EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 777

PHARMACEUTICAL COMMITTEE
7 November 2019

Subject: **Pharmaceutical Committee: mapping policy needs and working method**[1]

Agenda item 2

1. Introduction

The Pharmaceutical Committee's role as a consultative Committee to the Commission, is to discuss policy matters and questions in the field of medicinal products covered by Regulation (EC) No 726/2004 and Directive/2001/83/EC.

The Committee recently held a discussion on the challenges and opportunities presented in the EU Pharmaceutical legislation and identified several policy areas requiring attention. The next step to this process is to organise the elements identified in these discussions around broad themes with the aim to set a work plan for the Committee.

2. The new Commission and initially identified priorities

The new Commission's specific actions and priorities will largely depend on political deliberations and be communicated after the Commission is confirmed by the EP as a college and it formally takes office. However, we can already identify certain policy areas highlighted by President-elect Ursula von der Leyen in her mission letter[2] to Commissioner-designate for Health, Stella Kyriakides.

Concerning the area of health, these are:

- Look at ways to help ensure Europe has the **supply of affordable medicines** to meet its needs. In doing so, support the European pharmaceutical industry to ensure that it remains an innovator and world leader.
- Full implementation of the European One Health Action Plan against **Antimicrobial Resistance** and work with our international partners to advocate for a global agreement on the use of and access to antimicrobials.

[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.
[2] https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf

- Communication on **vaccination.**
- Europe's **Beating Cancer Plan** (prevention, diagnosis, treatment).

3. Proposed process supporting the work on priority actions in the context of the Pharmaceutical Committee

The process of mapping and organising the work of the Committee around several policy issues and questions is a complex one. It is for that reason that the Commission services are proposing a working process specifically for the purpose of this exercise. The process is depicted in a diagram (Annex I).

The **main** elements are the following:

- This process relates to policy areas covered by the core business of this Committee;

- The Committee identifies priority areas which are based on the combined input of the Commission's political priorities and the input received from Member States but may also be influenced by information that reaches the Committee from processes happening in the EMA, the HMA or other relevant fora;

- The work plan of the committee is organised around work strands, which group actions of a similar policy nature. For practical reasons, the Commission proposes to have a low number of work strands (3) but this is subject to discussion;

- Actions identified can be assigned to ad-hoc working groups to conduct preparatory policy work and report to the Committee. These ad-hoc groups will be composed by interested Member States, the Commission, EMA or, if necessary, other stakeholders and follow the model of ad-hoc working groups already in place by this Committee;

- Policy recommendations from the ad-hoc working groups or recommendations developed directly in the Committee will form the output of the Committee;

- Output can entail the production of guidance or other action that serves the objective to optimise the use of the current legal framework. It can also take the form of advice about knowledge gaps that need to be filled or about possible future legislative actions which may be required to address specific challenges for the regulatory system;

- The Committee may refer issues to other more specific fora or hold joint meetings with other experts or stakeholders as required.

➢ Members of the Committee are invited to comment and discuss the proposed working process.

4. Identifying specific policy needs and developing work strands

The main input from previous Committee discussions and elements of ongoing work have been organised under the following three themes (the boxes highlighted in grey are linked to ongoing actions):

Sustainable innovation	Ensuring access and affordability while addressing shortages, unmet needs	Ensuring security and oversight of the global manufacturing supply chain
Need to ensure flexibility, forward thinking, sustainability of the network, traceability, trust in the system and reduce regulatory burden (across the board)		
Action plan on pharmaceuticals in the environment	Reinforce market launch for CAPs	(API) Action plan to enhance oversight of the global manufacturing and supply chain
Joint Commission-EMA action plan to improve the regulatory environment for ATMPs	Reinforce obligation to supply and addressing shortages, measures on parallel trade	Monitor and ensure the supply chain integrity
Better regulation and common understanding on innovative "borderline" products	Supporting not for profit organisations and academia in drug repurposing	Reduce dependency on APIs from third countries especially for "strategic" medicines and vaccines
Product information and digitalisation: e-leaflet	Evaluation of orphan & paediatrics legislation	Quality of active substances
Discussing the paradigm of assessment, authorisation and pharmacovigilance in light of the possible use of Real Word Evidence, AI etc.	AMR action plan	
Addressing ethical, proprietary and security concerns incl. ownership and access to data and the algorithms behind AI applications	Uptake of generics and biosimilars	
Mapping and acquiring expertise to deal with new innovative products in a digitised environment in combination with medical devices	Medical use of cannabis	
Variations		

Questions:

- Are there any other topics not listed that should be added to this list?
- In the past Pharmaceutical Committee many Member States expressed the view that there should be a two-step approach to all these issues and try to identify short-term

and longer-term actions. **How should the work of the Committee around these issues (and other that may come up in the discussion) be organised and how should actions be prioritised?**

Annex I

Visual representation of the working process supporting priority actions in the Pharmaceutical Committee