Date: 15/09/2020

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

Organisation name

Knowledge Ecology International Europe (KEI Europe)

Transparency register number

274093330410-67

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

The EU should introduce market entry rewards (MERs), and examine the appropriate burden sharing for funding the MERs, across national boundaries. This is much better than extended monopolies or differential pricing. This can be done for products, but also for manufacturing capacity for APIs. But also, force more transfer of know-how and access to biologic resources, to generic suppliers

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

Stronger enforcement of the marketing authorisation holder responsibilities

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

If you wish, please elaborate your reply.

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

If “Other”, Please elaborate your reply.
500 character(s) maximum

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

If you wish, please elaborate your reply.
500 character(s) maximum

At least have a plan for doing so, and for making products affordable everywhere, and agreement to transfer IP and know-how to companies that will.

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?

No

If yes, please elaborate.
500 character(s) maximum

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

Yes

If you wish, please elaborate your reply.
500 character(s) maximum

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

No

If you wish, please elaborate your reply.

500 character(s) maximum

Reliable information regarding the costs and results of clinical trials, public sector subsidies, revenues and units sold by country are necessary to evaluate current and alternative policy measures on prices, access and innovation.

9. What are the most effective ways the EU can help improve affordability of medicines for health systems?
at most 3 choice(s)

More transparency on how the cost of a medicine relates to the cost of its research and development

Other

If “Other”, Please elaborate your reply.
100 character(s) maximum

The EU can progressively R&D incentives from the grant of monopolies and the price of products & services.

10. What actions at EU level do you consider most effective in supporting innovative research and development of medicines?
at most 3 choice(s)

Provide more public funding for research

Other (please specify)

If “Other”, Please elaborate your reply.

100 character(s) maximum

Delink R&D incentives from the grant of monopolies and the price of products & services, including by using product Market Entry Rewards and the Open Source Dividend incentives.

Subsidize clinical trial costs, transparently.

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)

Agree on a common understanding on what are the areas of unmet need in the EU

Funding more targeted research at EU level

Other (please specify)

If “Other”, Please elaborate your reply.
100 character(s) maximum

Introduce the open source dividend incentive to share knowledge. Force pooling of upstream patents, with market entry rewards for successful products.

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

Better reporting of real world outcomes.

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

Flooding the market with AI generated IP. Concentration due to increasing returns to data.

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?

No

If yes, could you please specify.
500 character(s) maximum

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 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)

If "Other", 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 disagree

* 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 European Medicines Agency should not have to define cell and gene therapies as products to justify its regulatory activities and expand use of patent exceptions for medical treatments. The Commission should conduct a feasibility study to evaluate the design, cost, feasibility and efficacy of market entry rewards as the alternative incentive for development of new cell and gene therapies, and evaluate the status of patent thickets for gene and cell therapies.

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)

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

If “Other”, Please elaborate your reply.
100 character(s) maximum

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)

Public finance research and innovation on new antimicrobials, their alternatives and diagnostics

Other (please specify)

If “Other”, Please elaborate your reply.
100 character(s) maximum

Better diagnostics are very important to avoid overuse. User fees on agricultural use, to fund R&D and/or market entry rewards to delink incentives from prices and utilization.

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

Other (please specify)

If “Other”, Please elaborate your reply.
100 character(s) maximum

User fees on agricultural use, to fund R&D and/or market entry rewards to delink incentives from prices and utilization

20. How has the coronavirus (COVID-19) pandemic affected you in relation to access to medicines and treatments?
600 character(s) maximum

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

The EU should mandate rapid and open sharing and full and deep technology transfer for inventions, data, know-how and biological resources, for any effective COVID-19-related

vaccines, therapeutics or diagnostic tests (including rights in any test data needed to register products).

The EU should require all funding agencies to license patents, know-how, data on cell lines to the WHO's COVID-19 Technology Access Pool (C-TAP), and to provide transparency of (1) all funding and procurement contracts (2) all clinical trial results and (3) information on the costs for all trials used to obtain regulatory approval, including public sector subsidies.

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)

Support innovation for unmet needs

Other (please specify)

If "Other", Please elaborate your reply.
100 character(s) maximum

Progressively delink innovation incentives from prices. This is a manageable task, but requires time and attention to get to a better place.

23. If you were asked before the coronavirus (COVID-19) pandemic, would you have responded differently to any of the previous questions?

No

If yes, please explain how your responses were influenced by the COVID-19 pandemic.
500 character(s) maximum

24. Is there anything else you would like to add that has not been covered in this consultation?
900 character(s) maximum

Transparency. IP systems should be more transparent. Patent landscapes on medical technologies should be transparent. Government funding of patents should be disclosed in patents. All licenses of government funded patents should be fully transparent and available in a central repository. Member states should implement the transparency provisions of WHO's transparency resolution (WHA72.8)

TRIPS Article 31bis. The Commission should reverse an earlier decision to voluntarily opt-out of WTO rules to enable WTO members to import medical technologies manufactured under a compulsory license in another country.

Delinking incentives from prices and exclusive rights. The Commission should conduct a feasibility study to evaluate the design, cost, feasibility and efficacy of market entry rewards as an alternative incentive for development of medical products and services.