EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 819

PHARMACEUTICAL COMMITTEE
22 February 2021

Subject: Discussion of a work plan of the Committee on the revision of the general pharmaceutical acts[1]

Agenda item 3

The implementation of the Pharmaceutical Strategy involves a major deliverable, which is the revision of the general pharmaceutical legislation (Regulation (EC) No 726/2004 and Directive 2001/83/EC) by the end of 2022. The steps leading to this revision (Roadmap/Inception Impact Assessment, study supporting the evaluation – impact assessment, consultation process etc.) will be briefly outlined in the meeting. Along the process for this revision the Commission will consult the Committee and therefore a work plan needs to be discussed.

We propose to focus the discussions of the Committee on the key policy interventions of the revision. In addition, we propose having a series of workshops in the course of March-April. These will be open to the participation of members of the committee and other policy makers from fields such as P&R, HTA, medical devices where relevant and their aim will be to use the participatory method to make the relevant links across policies in cross cutting issues relating to the revision of the general pharmaceutical acts. Later on, the meetings of the Committee will be extended on an *ad hoc* basis to other relevant stakeholders.

In addition, we would like to discuss the best way to bring into our discussions, where relevant, the results/ recommendations of work conducted by EMA/HMA on specific issues under the Network Strategy to 2020. This will help avoid duplication of discussions and build on existing results.

Annex: Draft work plan for the Committee

[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.

Annex - Work plan

<table>
<tr><td colspan="8">Work plan with MS - revision of general pharmaceutical acts</td></tr>
<tr><td colspan="3"></td><td colspan="5">DISCUSSION THEMES</td></tr>
<tr><td></td><td>MAJOR DELIVERABLES**</td><td>EVAL. IIA STUDY**</td><td colspan="3">ACCESS TO AFFORDABLE MEDICINES</td><td>INNOVATION</td><td>RESILENCE & ATTRACTIVENESS</td><td>ENVIRONMENT</td><td>SUPPLY</td></tr>
<tr><td>JAN</td><td></td><td rowspan="6">Draft ToR</td><td>PRP: Affordability brainstorming workshops legal review – 26/1</td><td>STAMP: Unmet needs (O/P) – 29/1</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>FEB</td><td></td><td colspan="6">- Pharmaceutical Committee – discuss WORKPLAN</td></tr>
<tr><td>MAR</td><td></td><td colspan="6">Pharmaceutical Cttee thematic WORKSHOPS*</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td colspan="2" rowspan="2">Access to affordable medicines - unmet needs</td><td rowspan="2">Innovation (future proofing of legislation)</td><td></td><td rowspan="2">Environment</td><td rowspan="2">Availability and supply chains</td></tr>
<tr><td rowspan="2">Roadmap/ IIA feedback</td></tr>
<tr><td>APR</td><td colspan="2">Resilience & attractiveness of the regulatory system</td></tr>
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			PT Presidency events - Directors meeting - Conference on Access, Affordability, Availability				
MAY			**Pharmaceutical Committee (EXTENDED TO STAKEHOLDERS)**				
JUN							
JUL		- Kick off - Inception report	SI Presidency event(s): **Joint Directors – Pharmaceutical Committee meeting**				
AUG							
SEP	**OPC**		**Pharmaceutical Committee**				
OCT		Interim report	Thematic workshop(s) with **stakeholders**/MS				
NOV			**Pharmaceutical Committee**				

DEC							

*Post meeting note: the workshop topics and dates may be adjusted to focus on areas where policy discussions are most needed and avoid duplication with discussions taking place in ad-hoc working groups of the Committee. The workshops will span from March to June 2021.

**Post meeting note: The dates of the deliverables are indicative, study deliverables may differ to the ones included in the terms of reference of the evaluation/impact assessment study.