EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

Pharm 796

Pharmaceutical Committee

12 March 2020

Subject: **Mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment**[1]

Agenda item 10

1. General considerations

The Pharmaceutical Committee endorsed in the November and December 2019 meetings the establishment of an ad-hoc working group (WG) to focus on the EU strategic Approach on pharmaceuticals in the environment[2], in particular on the actions and measures that fall under the competence of the Member States.

The following Member States joined this WG: Austria, The Czech Republic, Finland, France, Germany, Ireland, The Netherlands, Slovenia, Spain, Sweden and the European Medicines Agency (EMA). The chairmanship of this WG was taken up by Sweden. A first meeting of the WG was organised on the 21st February 2020 when the WG discussed further the mandate and the working arrangements.

This document elaborates further on the mandate and the working arrangements as discussed within the WG and it requests the endorsement of its mandate from the Pharmaceuticals Committee.

2. The mandate of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment

[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] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, European Union Strategic Approach to Pharmaceuticals in the Environment COM/2019/128 final, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2019:128:FIN - Within the European Commission, DG Environment has the main responsibility for this policy. DG Sante was closely associated in the adoption and implementation of this act. This EU strategic approach with intersectorial actions is also part of the Green Deal of the next European Commission. For the health of the European citizens, Europe needs to move forward towards a zero-pollution ambition. This cross-cutting strategy aims to protect the health and the environment and it addresses air and water quality, among other sectors.

The ad-hoc working group is set up to focus on the EU strategic Approach on pharmaceuticals in the environment, in relation to human medicines, in particular on the actions and measures of the Commission Communication (COM(2019) 128 final of 11 March 2019) that fall under the competence of the Member States. The scope of the working group is to provide recommendations for the following areas:

- "Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment;
- Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development programmes;
- Foster best-practice exchanges between Member States on how environmental considerations are taken into account in the advertising and prescription of medicinal products and the choice of therapy more generally, where appropriate;
- Explore the possibility of reducing waste by optimising the package size of pharmaceuticals so that medicines can be dispensed in quantities better matching needs, and by safely extending use-by (expiry) dates so that fewer medicines that are still usable have to be thrown away;
- Facilitate the exchange of best practices among healthcare professionals on the environmentally safe disposal of medicinal products and clinical waste, and the collection of pharmaceutical residues as appropriate;
- Assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal; [3]"

The working group may also provide recommendations on the actions under the section 5.3 ("Improve the environmental risk assessment and its review for the human medicines") that fall under the competence of the Member States. On this aspect, the work of the EMA on section 5.3 of the Commission Communication should be taken into account to ensure alignment and avoid duplication.

The tasks of the working group relate to human medicines. The working group will exchange views and information about the experience of Member States, examine national initiatives, share best practices and/or develop guidance or propose specific measures and/or further actions, where relevant, in relation to the above-mentioned actions in the Commissions Communication.

The mandate for the ad-hoc working group shall be three years that could be further prolonged. One of the participating Member States will chair the working group. The Secretariat of the working group will be carry out by its members. Other Member States may take the lead in relation the different thematic strands of the above-mentioned actions. The ad-hoc working group will meet mainly via teleconference (in English) in a frequency decided by the group. The ad-hoc working group will also agree on an agenda, work plan and its working methods. The ad-hoc working group will report to the Pharmaceutical Committee.

[3]Commission Communication COM(2019) 128 final of 11 March 2019, from the sections 5.1, 5.3 and 5.4.