EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

Pharm 787

Pharmaceutical Committee

17 December 2019

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

Agenda item 6

1. General considerations

The Pharmaceutical Committee endorsed in the November 2019 meeting the idea of establishing an ad-hoc working group 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. This document elaborates further on the possible mandate and the working arrangements of that working group (WG).

2. Some reflections on the mandate and objectives

The tasks of the ad-hoc Working Group relates to human medicines. The WG would be responsible for the following working areas:

- Develop guidance, where relevant, in relation to the actions and measures foreseen in the Commission Communication that fall under the competence of the MS
- Share best practices/develop guidance or propose specific measures/further actions, where relevant, in relation to the following actions in the Commission communication:

Section 5.1. - Increase awareness and promote prudent use of pharmaceuticals, in particular:

[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.

- 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;

Section 5.4 - Reduce wastage and improve the management of waste

- 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;

For an efficient implementation, the WG is invited to consider establishing either one leadership or several leads with different thematic strands of the abovementioned actions under the Commission Communication.

Update and some practical arrangements

This WG is composed of the Member States, EMA and Commission representatives. So far, the following Member States demonstrated interest in joining this Working group: SE, IE, DE, SL, ES, NL, CZ, FI. Further Member States are welcome.

The WG should be led by one of the participating Member States and willmeet via teleconferences (in English). The first call will be organised by the Commission.

On the basis of the objective described above, the group will draft a mandate that will be shared and approved by the Pharmaceutical Committee. The WG will determine its agenda and the working methods in its first meeting(s). It may be considered to work separately on different packages to facilitate the work. The WG is also invited to further discuss the timeframe needed for its work.

The WG will report regularly to the Pharmaceutical Committee.