EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 805

PHARMACEUTICAL COMMITTEE
18 September 2020

Subject: Discussion paper: Pharmaceutical strategy for Europe[1]

Agenda item 2

The Pharmaceutical Strategy for Europe will be launched later this year, providing a framework for a comprehensive policy answer to many of the challenges the pharmaceutical system is confronted with, today and in the future. This will include lessons learnt from the current pandemic. However, the strategy will be much more than a crisis response, as it aims to tackle problems from access to affordability and innovation.

The strategy will outline in detail those challenges and take the form of a Commission Communication. It will build on the roadmap published by the Commission earlier this year and take account of the feedback received through previous discussions in the Pharmaceutical Committee and in the consultations that have taken place over the past months. This is a Pharmaceutical Strategy for Europe and not just a Commission Strategy. Hence, the outreach activities and the continuous dialogue with Member States have been a crucial element in its development.

Implementing the objectives of the Strategy will require specific legislative and non-legislative actions that will be taken over the next years during the current mandate of the European Commission.

The Commission cannot implement those actions on its own. Strong collaboration, especially with Member States is needed to ensure that the policy answers are appropriately designed. This also means that actions outlined in the Communication will be at high level to allow for policy choices in the implementation phase in cooperation with the Member States and allow for coordination among the different actors at EU and national level.

At the meeting, the Commission will present the current state of play of the strategy.

The aim is to discuss and get input and ideas from the Committee members on possible actions for the Pharmaceutical Strategy and its implementation.

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[1] This document has not been adopted by the European Commission and, therefore, it does not reflect an official position of the European Commission. It is only meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.

In previous meetings and in your feedback to the roadmap, we have received specific input on possible actions across most objectives of the strategy. Having read the interesting feedback of several Member States to the Roadmap, we have formulated some questions to facilitate your additional input and discussion. Member States are welcome to mention specific actions in other areas. We are particularly interested in actions that contribute to synergies between the national and EU levels.

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Crisis preparedness and security of supply

The Roadmap of the strategy emphasises that the unprecedented coronavirus pandemic clearly demonstrates the need to modernise the way the EU ensures access to medicines for its population. The crisis shows the scale of the necessary and coordinated public health responses that are required to tackle such kind of pandemics. It demonstrates the need to have a future-proof and crisis-proof system to ensure timely access to safe, quality and affordable medicines under all circumstances.

> *In their feedback to the roadmap, many Member States mentioned the need for a European approach, so that the EU is better prepared for future pandemic crises. Specific and interesting ideas were submitted with regards to i) efficient monitoring and possibility of data sharing, (ii) coordination of supplies, (iii) research and innovation, (iv) the regulatory framework, (v) global value and supply chains, and (vi) production facilities.*

- The valuable input of the Member States on this essential point of the strategy will be thoroughly taken into account. In addition the security of supply chain is also discussed in a dedicated ad hoc meeting of the Pharmaceutical Committee. For this reason we propose not to specifically discuss this topic; at the same time any specific input from the members of the Committee will be welcome.

Research, innovation and digital transformation

Supporting innovation has many aspects, one of which is investing in clusters of excellence at regulators' level throughout the EU. The role of data and digitilisation in an innovation setting is evident. This aspect will also be highlighted in the forthcoming network strategy currently finalised by the Heads of Medicines Agencies and EMA. In this respect we may have to adapt the authorisation process to take into account Real Wold Evidence and take action to broaden the scope to better accommodate medical devices and borderline products.

> *In their feedback to the roadmap, the Federal Ministry for Digital and Economic Affairs of Austria speaks of Biotech Hotspot in the EU.*
> *The Ministry of Social affairs and health of Finland mentions that "Real-world evidence (RWE) can be used to support the re-evaluation of the safety and efficacy of medicines after the initial marketing authorisation."*
> *Some Member States replied in their feedback, speaking of a need to cover in the strategy medical devices and in vitro diagnostics in terms of availability and regulatory convergence with medicines (combinations products, software etc)*

- How would you see a "clusters of excellence" approach work in the EU and what actions would it require at national and EU level?

- What are the main elements we need to take into account in the regulatory process for the medicines approval (including type of evidence and challenges of expertise) to accommodate for the scientific advances and digital transformation?

AMR and other unmet needs

Unmet needs are often the result of market failures where the system simply does not facilitate the investment needed or the rewards of potential investment in unmet needs do not outweigh the risks of investment.

> *In the context of Covid response, in a non-paper signed by Belgium, Germany, Denmark, Spain, France and Poland, it is considered that the creation of important "projects of common European interest" for the production of active substances, vaccines, medical equipment where appropriate can address specific market failures.*

This is one of the answers and could be combined with other measures.

- What in your view are the most effective ways of levelling the playing field when it comes to market failures and what can the EU and its Member States do in terms of concrete action?

Affordability

When it comes to affordability there are clear ideas on how we can build on current cooperation mechanisms, to further support and reinforce cooperation between national authorities which will include the exchange of information on prices as well as best practices on pricing, payment and procurement policies and in general measures to stimulate market competition.

- Are there other actions at national and EU level that can contribute to the objective of affordability?

Regulatory efficiency

Regulatory efficiency is probably the least contentious area of the strategy. Both regulators and stakeholders agree that wherever there is room for simplification and reduction of administrative burden we should be ready to make the necessary changes.

> *In its feedback to the roadmap France mentions: "La France souhaite oeuvrer à une harmonisation des pratiques réglementaires européennes et promouvoir à simplification réglementaire et administrative, par exemple par une meilleure utilisation de l'information électronique sur les produits et des dossiers multilingues".*

- Issues such as electronic Product Information, or multi-language packs are low hanging fruits that we can easily implement as measures that will contribute to the objectives of the strategy, what are other low hanging fruits in terms of simplification and reduction of administrative burden?

International aspects

Enhancing the EU's bilateral and multilateral relations to advance international harmonisation and promoting the uptake and implementation of international standards as a way to level the playing field for European operators on the international market are evident thoughts.

> *In its feedback to the Roadmap the Irish Department of Business, Enterprise and Innovation mentions that the Pharmaceutical Strategy should ensure alignment with the EU's International Trade Policy, noting that the Commission has recently launched a Review of that Trade Policy and that in order to build additional resilience into*

European pharmaceutical supply chains, it would be preferable to supplement existing capacity rather than to simply repatriate certain operations.

- What else can the EU at global lever as a joint, collaborative effort to bring safe, effective and high-quality medicinal products to the market as well as to address environmental aspects and AMR? Are there specific aspects we should prioritise?

Working together in implementing the strategy

The success of the strategy will depend on its implementation.

- What would be for you key success factors and how would you envisage the further collaboration on the implementation of the strategy with the involvement of relevant stakeholders.