EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 783

PHARMACEUTICAL COMMITTEE
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Working method and main priorities[1]

The Pharmaceutical Committee is an important advisory body for Commission-led legislative and policy actions. It is a forum where the Commission, Member States, EMA and its other members, such as EEA countries, can interact on policy and implementation issues relating to the Pharmaceutical acquis (notably Directive 2001/83/EC & Regulation (EC) 726/2004 and sectorial legislation).

In view of the new legislative cycle after the 2019 European elections and the appointment of the new Commission, the Committee reaffirmed its priorities in view of the challenges and opportunities presented in the area of pharmaceuticals. In this context, it also adopted a working method aiming to turn its priorities into action.

Working method

The work of the Pharmaceutical Committee is not isolated; it takes place in the context of a wider activity of relevant decision makers, which includes the Council, the EMA, the HMA and other relevant Committees. The Committee strives to deliver comprehensive, multidimensional responses to policy challenges. To do this, it is necessary to promote synergies with relevant policy areas and avoid duplication of work.

The Committee's input comprises elements from the Commission's political priorities and input received from Member States but may also be influenced by information that reaches the Committee from other relevant fora and may also refer issues to those if necessary. Output can take the form of advice on legislative action, guidance or other actions. It is also possible to hold joint meetings with other relevant Committees (such as payers) and to involve stakeholders and experts on an ad-hoc basis.

[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.

The Committee's work plan is organised around groups of actions of a similar policy nature. Three groups are identified:

- Sustainable innovation;
- Access and affordability while addressing shortages, and unmet medical needs;
- Security and oversight of the global manufacturing supply chain.

These may be updated in the future.

The Committee has the flexibility to form ad-hoc working groups (chaired by any interested member) to conduct in depth technical discussions in preparation of policy recommendations or analysis. Such discussions can also take place in STAMP or other Commission groups. The result of this process will be reported back to the Committee.

Main priorities

The main priorities identified by the Committee are structured under the three work strands as follows:

An ***overarching*** need to ensure flexibility, forward thinking, sustainability of the network, traceability, trust in the system and reduce regulatory burden.

Sustainable innovation

- Action plan on pharmaceuticals in the environment, which involves measures following the Commission Communication on the EU Strategic approach on pharmaceuticals in the environment (ongoing).
- Joint Commission-EMA action plan to improve the regulatory environment for ATMPs (ongoing).
- Better regulation and common understanding on innovative "borderline" products.
- Product information and digitalisation: e-leaflet.
- Paradigm of assessment, authorisation and pharmacovigilance in light of the possible use of Real Word Evidence, AI etc.
- Ethical, proprietary and security concerns including ownership and access to data and the algorithms behind AI applications.
- Expertise to deal with new innovative products in a digitised environment in combination with medical devices.
- Examination of the variations framework.

Ensuring access and affordability while addressing shortages, unmet needs

- Evaluation of the legislation on orphan and paediatric diseases (ongoing).
- Action plan on Anti-Microbial Resistance (ongoing).
- Improve market launch for CAPs (ongoing).
- Reinforce obligation to supply and addressing shortages, measures on parallel trade (ongoing).
- Support not for profit organisations and academia in drug repurposing (ongoing).
- Increase the uptake of generics and biosimilars.
- Measures on the medical use of cannabis.

Ensuring security and oversight of the global manufacturing supply chain

- Action plan to enhance oversight of the global manufacturing and supply chain of Active Pharmaceutical Ingredients (ongoing).
- Monitor and ensure the integrity of the supply chain (ongoing).

- Reduce dependency on Active Pharmaceutical Ingredients from third countries especially for “strategic” medicines and vaccines.
- Ensure the quality of active substances.

The Committee has agreed that priority will be given to actions that are ongoing. It should be noted that these are the priorities identified by the Committee. They cannot be considered as Commission priorities, even though some are common to or may inform Commission initiatives.