be a fair return on public investment when public funds were used to support the research and development of medicines
- I don't know
- Other

* Please explain.

100 character(s) maximum

Evaluation criteria capturing the value of innovative medicines, especially for small patient groups

Innovation in early development and authorisation

The European Commission actively supports health research and development through various funding mechanisms (e.g. Multiannual Financial Framework, [Horizon 2020](#), [Innovative Medicines Initiative](#) partnership) and through collaborations between academia, healthcare systems and industry. Furthermore, the EU pharmaceutical legislation includes incentives to stimulate the development of innovative new medicines in areas such as paediatric and rare diseases; and market exclusivity rights to industry.

10. What actions at EU level do you consider most effective in supporting innovative research and development of medicines?

at most 3 choice(s)

- Make the legislative framework more adaptive to new technologies and advances in science
- Provide more public funding for research
- Support (including through funding) private-public partnerships
- Support (including through funding) the creation of start-ups in medical research
- Foster research collaboration between universities, research centres and industry
- Provide research and development incentives in the form of intellectual property or market exclusivity rights for pharmaceutical companies investing in research
- Simplify the requirements for the conduct of clinical trials
- Other (please specify)
- I don't know

Please elaborate your reply.

100 character(s) maximum

All are important for a strong EU innovation ecosystem from strong basic research to strong IPRs.

Expected return on investment in research and development for the pharmaceutical industry depends also on the expected volume of sales; this seems to be one of the root causes of limited availability of certain medicines (e.g. medicines for rare diseases or medicines for children).

11. What do you consider are the most effective actions related to research and development of medicines in areas where there are limited or no therapeutic options (unmet needs)?

at most 3 choice(s)

- Provide market protection (protect a new medicine from competition)
- Provide intellectual property protection
- Provide data protection (protection of the data related to a medicine's clinical trials)
- Agree on a common understanding on what are the areas of unmet need in the EU
- Funding more targeted research at EU level
- Funding more targeted research at national level
- Provide national schemes to support companies economically
- I don't know / no opinion
- Other (please specify)

The health sector is becoming more digitised, thanks to the increased availability and collection of health data from sources such as electronic health records, patient and disease registries and mobile apps (i.e. real world data) and through the use of artificial intelligence (AI) (i.e. systems that display intelligent behaviour and the use of complex algorithms and software in the analysis of complex health data). These developments, combined with real world data are transforming health, including the discovery of medicines.

12. Which **opportunities** do you see in digital technologies (such as artificial intelligence and use of real world data) for the development and use of medicines?

600 character(s) maximum

AI opens up opportunities for companies to use digital technologies in early stage drug discovery, clinical trial design & enrollment, and commercial marketing.

Digital health/technology transforms the patient experience in clinical research, thereby improving the recruitment, engagement and retention in studies while increasing the power and sensitivity of data. RWE can be a viable option to provide pivotal evidence of treatment benefit in areas of high unmet needs. It can provide valuable evidence when combined with pivotal clinical trial data to show the effectiveness of a given treatment.

13. Which **risks** do you see in digital technologies (such as artificial intelligence and use of real world data) for the development and use of medicines?

600 character(s) maximum

The main risk is not to capitalise on these advances. Multiple factors contribute to a slower adoption of these technologies:

- data governance and accessibility – GDPR is a global standard, but its current implementation creates burdens for accessing of data necessary to drive innovation;
- public trust – build on the recognition of GDPR to increase public trust on data use for R&D;
- data interoperability – eHealth data, RWE/D for use in clinical trials and similar require standardised platforms to encourage uptake;
- skills and IT infrastructures at national and regional level

Continuous manufacturing, advanced process analytics and control, 3D printing and portable/modular systems, may revolutionise the way medicines are manufactured.

14. Are you aware of any obstacles in the EU in taking advantage of technological progress in the manufacturing of medicines?

- Yes
- No
- I don't know

If yes, could you please specify.

500 character(s) maximum

- No strategic approach to support innovative manufacturing in the EU
- Lack of investment to support SMEs to build specialised facilities to produce next generation biotechnology-derived medicines;
- Appropriate data governance structures to enable data flow necessary to achieve smart logistics /manufacturing platforms;
- (Digital) skills and appropriately trained workforces.

