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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
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- ○ Public authority
- ○ Trade union
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* Organisation name

255 character(s) maximum

American Chamber of Commerce to the European Union (AmCham EU)

* Organisation size
- ○ Micro (1 to 9 employees)
- ◉ Small (10 to 49 employees)
- ○ Medium (50 to 249 employees)
- ○ Large (250 or more)

Transparency register number

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

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* 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)

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

- ○ Yes
- ◉ No

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* Country of origin

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

- Afghanistan
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- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
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- Belarus
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- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan

- 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
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- 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
- North Macedonia
- Norway
- Oman
- Pakistan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
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- Syria
- Taiwan
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- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands

- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
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- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
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- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
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- Yemen
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- Zimbabwe

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

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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

76% of the APIs used to manufacture innovative medicines in Europe is sourced in the EU, while 11% comes from the US. AmCham EU advocates for a holistic approach to strengthening manufacturing and supply chain resilience. We encourage the EU to implement a comprehensive set of measures, including:
-Expand advanced manufacturing and related technologies capabilities and capacity in the EU
-Reduce regulatory burdens/streamline regulations
-Sustain and grow the European skilled workforce
-Strengthen IP standards in trade agreements with other countries and trade policies that focus on diversity of supply
-Maintain a strong IP and regulatory incentives framework
-Maintain and expand regulatory flexibilities developed during the COVID crisis to enable faster access to critical products

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

Increased international regulatory convergence to ensure high quality standards (e.g., ICH).

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

Manufacturers and other stakeholders should be prepared to tackle potential shortages. However, we need to identify and address their real root causes, which are multi-factorial and involve all supply chain stakeholders. These include e.g. parallel trade, but also unilateral nationalistic actions by governments, such as export restrictions and local stockpiling.

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
- [x] Transparent information exchange among authorities on medicine stocks available in each country
- [ ] Increased cooperation among public authorities/national governments on shortages

- [x] 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
- [x] Other (please specify).

Please elaborate your reply.

500 character(s) maximum

Work more closely with like-minded partners, notably via future trade agreements with the U.S.

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 the manufacturer's best interest to reach as many patients as possible, in as many countries as possible. However, many factors come into play beyond a company's control, which contribute to products not being available in a given country: e.g., regulatory requirements, reimbursement process, lack of demand /need. It is unclear what 'make available' means in reality. We do not believe an 'obligation to launch' to be an appropriate nor proportionate policy to expand access.

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

Reasons for market withdrawals are complex and multifactorial, and do not necessarily affect patient care negatively, for example when alternative treatments are available. In some cases, they relate to the lack of (or very low) demand, weak economic incentives to keep a product on the market, regulatory requirements, efforts and costs for product maintenance (renewal, variations, inspection, new regulations), as well as pricing and reimbursement issues in Member States.

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

- [ ] Yes
- [x] No

If you wish, please elaborate your reply.

500 character(s) maximum

Cost that patients pay for medicines is ultimately set by governments and insurers. Healthcare costs differ by country, reflecting the local health system, including for out of pocket costs that individual patients have to bear. We flexibility in setting local prices to improve patient access to our medicines, whilst providing manufacturers the ability to discover next generation cures. Access models should be refocused on the value treatments bring to patients.

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

- [x] Yes
- [ ] No
- [ ] I don't know

If you wish, please elaborate your reply.

500 character(s) maximum

Correlating medicine prices solely with costs related to development and manufacturing (cost-plus) does not properly capture all elements to be factored in when looking at the price of a medicine. Such narrow approach would ultimately reward high-cost manufacturing/R&D, not high-value products and would likely discourage future investments in cutting-edge innovation. AmCham EU calls for a shift towards value-based approaches, where a medicine is priced based on how well it works for patients.

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)

- [x] 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
- [x] 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
- [x] Other

* Please explain.

100 character(s) maximum

Enable and support implementation of novel payment, pricing models and MEAT-based procurement.

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

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

Digital technologies open up opportunities to improve early stage drug discovery, clinical trial design and enrollment, diagnosis, patient monitoring and ultimately health outcomes. For example, they can replace /replicate clinical trials and arms when possible through RWE and optimize the patient experience through decentralized approaches.
In addition, COVID-19 has shown how existing digital tools can enable more patients to be treated while observing social distancing measures. These need to be supported with adequate reimbursement policies /financial incentives.

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

Advances in technology should not be held back by gaps or unclear provisions in the existing regulation. For example, digital items that constitute Medical Device Software (MDSW): the medical devices legislation and associated guidance are not necessarily envisaging true artificial learning.
Another risk is the lack of digital strategy and utilization in general. The standardization, privacy and security of data will always be a risk and should be a priority for regulatory guidance and industry processes.

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

Regulations generally are sufficiently flexible to enable technological progress; however, overly conservative interpretation by the Union and Member States can result in barriers to innovation - harmonisation of legislation across Member States would help. Scientific engagement between regulators and industry needs to be improved. EU International competitiveness is hindered by barriers to innovation and its attractiveness as a manufacturing location, affecting companies investment decisions.

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
- [x] 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)
- [x] 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
- [x] Other (please specify).

Please elaborate your reply.

100 character(s) maximum

More flexible clinical trials design, especially for complex rare and ultra-rare diseases.

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

The Hospital Exemption (HE) has been interpreted differently across Member States, creating unnecessary fragmentation. The European Commission should develop clear guidelines to clarify the scope and exact interpretation of the HE, that is to limit HE to scenarios in which no licensed product is available for the same indication.

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)

- [x] Medicines dispensed to patients in the quantity actually needed (e.g. number of pills, volume of solution)
- [x] 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)
- [x] 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
- [x] 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
- [x] 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)

- [x] Support academia for researching/discovering new antimicrobials or their alternatives
- [x] 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

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

The COVID-19 pandemic has shown the critical role industry and innovation can play in dealing with emergency health situations. The whole sector has mobilised to find ways to share its expertise and collaborate with governments to ensure greater access and availability of pharmaceuticals to patients. For example: manufacturing therapies at risk and at scale, voluntary licensing, donations, public-private collaboration to accelerate research, access through compassionate use etc. PPEs and training in their use for continued access to healthcare facilities is also key.

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

AmCham EU believes that the EU should maintain an ecosystem friendly to innovation. Any policy-making should be evidence-based and made in dialogue with pharmaceutical industry. Global supply chains should remain open and diversified. Collaboration with the US should be strengthened as it brings benefits to Europe's industry and its citizens.

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)

- [x] Improve patients' access to medicines

- [ ] Reduce shortages
- [ ] Help national authorities ensure affordability for patients and increase health systems sustainability
- [x] Support innovation for unmet needs
- [ ] Use of digitalisation to develop medicines
- [x] 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

Resilient healthcare systems and collaboration between Member States and with industry have shown vital to tackle the COVID-19 pandemic. The recovery of the European healthcare systems are now essential for a successful European pharmaceutical strategy. Health Information Systems to classify patient groups anonymously could be one of several tools to measure a patient’s burden of illness and risk during this and future pandemics by identifying at risk cohorts in a population. Further, it can help address the treatment backlog that has been created as a result of COVID-19 by increasing focus on GIRFT (Getting It Right First Time) programs as healthcare systems try to ensure their efforts and energies are not diluted with the treatment of re-admissions.

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