Contribution ID: 635c3c0e-6c83-466d-ad39-25c1a6852fed
Date: 31/08/2020 15:40:45

# 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*

GIRP - European Healthcare Distribution Association

* 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.

0757172464-29

* 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

* First name

Monika

* Surname

Derecque-Pois

* Email (this won't be published)

girp@girp.eu

* Country of origin

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

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Djibouti
- 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
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- 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
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Palau
- 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
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

* 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*

GIRP recommends tracking for transparency of shortages of APIs on European level to improve earliest information of unavailability of medicines for the supply chain at EU level. GIRP also supports the proposition put forward by MEP Nathalie Colin-Oesterlé in the European Parliament INI report on medicine shortages that investments in the manufacture of active ingredients and finished products in the EU be a criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU

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*

Channeling the distribution of medicines via full-service healthcare distributors (FHSD), who maintain high quality standards according to GDPs ensuring appropriate and continued supplies of medicinal products to points of dispense. These standards include careful monitoring of temperature during storage and transport, high training standards for responsible staff, detailed documentation and self-inspections and the utilisation of end-to-end verification of medicines to ensure patient safety.

## 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*

With its members being directly affected by the increasing number of medicines in shortage, GIRP has been consistently monitoring the issue over the years. Our findings show that shortages in the EU have increased in many countries, e.g. from 269 in 2007 to 761 in 2019 in Spain, or from 44 in 2008 to 871 in 2018 in France. Hurdles to access to medicines include supply quotas or selective distribution models and are continuing to prevent patients from gaining access to medicines.

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

*at most 3 choice(s)*

- [x] 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
- [ ] 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*

1. An early warning system for anticipated and existing shortages, involving all supply chain stakeholders; 2. Harmonisation of root causes (see annex); 3. MS to recognise right for full-service healthcare distributors to be appropriately and continuously supplied by MAHs with the full range of products in order to fulfil the needs of patients in the MS; 4. Additional EU and national safety stocks for essential medicines should be held in cooperation with full-service healthcare distributors.

*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*

Multi-country packs could be made available in countries where the product is not actively marketed leading to a genuine EU Single Market for medicines. Currently, there are too many national specificities that result in a delay in products being marketed in all MS. Measures of parallel trade should be taken in respect of the accessibility of medicines throughout Member States.

*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*

An analysis by GIRP of root causes of shortages (April 2020) based on public databases showed that in many EU countries, market withdrawal is one of the major reasons of shortages. The data analysis shows that in CZ 8%, in IT 30%, in HR 40% and in HU 56% of shortages are caused by market withdrawal. The issue is especially pronounced in Eastern countries, where the average price of a medicine is lower than in most of Europe.

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*

Patients in countries with low-priced medicines are often faced with the withdrawal of a product from their market. Equally patients can sometimes not access treatments due to extremely high-priced medicines. In some countries, patients rely on parallel trade to benefit from a treatment which would otherwise not be available in their market. National measures which restrict intra-community exports present challenges for those small markets in particular which do rely on parallel imports.

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

*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
- [x] Facilitate, market entry and a healthy market functioning for generics and biosimilars
- [x] 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*

Savings through bundled orders through Full-Service Healthcare Distributors (see attachment)

## 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)*

- [x] Make the legislative framework more adaptive to new technologies and advances in science

- [ ] Provide more public funding for research
- [x] Support (including through funding) private-public partnerships
- [x] 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
- [x] Other (please specify)

Please elaborate your reply.

*100 character(s) maximum*

Incentivise the digitalisation of the healthcare sector

*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*

- Forecasting of medicines demand and improved market predictability
- Improved patient adherence and compliance
- Improved patient information
- Improved access to healthcare providers and distributors
- Coherence between all stakeholders of the patient care ecosystem
- Personalised medicine
- Reduced lead-times

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*

- Data ownership: Set mechanisms for data owners to follow journey and use of data and tools allowing for dynamic consent. It has to be secured, that who generates the data owns the data.
- Security risks, including leakage of data and / or cyberattacks.
- Lack of digital literacy

*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*

- Regulation not incentivising innovation.
- Digital skills shortage.
- Lack of infrastructure and adjacent regulation (e.g. 3D printing).
- Need for data standardisation.

*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

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

Please elaborate your reply.

*100 character(s) maximum*

EU Green Deal should support a more positive environmental footprint of the EU pharmaceutical sector

*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)
- [x] 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*

- Sharp rise in demand (2-3 times normal levels) followed by critically low activity
- Export bans
- Border closures
- Lack of PPE, uncoordinated and competitive governmental purchasing plans
- Non-recognition as critical infrastructure in some countries
- Lockdown measures impacting staff, service levels

FSHD developed coordinated contingency plans and aligned their quality and risk management systems, allowing for the deployment of measures at record short notice. They proved their value in acting fast to optimise allocation of available quantities of medicines to dispensing sites.

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*

- EU Medicines stockpile via FSHD, who employ advanced management systems to ensure optimised rotation of stocks (First Expired First Out)
- MAHs to give early warning to NCAs, the EMA and all supply chain partners as soon as it is foreseeable that stock levels of medicines are insufficient to cover demand
- FSHD recognised a critical infrastructure
- FSHD competence should be used for distribution to hospitals
- Better solidarity among MS and information sharing among stakeholders
- Enforce the right-to-be-supplied for FSHD as safe-guarding to their PSO.

## 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
- [x] 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
- [x] 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*

Full-service healthcare distributors are crucial to the medicines supply chain as they are the only ones to assume a financing function towards manufacturers and pharmacies. On average, they finance medicines worth 11.8 bn for 47 days, 7.8 times a year. They guarantee the continuous supply of all medicinal products and also secure the cash flow of the social insurers. Despite their crucial function for healthcare systems, distributors experience extreme margin pressure and are reaching the limit of their sustainability. E.g. in France, only 2.2% of the price of a medicines go to the distributor (or 2.7% in IT) - an unsustainable remuneration given the high service costs related to bundling and pre-financing the majority of medicines distributed in the EU and an issue that, if left unaddressed, could further exacerbate the severity of shortages in the future.

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