EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 768

PHARMACEUTICAL COMMITTEE
11 July 2019

Subject: Agenda of the 83rd meeting of the Pharmaceutical Committee
11 July 2019

Venue: **Centre Albert Borschette, 36, rue Froissart, Brussels, meeting room AB-4A**

Welcome coffee: 10:30 am – 10.45 am

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
10:45h – 17:30h
83rd meeting, 11 July 2019

1. Adoption of the draft Agenda

2. Pharmaceutical Legislation: challenges and opportunities

- All items under this point build on the Pharmaceutical Committee's main role as a consultative Committee to the Commission and aims to launch a strategic discussion on the challenges and opportunities presented in the EU Pharmaceutical system given the new technological developments and the outlook for the sector.

a. Orphan and paediatric medicines: evaluation of the current legislation

- The EC will kick off the discussion with a follow-up on the main takeaways from the June 17 conference titled: "Medicines for rare diseases and children: learning from the past, looking to the future". These findings which will largely comprise the work of the conference's rapporteurs will then be linked to the general discussion on the outlook for the sector and the next agenda point below.

b. Scenario-based discussion

- After a brief presentation by the EC on the basis of a background document which will outline the major new technological developments, challenges and opportunities for the sector. The NCAs will be asked to react to hypothetical scenarios. We will examine how the future policy actor can fulfil their role in the context of a scenario based on a linear continuum of today's framework or a scenario based on a holistic, flexible framework which utilises soft law, best practices, benchmarking and other relevant actions at national level to respond to new challenges.

c. Market launch of centrally authorised products

- The EC will update the group on the activities of the WG on Market launch of centrally authorised products. It will present the work conducted so far and raise further questions to NCAs based on the working document already presented in the 1 April Pharma Committee.

3. ATMPs
   a. Hospital Exemption
   b. Guidelines on GCP for ATMPs

- This point follows the discussion of 1 April on Hospital exemption for ATMPs where the MSs were invited to submit their views on the questions raised in the working document presented to them. The EC will

also discuss the guidelines on good clinical practice specific to advanced therapy medicinal products

4. Repurposing of medicines following STAMP

- Presentation for endorsement of the final documents on a framework for repurposing of medicines and proposed pilot to test the framework.

5. A.O.B.

- BE to very briefly present a list of questions on bacteriophages for MSs to prepare in advance of the October Pharmaceutical Committee, which will discuss the issue in the context of AMR.

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