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

* Scope

International Local National Regional

* Organisation name

*255 character(s) maximum*

* 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](http://ec.europa.eu/transparencyregister/public/homePage.do?redir=false&locale=en). It's a voluntary database for organisations seeking to influence EU decision- making.

* 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

Citizen Patient

Care provider

We assume this category to include replies from the perspective of healthcare services. Are you replying only from the perspective of hospital procurement of healthcare goods?

Yes No

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
* Surname
* Email (this won't be published)
* Country of origin

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

|  |  |  |  |
| --- | --- | --- | --- |
| Afghanistan | Djibouti | Libya | Saint Martin |
| Åland Islands | Dominica | Liechtenstein | Saint Pierre |
|  |  |  | and Miquelon |

Albania Dominican Republic

Lithuania Saint Vincent and the Grenadines

Algeria Ecuador Luxembourg Samoa

American Samoa

Egypt Macau San Marino

Andorra El Salvador Madagascar São Tomé and

Príncipe

Angola Equatorial Guinea

Malawi Saudi Arabia

Anguilla Eritrea Malaysia Senegal Antarctica Estonia Maldives Serbia

Antigua and Barbuda

Eswatini Mali Seychelles

Argentina Ethiopia Malta Sierra Leone

Armenia Falkland Islands Marshall Islands

Singapore

Aruba Faroe Islands Martinique Sint Maarten Australia Fiji Mauritania Slovakia Austria Finland Mauritius Slovenia Azerbaijan France Mayotte Solomon

Islands

Bahamas French Guiana Mexico Somalia

Bahrain French Polynesia

Bangladesh French Southern and Antarctic Lands

Micronesia South Africa

Moldova South Georgia and the South Sandwich Islands

Barbados Gabon Monaco South Korea Belarus Georgia Mongolia South Sudan Belgium Germany Montenegro Spain

Belize Ghana Montserrat Sri Lanka

Benin Gibraltar Morocco Sudan Bermuda Greece Mozambique Suriname

Bhutan Greenland Myanmar

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Bolivia Grenada Namibia Sweden

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Bosnia and Herzegovina

Guadeloupe Nauru Switzerland

Guam Nepal Syria

Botswana Guatemala Netherlands Taiwan Bouvet Island Guernsey New Caledonia Tajikistan Brazil Guinea New Zealand Tanzania

British Indian Ocean Territory

Guinea-Bissau Nicaragua Thailand

British Virgin Islands

Guyana Niger The Gambia

Brunei Haiti Nigeria Timor-Leste

Bulgaria Heard Island and McDonald Islands

Niue Togo

Burkina Faso Honduras Norfolk Island Tokelau

Burundi Hong Kong Northern Mariana Islands

Tonga

Cambodia Hungary North Korea Trinidad and

Tobago

Cameroon Iceland North Macedonia

Tunisia

Canada India Norway Turkey

Cape Verde Indonesia Oman Turkmenistan Cayman Islands Iran Pakistan Turks and

Caicos Islands

Central African Republic

Iraq Palau Tuvalu

Chad Ireland Palestine Uganda

Chile Isle of Man Panama Ukraine

China Israel Papua New Guinea

United Arab Emirates

Christmas Island

Italy Paraguay United Kingdom

Clipperton Jamaica Peru United States

Cocos (Keeling) Islands

Japan Philippines United States Minor Outlying Islands

Colombia Jersey Pitcairn Islands Uruguay Comoros Jordan Poland US Virgin

Islands

Congo Kazakhstan Portugal Uzbekistan Cook Islands Kenya Puerto Rico Vanuatu Costa Rica Kiribati Qatar Vatican City Côte d’Ivoire Kosovo Réunion Venezuela Croatia Kuwait Romania Vietnam Cuba Kyrgyzstan Russia Wallis and

Futuna

Curaçao Laos Rwanda Western Sahara

Cyprus Latvia Saint Barthélemy

Czechia Lebanon Saint Helena Ascension and Tristan da Cunha

Yemen 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](https://ec.europa.eu/info/law/better-regulation/specific-privacy-statement_en)

# 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*

1. 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

# 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.*

1. 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*

1. 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).

*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.*

1. 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*

*In recent years, there has been an* [*increase*](https://www.ema.europa.eu/en/documents/annual-report/2018-annual-report-european-medicines-agency_en.pdf) *in the number of medicines withdrawn from the market upon decisions by the manufacturers.*

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

No

If yes, please elaborate.

*500 character(s) maximum*

1. 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*

1. 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*

*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*](https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview) *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.*

1. 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*

# 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*](https://ec.europa.eu/programmes/horizon2020/)*,* [*Innovative Medicines Initiative*](https://www.imi.europa.eu/) *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.*

1. 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*

*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).*

1. 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)

Please elaborate your reply.

*100 character(s) maximum*

*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.*

1. 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*

1. 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*

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

1. 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*

[*Clinical trials*](https://www.ema.europa.eu/en/glossary/clinical-trial) *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.*

1. 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).

Please elaborate your reply.

*100 character(s) maximum*

*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.*

1. 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*

# 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.*

1. 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)

Please elaborate your reply.

*100 character(s) maximum*

*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.*

1. 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

Please elaborate your reply.

*100 character(s) maximum*

*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.*

1. 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*

*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*](https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response_en)*, which includes actions ensuring the availability of medicines.*

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

*600 character(s) maximum*

1. 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*

# Summary question

1. 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)

Please elaborate your reply.

*100 character(s) maximum*

1. 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

If yes, please explain how your responses were influenced by the COVID-19 pandemic.

*500 character(s) maximum*

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

*900 character(s) maximum*

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