



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Pharmaceutical Strategy for Europe Workshop

14-15 July 2020

Summary

14 July

SESSION 1: INTRODUCTION AND DISCUSSION ON THE PHARMACEUTICAL STRATEGY ROADMAP

Chair: Andrzej Rys (Directorate-General for Health and Food Safety - Director Health systems, medical products and innovation)

Mr Rys welcomed the participants and gave the context and policy challenges that lead to the creation of the strategy. Participants included representatives from patients, consumers and healthcare professionals groups, academia and research organisations, industry, regulatory authorities, health technology assessment bodies and pricing and reimbursement bodies as well as the EU Institutions and Agencies. Mr Rys highlighted that the strategy is part of an ambitious plan not only concerning the supply of affordable medicines but also supporting the European pharmaceutical industry to remain an innovator, as well as contributing to other initiatives. The coronavirus pandemic had brought even more focus on the strategy. The **European Medicines Agency** explained the role the medicines agencies 5 year action plan (Regulatory science strategy to 2025) which addresses the operational aspects of the assessment and monitoring of medicines for humans and animals and that a consultation is open until 4 September. The **German Presidency** explained that the lessons learnt from the coronavirus pandemic was one of their priorities aiming to work on containing the virus and coordinating the recovery. Focus in health would be on enhancing EU resilience by strengthening preparedness and the EU in global health, the supply of medicines and the European Health Data Space.

ROUND TABLE ON THE PHARMACEUTICAL STRATEGY ROADMAP

Main question:

Based on what is included in the roadmap to the Pharmaceutical Strategy, do you think there are additional policy objectives that the strategy should address?

Participants expressed their support for the strategy and the concept of holistic, patient centred approach. Some participants stressed that the lifecycle approach should consider the potential impact that interventions in one step of the lifecycle have on other steps. There was a call for reduction of the fragmentation in the development of medicines, reducing data silos and increasing connection with industry. Some noted that the strategy is an opportunity to support the EU ecosystem and for the EU to take a leading global role in development and production of medicines, as well as having a stronger role on the global stage and coordination with other countries. It was noted that the issue of affordability is not easy to resolve but important for the sustainability of healthcare systems. Other aspects suggested to be considered were: taking the experience of COVID-19 in the design of clinical trials; the role of academia and other research organisations; identifying essential medicines; the links between medicines with medical devices, such as combination products and companion diagnostics; action on reasonable pricing and joint procurement of medicines; health literacy.

SESSION 2: ACCESS AND INCENTIVES FOR PATIENT CENTRED INNOVATION AND UNMET NEEDS

Chair: Olga Solomon (Directorate-General for Health and Food Safety - Head of Unit Medicines: policy, authorisation and monitoring)

Main questions:

How can we attain patient centred innovation (addressing unmet medical needs), and how do we make sure these products are available?

How important are incentives for the development of pharmaceuticals and should there be additional conditions for incentives?

What needs to be done to promote innovation in Europe from science and research to clinical trials and manufacturing?

While there was no general agreement on a common definition of ‘unmet medical need’, there was support from all stakeholder constituencies to work on a definition and several proposals on aspects of a definition were mentioned, e.g. a definition should be patient-centred and take into consideration the burden of disease and quality of life. Unmet medical need should be addressed throughout the lifecycle of a medicine from research to access decisions on health technology assessment, pricing and reimbursement and should not only cover diseases for which there is no treatment. Prevention was highlighted as an important element of a future pharmaceutical policy. Barriers to access to medicines were a central point of discussion. Participants highlighted that the evidence requirements and assessment criteria by regulators for medicine authorisation, by health technology assessment bodies and by pricing and reimbursement authorities differ among them and between Member States. This is a source of fragmentation that influence availability among EU countries, though the reasons are multi-factorial.

In general, incentives were recognised as an important tool to ensure development of medicines. A broad range of incentives is necessary, but incentives should not have a negative impact on availability and affordability. Non-market incentives, like research funding for academia, are important ways to support innovation. Non-industry stakeholders were in favour of balancing incentives with obligations to ensure access, while industry stakeholders emphasised that incentives are necessary to allow for risky investments and ensure innovation.

The participants found that it is important to keep innovation in the EU, but only moderate optimism was expressed as to EU’s position as an innovation hub. Improvement of the regulatory framework, reduction of fragmentation in EU as well as patient involvement were amongst areas identified where action is needed to keep innovation in EU.

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SESSION 3: ENSURING AVAILABILITY OF PHARMACEUTICALS TO PATIENTS

Chair: Sylvain Giraud (Directorate-General for Health and Food Safety - Head of Unit Medical products: quality, safety, innovation)

Main questions:

What are the main reason for structural shortages in the EU?