Clinical trials are investigations in humans to discover if a new medicine is safe and effective. Clinical trials can also be used to test if a new treatment is more effective and/or safer than the standard treatment. Finally, so called “pragmatic clinical trials” can be conducted to compare the safety and effectiveness of different standard treatments in real world setting.

15. How could clinical trials in the EU be driven more by patients' needs while keeping them robust, relevant and safe for participants?

at most 3 choice(s)

- By providing more national support for the conduct of so-called "pragmatic trials" with the aim to optimise treatment to patients
- By better coordination for larger trials comparing different treatment strategies (covering medicines and other treatments such as surgery, radiotherapy, physiotherapy)
- By providing support for non-commercial organisations to conduct clinical trials in fields where financial interest is weaker
- By involving patients' experiences in early phases of medicine design (e.g. factor-in how the disease affects their lives and develop medicines to target symptoms that are particularly important to patients)
- By designing more trials that collect information on medicine tolerability or the impact of a treatment on the quality of life
- By taking into consideration during the design of a trial the burden of trial participation on patients' life
- Other (please specify).

Certain medicines are developed based on genes, cells or tissue engineering. Some of these products are developed in hospitals. These are covered by the notion of advanced therapy medicines.

16. Is the current legal framework suitable to support the development of cell-based advanced therapy medicines in hospitals?

- I strongly agree
- I partially agree
- I disagree
- I don't know

* If you responded partially agree or disagree, please provide examples of changes that, in your view, would be required to support the development of these products.

500 character(s) maximum

Yes, through the hospital exemption. EuropaBio generally support its use and remind that actions remain necessary to protect the patient's right to safe treatments and address the inconsistent interpretation and implementation of the HE. The Commission should make clear that any medicinal product approved via the ATMP Regulation should take precedence, and, in collaboration with the EMA and NCAs, provide clear harmonised guidance for consistent interpretation and use of the HE across the EU.

Environmental sustainability of medicines and health challenges

Residues of several medicines have been found in surface and ground waters, soils and animal tissues across the Union. As of yet, no clear link has been established between medicine residues present in the environment and direct impacts on human health. However, the issue cannot be ignored and there is a need for a precautionary approach.

17. What actions at EU level do you consider most effective in limiting the negative environmental impact of medicines?

at most 3 choice(s)

- Cleaner manufacturing processes
- Enhanced application of the polluter pays principle
- Review the way the Environment Risk Assessment of a medicine is conducted and its consequences on the authorisation process
- Clear labelling of environmental risks to allow informed choices among equivalent therapeutic options
- Reference to environmental risks in advertising for over-the-counter medicines
- Make medicines known to pose an environmental risk available by prescription only
- Strict disposal rules for unused medicines
- Prescribe medicines only when it is absolutely necessary (more prudent use)
- Medicines dispensed to patients in the quantity actually needed (e.g. number of pills, volume of solution)
- Enhanced wastewater treatment if certain residues could be better removed
- Other (please specify)

Antimicrobial resistance (AMR) is the ability of microorganisms (such as bacteria, viruses, fungi or parasites) to survive and grow in the presence of medicines. It reduces progressively the effectiveness of antimicrobials and is caused, among other things, by extensive and improper use of antimicrobial medicines. Antimicrobials include antibiotics, which are substances that fight bacterial infections. AMR can lead to problems such as difficulties to control infections, prolonged hospital stays, increased economic and social costs, and higher risk of disease spreading. AMR is one of the most serious and urgent public health concerns.

