



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 835

PHARMACEUTICAL COMMITTEE
20 January 2022
98th meeting

SUMMARY RECORD

The meeting was organised via video conference and was attended by representatives from the Commission, 24 EU Member States, Norway, Iceland and the European Medicines Agency (EMA), the Council of Europe (European Directorate for the Quality of Medicines), the Chair of the Heads of Medicines Agencies Management Group and contractor representatives responsible for the impact assessment study supporting the revision of the general pharmaceutical legislation.

1. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 833) was adopted.

2. Pharmaceutical strategy for Europe: definition of criteria for ‘Unmet Medical Needs’ and the use of the concept in EU pharmaceuticals legislation

The study contractor outlined the work in the study that focused on the concept of unmet medical need (UMN). The discussions focused on the criteria that could be included in the concept of UMN and on how this would be operationalised. Disease severity, available alternative treatments were particularly discussed. Medicines that fulfilled the criteria of unmet medical needs would be eligible for administrative benefits (such as expedited pathways and early scientific advice) and/or specific regulatory incentives.

The discussion provided additional clarity to the concept and showed that there is a need to have a system that is predictable and offers legal certainty. Operational aspects around four key aspects (see below) were discussed.

1. Benefits received from classification ‘addressing UMN’

2. Elements relevant for concept of UMN
3. How to make the UMN elements operational
4. Potential vs. demonstrated ability to address UMN

3. A.O.B.

- The Commission updated Member States on the revision and next steps. SANTE presented preliminary results of the public consultation, which closed on 21 December 2021 and received 478 replies. The Commission mentioned that next discussions would focus on issues of specific policy interest.

- Next scheduled meeting: 5 April 2021