What should be done to address shortages in the EU?

How can we ensure that manufacturing chains for EU medicines are sufficiently robust?

The European Commission raised its concerns about the increasing reports of shortages of medicines in Europe, which affect all Member States and patients across the EU. The pharmaceutical strategy aims to ensure greater access and availability of the medicines in the EU based on a strong political mandate to tackle this issue. Furthermore, the European Commission has launched a study that will provide data on the causes of medicine shortages and identify possible future actions to further address this risk. The Commission also aims to enhance oversight of global manufacturing and clarify responsibilities to ensure the quality of medicines. The study was welcomed by participants as a means to increase knowledge, mapping, and understanding of pharmaceuticals supply chain. Different types of interventions at the EU level (legislative and cooperative) should be combined.

Concerns were raised on shortages of oncology medicinal products and innovative medicines. The generic market is also suffering from shortages, especially in Eastern Europe. This may be caused by parallel trade and pricing. It was mentioned that market models used for generics are unsustainable and the Member States during this pandemic crisis took action undermining the solidarity across the EU.

Some participants mentioned that challenges on availability start with chemical products and starting materials. These are not subject to the pharmaceutical regulation as are active pharmaceutical ingredients (API) and it is important to diversify the sources and suppliers and strengthen sourcing systems. Over reliance on supply from outside EU links to reduced costs. Less dependency on third countries would increase prices. The lack of transparency is also about demand and not only about supply and production. There is a need for better communication between industry and public authorities and pharmaceutical companies should prepare supply risk plans.

Several participants emphasised the importance for health care professionals to work with the European Commission to give a better overview of the real shortages experienced on the field. Doctors should be given data on the availability of medicines. A list of essential medicines and strategies to mitigate their shortages should also be created. As an example, the shortage numbers in France have increased over time, with around 60% in the last 2 years. More data is needed about the impact of shortages on patient's health, both physical and physiological.

SESSION 4: ENSURING AFFORDABILITY OF MEDICINES FOR PATIENTS AND HEALTH SYSTEMS SUSTAINABILITY

Chair: Sylvain Giraud (Directorate-General for Health and Food Safety - Head of Unit Medical products: quality, safety, innovation)

Main questions:

Which are the options at EU level to improve patients' and health systems' affordability of medicines?

Is there a need for more coordination between the national and the EU level to address the challenges of high prices/ costs?

The affordability session welcomed a balanced mix of stakeholders with a majority of public authorities, industry – similar to other sessions. To ensure affordability, there was consensus that a mix of approaches should be considered and it is essential to ensure that EU citizens have equal and timely access to affordable medicines. Not surprisingly, opinions on the precise direction of the approaches at times differed.

Participants mentioned there are several innovative medicines on the market covering unmet needs, however, there are challenges regarding pricing and reimbursement. Pricing has a direct impact on availability, also for rare diseases. Patient, consumer and health professional organisations highlighted the importance of transparency and stepping up information sharing efforts with Member States such as through the EURIPID¹ co-operation as well as more clarity on reimbursement criteria in different countries.

Many highlighted the need for new procurement/payment models that can manage the uncertainty of effectiveness, which is particularly important for innovative products with high prices. Better coordination on real world evidence can allow the use of data to support such innovative payment schemes. The definition of a “fair price” from a European perspective should be discussed. A more holistic view of the health system is also needed to afford innovation.

The European Commission should support Member States to stimulate competition. Strengthening competition in research is critical because stronger competition can lead to price reductions and greater affordability. This applies to on-patent as well as “older” off-patent medicines. In particular, competition in the generics/biosimilars, market should tackle “evergreening” practices, as well as market withdrawals, which can result in shortages.

A number of participants, mainly patient representatives and authorities called for a progress on the Commission's health technology assessment proposal as it is an important tool to pool the resources of Member States and highlighted the importance of good data for the assessments. The interplay between the four objectives of the pharma strategy should be examined. For example, affordability and accessibility were seen as more aligned than affordability and innovation.

¹ European Integrated Price Information Database Collaboration

SESSION 5: CLOSING

Andrzej Rys (Directorate-General for Health and Food Safety - Director Health systems, medical products and innovation)

Mr Rys closed the workshop summarizing the main outcomes from each session and explained the timeline and consultation process leading to the adoption of the strategy in the form of a Commission Communication by the end of the year. The Communication will include high-level actions outlining the policy directions and the areas of intervention.

Mr Rys reminded that the Commission is collecting written input through an online public consultation survey and that interested parties should submit their feedback by 15 September. He also underlined that this is not the end of the process. Further consultation will take place in the implementation phase of the strategy on the basis of specific actions and following better regulation principles and procedures.