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.

International dependency and manufacturing

SECTION 1
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

Procurement criteria/requirements:
- Sustainability: ambitious targets for (i) AMR/water (ii) Carbon emissions
- Deep supply chain: allocate points for EU-made (i) FDF (ii) API (iii) Intermediates
- Strategic supply chain: local content rules for products categorized as WHO essential medicines

EU grant programme & state aid rules:
- Saving, upgrading or expanding existing & constructing new EU production sites
- Develop & optimize pharmaceutical manufacturing processes

Greening pharmaceuticals manufacturing:
- State aid or tax breaks to achieve highest sustainability goals (e.g. in line with Paris Accord)
- Application of higher EU environmental standards on pharmaceuticals imports
- Support EU carbon border tax to increase price of carbon-intensive imports of FDFs, APIs, Intermediates

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

500 character(s) maximum

Focus on actions that drive up quality of products and production processes. Create a level playing field with respect to GMP enforcement in non-EU countries and FMD implementation in the distribution chain. Increase inspectorate resources. Systematically incentivise EU-based development and deployment of green pharmaceutical manufacturing technologies. Map manufacturing footprint of FDFs, API, intermediates in the EU.

Access to affordable medicines

SECTION 2
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

Centrient produces FDFs, APIs and intermediates vital to WHO's 'essential medicines' and critical 'Access' antibiotics. We firmly believe that the EU and its member states must ensure an attractive pharmaceutical marketplace and conditions that guarantee the reliable availability of affordable essential drugs.

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

at most 3 choice(s)

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

500 character(s) maximum

Predictable pricing and reimbursement policies and longer-term supply contracts that justify investments in production capacity and presence across markets. For essential medicines, this could be coupled with stronger supply security obligations on producers. EU grant schemes to offset higher CAPEX costs for manufacturing sites in the EU compared to third countries.

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

Many generic companies are not present in all EU countries which makes it challenging to launch the product across the EU - both from a cost perspective and from an operational perspective (e.g. artwork in all EU languages, ensuring pharmacovigilance, etc) From a regulatory perspective in terms of off-patent, inexpensive generic medicines such a step would only makes sense if EU-wide pricing (and possibly procurement) applied for such products.

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

Withdrawals of off-patent medicines are a sign of market unsustainability. EMA data shows increase in number of withdrawals for commercial reasons, indicating that P&R, procurement and country pharmaceutical policies are not conducive to sustained competition, leading to market concentration & increasing risk of shortages. E.g. in tender markets, little incentive to keep product on the market if no tender was won. Increasing regulatory rqmts lead to add'l costs disproportionate to market share.

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

Drug shortages have afflicted many countries in Europe and represent a symptom of an unsustainable market. Healthcare budgets in Europe have been under pressure. National authorities have adopted short-term cost-containment measures for off-patent medicines despite their competitive prices and relevance for patient care, while regulatory costs and burden has increased. This has caused manufacturers to withdraw medicines, resulting in the increased risk of shortages for patients.

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

Most EU member states have dedicated regulation for off-patent medicines designed to minimise prices of life-saving medicines. However, price-only tenders tend to favour production in third countries to lower standards, reduce the number of available suppliers, and hamper green innovation, to the detriment of EU interests. The addition of new rqmts (e.g. environmental footprint or supply chain security) will require a broadening of procurement criteria to Most Economically Advantageous Tenders.

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
- [x] 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
- [ ] 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

EU HTA guidelines for essential medicines would help establish actual value and sustainable prices.

Innovation in early development and authorisation

SECTION 3
Innovation in early development and authorization

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

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

at most 3 choice(s)

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

Please elaborate your reply.

100 character(s) maximum

Dedicated EU funding for R&D&I in innovative & green pharmaceutical manufacturing technologies.

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)

Please elaborate your reply.

100 character(s) maximum

N/A

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 can make pharmaceutical supply chain management and production processes greener, safer and more cost-efficient. New digital data will complement existing knowledge and offer new ways of evidence. This data should be further used to avoid unnecessary repetition of studies and generation of data not essential for regulatory purposes.

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

N/A

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

The EU's green & digital "twin transition" underestimates the importance of life sciences as a third pillar to this strategy. R&D&I in advanced life science technologies and processes will be a key enabler for EU leadership in pharmaceuticals. Our proprietary enzyme technology is a positive example of how life science innovation can mitigate anti-microbial resistance, environmental footprints, and reliance on third party suppliers. Supporting digital technologies is necessary but not sufficient.