18. Which actions do you think would have the biggest impact on fighting AMR concerning the use of medicines for patients?

at most 3 choice(s)

- More prudent use of antimicrobials (if necessary through restrictions on prescriptions)

- Improve the treatment of wastewater and/or manure to lower the levels of antimicrobials
- Raise citizens' and healthcare practitioners' awareness by informing them on appropriate use of antimicrobials and the correct disposal of unused medicines
- Introduce an obligation to use diagnostic tests before prescribing antimicrobials, for example to verify whether it is a bacterial infection before prescribing antibiotics and to define the most adequate antibiotic
- Public finance research and innovation on new antimicrobials, their alternatives and diagnostics
- Encourage public health campaigns that prevent infection through better general health including increased immunity
- Encourage public health campaigns that prevent infection through the use of vaccines
- Encourage better hygiene measures in hospitals
- Other (please specify)
- I don't know

Innovation in antimicrobials is limited. For example, no new classes of antibiotics have been discovered for decades. Restricting the use of antibiotics to minimise the risk of developing resistance is a commercial disincentive for investment, as potential investors are concerned that their investment will not be profitable.

19. Where, in your view, should the EU focus its support for the creation of new antimicrobials or their alternatives?

at most 2 choice(s)

- Support academia for researching/discovering new antimicrobials or their alternatives
- Support industry for developing new antimicrobials or their alternatives
- Provide specific support to small and medium-sized enterprises (SMEs)
- Other (please specify)
- I don't know

Please elaborate your reply.

100 character(s) maximum

All 3 should be pursued. At EU level, specific pull incentives should be implemented.

Health threats such as the coronavirus disease test the limits of public health systems, the pharmaceutical industry and of the pharmaceutical legislation. From the beginning of the coronavirus (COVID-19) pandemic, the EU has taken measures to coordinate a [response](#), which includes actions ensuring the availability of medicines.

20. How has the coronavirus (COVID-19) pandemic affected you in relation to access to medicines and treatments?

600 character(s) maximum

COVID-19 has revealed the critical role of medicines and vaccines in dealing with health emergencies and the necessity of an agile regulatory response. It has also resulted in limitations to chronic patients accessing their treatments in hospitals and interruptions in the conduct of clinical trials.. Biotechnology companies responded by finding alternative solution/home-based treatment. Healthcare systems should anticipate such interruptions to treatment in the future affecting all patients and not only COVID-19 patients.

21. In your opinion and based on your experience, what can the EU do to prepare for and manage such a situation better in the future in relation to pharmaceuticals?

600 character(s) maximum

Based on the experience of the Covid-19 pandemic, there is an obvious need for long-term healthcare investment. The biotechnology sector is a solution provider both through its technology and its industrial sector which are agile and cutting-edge. It is of utmost importance to nurture the bio-science sector and stimulate innovation to meet emerging patient needs and potential new pandemic threats EuropaBio sees the Pharmaceutical Strategy as a crucial chance to strengthen the EU life sciences & biotechnology ecosystem; protecting citizens' health and enhancing EU's competitiveness globally.

Summary question

22. While the Commission is working on improving the EU pharmaceuticals framework, which areas of work do you find most urgent?

at most 3 choice(s)

- Improve patients' access to medicines
- Reduce shortages
- Help national authorities ensure affordability for patients and increase health systems sustainability
- Support innovation for unmet needs

- Use of digitalisation to develop medicines
- Help reduce anti-microbial resistance
- Reduce the dependency on essential active ingredients and medicines produced outside the EU
- Environmental sustainability of medicines
- I don't know
- Other (please specify)

23. If you were asked before the coronavirus (COVID-19) pandemic, would you have responded differently to any of the previous questions?

- Yes
- No
- I don't know

24. Is there anything else you would like to add that has not been covered in this consultation?

900 character(s) maximum

EuropaBio sees 8 critical pillars to unlock life sciences & biotechnology's potential to help achieve a healthier, more resilient & sustainable EU.

- 1.Capital and financing for cutting-edge innovative solutions by start-ups and SMEs
- 2.Skills and labour for a progressive knowledge-based economy
- 3.R&D and innovation for competitive innovation
- 4.IP and incentives for a sustainable biotech business model
- 5.Manufacturing for sustainable production and circular (bio)economy
- 6.Digitalisation accelerating research and innovation
- 7.Regional development for jobs and growth creation
- 8.Global competitiveness for sustainable recovery and competitive sustainability

EuropaBio calls on the Commission to align its Pharma Strategy with the Industrial Strategy. Within the existing regulatory framework, all its objectives can be achieved. The EU must be at the forefront of the global post-COVID 19.

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