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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

English

*I am giving my contribution as

Non-governmental organisation (NGO)

*Organisation name

255 character(s) maximum

Pharmaceutical Group of the European Union (PGEU)

*Organisation size

Micro (1 to 9 employees)

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.

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*Which stakeholder group do you represent?

Healthcare professional

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

- ○ Yes
- ◉ No

*First name

Jan

*Surname

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*Country of origin

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

Belgium

*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.
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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

We support incentivising the return of production to Europe of medicines, active pharmaceutical ingredients (APIs) and other excipients which are identified to be particularly critical and vulnerable in terms of supply. This can be done through developing a fair framework for pharmaceuticals which puts guarantees for security of medicines supply for patients at the core of medicines regulation and incentives in the EU.

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

between 1 and 1 choices

- [x] 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.

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

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Medicine shortages occur across all healthcare settings and involve both
essential life-saving medicines and very commonly used drugs. Community
pharmacists are very concerned about this phenomenon, which can compromise
patients' health. Moreover, pharmacies and pharmacists invest a lot of resources
dealing with shortages which constitutes not only a financial burden but also a
loss of opportunity to spend time with other patient-centred tasks and to
improve the quality of care.
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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
- [ ] Transparent information exchange among authorities on medicine stocks available in each country
- [x] 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

In addition to 'inform on and make available to patients suitable substitutes for medicines that are at risk of shortage', pharmacist should also be allowed to substitute with the most appropriate alternative as part of a shared decision-making process with prescribers and patients or in accordance with national protocols where appropriate.

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

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.

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

- (●) Yes
- ( ) No

If yes, please elaborate.

500 character(s) maximum

Market withdrawals for commercial reasons mostly affect cheaper and older products. Especially when commercial withdrawals affect medicines for which no or little alternatives are available on the market there should be sufficient safeguards in place to ensure continuity of access for patients and timely communication to healthcare professionals and patients. One of the solutions could be to allow pharmacists to prepare a compounded formulation as a replacing treatment where possible.

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

Community pharmacists are often faced with patients who are not able to pay for their medicine due to the high co-payment. This can result both from an inappropriately high price demanded by pharmaceutical companies and/or insufficient reimbursement by the healthcare system. Also the negative financial impact of medicine shortages on patients should be compensated through appropriate reimbursement provisions. The resource investment by pharmacies should equally be recognized and valued.

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

- ○ Yes
- ◉ No
- ○ I don't know

If you wish, please elaborate your reply.

500 character(s) maximum

It is challenging to assess whether medicines pricing is always justified taking into account their R&D and manufacturing costs, due to the asymmetry of information. There is evidence that high price for new medicines is not always justified by their effectiveness in combating the targeted disease. At the same time, low pricing strategies can also be considered unjustifiable as they may create barriers to market entry, thereby jeopardizing both competition and access to medicines.

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.

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

at most 3 choice(s)

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

- [ ] I don't know
- [ ] Other

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.

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)
- [x] 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
- [x] 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 have the potential to deliver more efficient, sustainable and high-quality healthcare services to patients, supporting and complementing their face-to-face interaction with healthcare providers. They can support healthcare professionals, including community pharmacists, to provide more personalized services and treatment to patients and robust, evidence-based information on issues related to therapies while promoting safe and rational medicines use. It also allows them to better follow up with at-risk patients on their conditions and to monitor their progress.

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

There are still several challenges to overcome in terms of usability, quality and interoperability of data collected as well as the quantity of those data. It has to be ensured that patient data must be processed under a high level of data protection standards within trustworthy infrastructures that enable the access to secure data services. It also has to be ensured that these technologies shall be accompanied by pharmacists' professional advice to improve the promotion of patient safety, therapy effectiveness and offering the highest standard of pharmacy services to patients.

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

For the possible development of 3D-printing of medicines in community and hospital pharmacies, a tailor-made regulatory framework would need to be developed in case this technology would prove to be able to produce safe, effective and value added therapies to complement existing more traditional medicines. Currently there is also lack of financial investment and reimbursement by the health insurance for this technology.

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.

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
- [x] 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

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Stimulating MAHs to commercialise the smallest package that is relevant for a specific treatment
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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)

- [x] 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
- [x] 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
- [x] Other (please specify)
- [ ] I don't know

Please elaborate your reply.

100 character(s) maximum

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Close involvement of community pharmacists in national AMR action plans and vaccination strategies.
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Innovation in antimicrobials is limited. For example, no new classes of antibiotics have been discovered for decades. Restricting the use of antibiotics to minimise the risk of developing resistance is a commercial disincentive for investment, as potential investors are concerned that their investment will not be profitable.

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

at most 2 choice(s)

- [ ] Support academia for researching/discovering new antimicrobials or their alternatives
- [ ] Support industry for developing new antimicrobials or their alternatives
- [ ] Provide specific support to small and medium-sized enterprises (SMEs)
- [ ] Other (please specify)
- [x] 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 (https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response_en), 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

Pharmacies have faced temporary shortages of certain medicines in high demand due to COVID-19. Due to several ongoing initiatives from EU, NCAs and the medicines supply chain - including pharmacies, the overall impact on medicines supply seems to be limited. We can however not exclude possible further supply disruptions in the coming weeks and months that can worsen the problem of shortages we are already facing. In addition, the sourcing prices of many of these products have raised significantly across Europe, putting pressure on the economic viability of pharmacies.

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 MS should maximize the scope of community pharmacy practice and enable pharmacists to offer rapid, effective and safe solutions to meet patients' needs and maintain continuity of services. Further expansion of community pharmacy services should be considered by introducing appropriate legislation and/or financial support, for instance to enable the home delivery of medicines to patients who are not able to physically visit the pharmacy, the safe renewal of repeat prescriptions for chronic medications and ensuring access to certain hospital medicines in pharmacies for patients' who need them

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
- [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

The promotion of rational use of medicines should be at the core of any policy aiming to enhance the affordability and outcomes of medicinal therapies for health systems. This can be implemented by appropriately remunerating cost-effective healthcare services which show to improve therapy outcomes and adherence and minimising the risks related to using medicines. Examples of such services are adherence-focused new medicines services, medicines use reviews, common ailment and chronic disease management services. Together with the promotion of the rational use of medicines also increasing the share of healthcare budgets’ investments in prevention strengthening primary care systems should be strongly encouraged. Lastly, generics uptake by community pharmacy should be incentivised to make medicines more affordable while rewarding community pharmacists for this important service.

You may upload a position paper here.

PGEU_Position_Paper_on_the_Pharmaceutical_Strategy_for_Europe.pdf

Contact

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