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 o p t i m i s e 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 o r g a n i s a t i o n s to conduct clinical trials in fields where financial interest is weaker
- ☐ By involving patients' experiences in early phases of medicine design (e.g. factor-in how the disease affects their lives and develop medicines to target symptoms that are particularly important to patients)
- ☐ By designing more trials that collect information on medicine tolerability or the impact of a treatment on the quality of life
- ☐ By taking into consideration during the design of a trial the burden of trial participation on patients' life
- ☐ Other (please specify).

Please elaborate your reply.

100 character(s) maximum

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

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

Environmental sustainability of medicines and health challenges

ECTION 4
Environmental sustainability of medicines health challenges

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

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

at most 3 choice(s)

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

Please elaborate your reply.

100 character(s) maximum

Grants & public procurement to create "race to the top": compliance w/ PNECs (AMR) & climate accord.

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

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

at most 3 choice(s)

- ☐ More prudent use of antimicrobials (if necessary through restrictions on prescriptions)
- ☐ Improve the treatment of wastewater and/or manure to lower the levels of antimicrobials
- ☐ Raise citizens' and healthcare practitioners' awareness by informing them on appropriate use of antimicrobials and the correct disposal of unused medicines

- ☐ Introduce an obligation to use diagnostic tests before prescribing antimicrobials, for example to verify whether it is a bacterial infection before prescribing antibiotics and to define the most adequate antibiotic
- ☐ Public finance research and innovation on new antimicrobials, their alternatives and diagnostics
- ☐ Encourage public health campaigns that prevent infection through better general health including increased immunity
- ☐ Encourage public health campaigns that prevent infection through the use of vaccines
- ☐ Encourage better hygiene measures in hospitals Other
- ☐ (please specify)
- ☐ I don't know

Please elaborate your reply.

100 character(s) maximum

Ensure compliance of antibiotic manufacturing wastewater w/ PNEC standards of AMR Industry Alliance.

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

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

at most 2 choice(s)

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

Please elaborate your reply.

100 character(s) maximum

Sustain research/repurposing; supply of older antimicrobials & incentives to keep them on market.

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

Centrient was able to meet increased demand for FDFs, APIs and intermediates for life-saving medicines, thanks to the introduction of additional shifts and a ramp-up of production to 100% of

capacity. We are assessing the viability of further increasing our EU manufacturing capacity for green antibiotics at short term. We consider the EU an attractive investment location yet must acknowledge material cost differentials compared to third countries. These create significant cashflow challenges for EU-based investments that can in most cases only be addressed through grant schemes.

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

- Map EU production capacity and supply chain bottlenecks from FDFs through raw materials
- Incentivise supply chain security and EU production capacity (c.f. question 1)
- Ensure procurement practices reflect a variety of factors besides lowest price (e.g. green manufacturing, compliance with PNECs, manufacturing location, etc)
- Safeguard integrity of EU single market
- Strategic stockpiling of WHO essential medicines and/or EU-wide list of critical medicines

Summary question

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

at most 3 choice(s)

- ☐ Improve patients' access to medicines
- ☐ Reduce shortages
- ☐ Help national authorities ensure affordability for patients and increase health systems sustainability
- ☐ Support innovation for unmet needs
- ☐ Use of digitalisation to develop medicines
- ☐ Help reduce anti-microbial resistance
- ☐ Reduce the dependency on essential active ingredients and medicines produced outside the EU
- ☐ Environmental sustainability of medicines I
- ☐ don't know
- ☐ Other (please specify)

Please elaborate your reply.

100 character(s) maximum

Increase reliance on EU manufacturers (in EU & abroad) by pushing highest sustainability standards.

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

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

500 character(s) maximum

The crisis confirms our analysis that Europe should systematically invest in life science technologies to achieve "health sovereignty" with a high grade of innovation in medicines and sustainable & safe production capacity. Incentivizing EU-based production will trigger more manufacturing innovation (to offset higher cost), thereby creating a virtuous circle for Europe. Backed by the right procurement criteria, this will increase supply security, mitigate AMR and reduce environmental footprints.

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

900 character(s) maximum

Centrient Pharmaceuticals is in a unique position to help secure sustainable EU pharmaceutical supply chains:

1. strong portfolio of WHO 'essential medicines' (incl. Amoxicillin, Amoxicillin + Clavulanic acid, Ampicillin, Cephalexin, Cloxacillin)
2. leading non-Chinese B2B merchant supplier of Active Pharmaceutical Ingredients (APIs) in our categories
3. largely independent from third party suppliers thanks to our vertical integration (FDFs, APIs, intermediates) and proprietary technologies
4. successful innovation to mitigate AMR and drastically reduce the environmental footprint of our products and operations

You may upload a position paper here.

The maximum file size is 1 MB

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed