EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 822

PHARMACEUTICAL COMMITTEE
28 May 2021

Subject: Agenda of the 94th meeting of the Pharmaceutical Committee

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Venue: Due to emergency public health protection measures relating to the Covid-19 outbreak, the physical meeting is replaced by a teleconference.

Connection details to be sent to participants through AGM

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA

Friday, 28 May 2021 (9:30 – 14:00)

1. Adoption of the draft agenda

2. Introduction by Commission

3. **Future proofing**: Adapting the legislative framework for medicinal products to support patient centred and need-driven innovation and scientific developments

   Elements of discussion:
   As indicated in the Commission Communication on the Pharmaceutical Strategy for Europe trends such as digitalisation, RWE, AI, personalised medicine, complex combination products, integrated therapies will influence innovation and scientific development.

   - What are the changes to make to the regulatory framework so that it is better adapted to support scientific developments and need driven innovation?

   - At which stage of the development are regulatory interventions necessary to support innovative product development? Which tools/instruments are necessary? (e.g. CMA, PRIME, Accelerated Assessment, Scientific Advice, rolling review, others?)

30 minutes COFFEE BREAK

4. Providing **incentives for innovation that reaches the patient**

   Elements of discussion:
   - Would it be possible to set in the legislation criteria to identify products addressing unmet medical needs? What criteria can be considered?
   - How can the system of regulatory incentives (data and market protection; possible novel incentives) better address unmet needs? Are changes to the existing system needed and what would these be?
   - How can the regulatory framework better support a wider access to medicines?

5. A.O.B.

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