



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 809

PHARMACEUTICAL COMMITTEE

21 October 2020

Subject: Action Plan of the ad-hoc working group to focus on the EU strategic Approach on pharmaceuticals in the environment¹

Agenda item 3 – for endorsement

1. General considerations

The Pharmaceutical Committee endorsed in the March 2020 meeting the mandate of an ad-hoc working group (WG) to focus on the EU strategic Approach on pharmaceuticals in the environment², in particular on the actions and measures that fall under the competence of the Member States.

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-

This document elaborates further on the actions to be taken within the WG during the period of its mandate that of first 3 years (2020-2023) that could be further extended as agreed in the mandate.

In line with the agreed mandate, 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 ad-hoc working group will then report to the Pharmaceutical Committee.

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

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 for the period 2020-2023 that can be further extended:

	Action	Time frame	Deliverables	Lead
1	Promote the development of guidelines for healthcare professionals on the prudent use of pharmaceuticals posing a risk to or via the environment;	2020-2022	Recommendations including exchanges of best practices and Possible guidelines	Leader: NL Collaborators: CZ, FR, SE, FI, ES
2	Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development programmes;	2020-2022	Recommendations including exchanges of best practices and Possible guidelines	Leader: - NL Collaborators: NL, FR, SE, ES, CZ
3	Foster best-practice exchanges between Member States on how environmental considerations are taken into account in the advertising and prescription of medicinal products and	2021-2023	Recommendations/ Exchanges of best practices	Leader: - Collaborators: To Be Decided at a later stage

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 choice of therapy more generally, where appropriate;			
4	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;	2020-2022	Recommendations/ Exchange of best practices	Leader: FR Collaborators: DE, EMA, SE, ES
5	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;	2021-2023	Recommendations/ Exchange of best practices	Leader: - To Be Decided at a later stage Collaborators: NL, SE
6	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;	2020- Q3 2021	Recommendations/ Exchange of best practices	Leader: ES Collaborators: NL, FI, SE
7	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.	2020-2023	Recommendations	Leader: DE Collaborators: AT, CZ, EMA, ES, IE, NL, SE, SI