EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

Pharm 829

Pharmaceutical Committee

Decision by written procedure

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

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 environment[2], in particular on the actions and measures that fall under the competence of the Member States.
Currently, the following Member States joined this WG: Austria, The Czech Republic, Finland, France, Germany, Ireland, The Netherlands, Slovenia, Spain, Sweden, Poland, Romania, Italy and the European Medicines Agency (EMA).
Following the adoption of the pharmaceutical strategy for Europe[3], the WG was also given the task to further work on a concept paper to address the environmental challenges and reply to certain flagship actions of the strategy, to bring the necessary support in the revision of the EU pharmaceutical legislation.
This document elaborates further on the revised mandate and the working arrangements as discussed within the WG and it requests the endorsement of its mandate from the Pharmaceuticals Committee.

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

The ad-hoc WG was 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

[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] COM(2019) 128 final 11.03.2019, 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.

[3] COM(2020) 761 final, 25.11.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN

Commission Communication (COM(2019) 128 final of 11 March 2019) that fall under the competence of the Member States. The scope of the WG 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;[4] "

The WG 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 WG relate to human medicines. The WG 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.

Following the adoption of the pharmaceutical Strategy for Europe[5] that also sets flagship actions to address the environmental challenges, the ad-hoc WG is also given the task to draft a concept paper. That concept paper should outline expert views that should be solutions oriented to bring the necessary support in the revision of the EU pharmaceutical legislation (Directive 2001/83/EC) and as considerations on main elements and business processes that may need to be reflected in the regulatory framework on the following aspects:

- **Strengthening the environmental risk assessment requirements and conditions of use for medicines and take stock of the results of research under the innovative medicines initiative;**
- **Greener pharmaceuticals with respect to antimicrobial resistance. For this point, the ad-hoc WG should also consult the EMA Good Manufacturing and Distribution Practices (GMDP) Inspectors working group on the aspect relevant to manufacturing of active pharmaceutical ingredients and finished medicinal products and GMDP and reflect their input in the finalised concept paper.**

The deadline for this concept paper is March 2022 with an interim deadline for a mature draft in January 2022.

The mandate for the ad-hoc WG shall be three years that could be further prolonged. **Due to the additional task, the original deadline** until March 2023 **is prolonged until March 2024.** The duration of the mandate could be further extended, if necessary and appropriate.

One of the participating Member States will chair the WG. The Secretariat of the WG 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 WG will meet mainly via teleconference (in English) in a

[4] COM(2019) 128 final, 11.03.2019, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2019:128:FIN from the sections 5.1, 5.3 and 5.4.

[5] COM(2020) 761 final, 25.11.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN

frequency decided by the group. The ad-hoc WG will also agree on an agenda, work plan and its working methods.

The ad-hoc WG will report to the Pharmaceutical Committee.
