EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Pharmaceutical Strategy for Europe Workshops

March to June 2021

Summaries

December 2021

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111

Workshop on unmet medical needs and access

26 March 2021

- **Presence**

Pharmaceutical Committee members, and representatives of the Health Technology assessment (HTA) Network and the group of National Competent Authorities on Pricing and Reimbursement (NCAPR).

- **Aim**

The aim of the workshop was to discuss the criteria/principles of unmet medical need (UMN) including the different policy perspectives to support the development of products addressing such UMN.

- **Summary**

The following issues were discussed in the workshop:

- The existing **definition of unmet medical need** (UMN), provided in Article 14-a of Regulation (EC) No 726/2004 regarding the conditional marketing authorisation, was considered to be imprecise and could be better defined.
- A **graduation of unmet needs** is important, and the whole lifecycle of a product should be considered including so called exit points.
- **Innovation** is not necessary coupled with addressing UMNs. There can also be non-innovative treatments addressing UMN.
- It is important to **involve all concerned actors** in the identification of specific UMNs, with a coordinated approach between regulators, health technology assessment (HTA) bodies and payers.
- Overall, the **current regulatory tools and initiatives** function well (scientific advice; Priority Medicines Scheme – PRIME; accelerated assessment; the repurposing pilot; EU Innovation Network and clinical trials facilitation group).
- **New post-authorisation incentives** were not considered to be a main driver to boost development in areas of UMN whereas early support tools, including so called push incentives, were considered to be good tools to boost such development.

Workshop on pharmaceuticals in the environment

7 April 2021

- **Presence**

Participants from Member States, the European Medicines Agency (EMA), the European Free Trade Association (EFTA) secretariat and the Organisation for Economic Co-operation and Development (OECD).

- **Aim**

The aim of the workshop was to discuss ideas for the possible options to address the environmental challenges in the context of the evaluation and revision of the EU pharmaceuticals legislation.

- **Summary**

The following issues were discussed in the workshop:

- The **environmental risk assessment** was considered and overall the revision of the legislation in this respect was broadly supported.
- The **environmental aspects of manufacturing** were considered. Overall, there was support to add environmental considerations in the good manufacturing practice (GMP) guidance. There was also discussion whether other guidance or legislation could be adapted to take account of manufacturing aspects.
- Ideas on potential areas for **international collaboration** were shared.
- The possible approaches to tackle **other environmental challenges**, such as prudent use of medicines, waste management etc. were considered.

Workshop on better market conditions for generic/biosimilar medicines

21 May 2021

- **Presence**

Pharmaceutical Committee members, and Health Technology assessment (HTA) Network and the group of National Competent Authorities on Pricing and Reimbursement (NCAPR).

- **Aim**

The aim of the workshop was to discuss the various tools and incentives that define the market conditions for generic and biosimilar medicines including how to improve availability, affordability and access for patients in the EU.

- **Summary**

The following issues were discussed in the workshop:

- **Generics and novel medicinal products** co-exist in a system of different data and patent protection periods, balancing affordability and innovation.
- There was support for a graduated approach regarding **regulatory data protection** in terms of different types of products.
- To further **stimulate innovation**, it was suggested that the data protection period may be shortened, and have a longer protection only for new classes of medicinal product or breakthrough therapies.
- Positive experiences exist with the **authorisation of generics** at national level. However, generics that are centrally authorised do not reach all EU markets.
- A harmonisation and a broad interpretation of the **'Bolar' exemption**, to be extended also to producers/suppliers of active pharmaceutical ingredients (APIs), was generally supported.
- The current incentives for **repurposing** should be maintained, however (additional) market entry rewards may be further explored.

Workshop on scope of the medicines legislation, interplay and classification aspects

1 June 2021

- **Presence**

Pharmaceutical Committee members, representatives from Blood Tissues and Cells and Medical Devices authorities. Some members of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) and Committee for Advanced Therapies (CAT), the Heads of Medicines Agencies (HMA) co-chairs of the EU-Innovation Network (IN) and EU IN borderline medicines group.

- **Aim**

The aim of the workshop was to provide input to the Commission evaluation and revision of the pharmaceutical legislation concerning the 'Scope of the medicines legislation, Interplay and Classification aspects'.

- **Executive Summary**

The workshop was structured around three main topics:

- **Scope of the pharmaceutical legislation** – discussion if the current definitions and scope fit to scientific progress, and continue to ensure high standards of quality, safety and efficacy of medicinal products as new emerging technologies are taken-up. While the current system covers many developments, participants acknowledged that there are certain gaps/regulatory questions that need revisiting to better serve technological developments. It was also noted that more harmonisation should be achieved in how the derogations to the marketing authorisation requirement are applied.
- **Borderline and classification aspects** – there are some products for which classification between different legal frameworks is not clear. One can therefore expect the same products to be classified differently in different Member States. While there was no support for a mandatory EU classification system, there was agreement on need for better coordination between sectors.
- **Interplay between pharmaceuticals and medical devices** – The European Medicines Agency (EMA) presented examples of scientific and regulatory challenges faced in the assessment of innovative medicinal products, notably complex digital-drug-device combination products. Participants recognised the ongoing work by the Heads of Medicines Agencies and EMA, and under the Medical Devices Regulation and mentioned the need for more clarity on roles and responsibilities of the different national competent authorities, particularly as regards data related to medical devices. There was a plea for a more integrated approach in relation to scientific advice on medicines and medical devices. Software was mentioned as an important element in the interaction with the medicinal product and assessment of benefit/risk of the medicine across the life cycle of the device.

Workshop on Resilience and attractiveness of the regulatory system

18 June 2021

- **Presence**

Pharmaceutical Committee members, national competent authorities responsible for medicines. Some members of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC), the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) and Regulatory Optimisation Group (ROG).

- **Aim**

The goal of the meeting was to provide input to the Commission revision of the general pharmaceutical legislation concerning the resilience and the attractiveness of the regulatory system.

- **Summary**

Four topics were discussed in the workshop:

- **Possibilities to build agility into the legal framework to respond to developments in science and technology** – most interventions supported this need, but current agilities were not used sufficiently. Ideas for additional agility included the 'regulatory sandbox' concept. Some cautioned that agility should not reduce evidence requirements for marketing authorisation, which might impact the ability of health technology assessment and pricing and reimbursement bodies to make decisions within their remit.
- **COVID-19 lessons learnt and lessons to be integrated into normal business** - overall, the EU regulatory system had delivered well the authorisation of new vaccines and treatments for COVID-19. The pandemic had help test the opportunities and limitations of existing tools. It was considered that best practices from the COVID-19 experience should be maintained if appropriate, taking full account of resource issues. The system showed a great flexibility. However, the network is at its critical limit on available resources and expertise.
- **How to streamline procedures and simplify requirements** – the need to streamline procedures and simplify requirements was recognised. Many ideas were brought forward, e.g. removing 5-year renewal of a marketing authorisation, single assessment of active substance master file, work-sharing on assessment of bioequivalence studies and core summary of product characteristics. Several interventions supported the idea that the centralised procedure focus on innovative products.
- **The scope of the centralised authorisation procedure** – Most interventions supported focus on innovative products that bring value to patients and society. There were different views on possible expansion of the scope. It was mentioned that the decentralised procedure works well, particularly for generics, and consideration could be given to all generics going through the decentralised procedure, allowing the CHMP more time for new innovative products.