EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 778

PHARMACEUTICAL COMMITTEE
7 November 2019

Subject: **EU strategic Approach on pharmaceuticals in the environment**
Background note[1]

Agenda item 3

The aim of this meeting is to discuss the EU Strategic Approach on pharmaceuticals in the environment and the follow-up actions to agree on the setting up an ad-hoc focused group for this area.

I. State of play

The Commission adopted the Communication on an EU strategic approach to pharmaceuticals in the environment (11.03.2019)[2]. It delivers on the legal obligation under the Priority Substances Directive (a daughter of the Water Framework Directive). DG Environment has the main responsibility for this policy. DG Sante was closely associated in the adoption of this act. Commission services together with relevant Agencies have started various implementation actions.

The EU Approach on pharmaceuticals in the environment has six areas of actions. They place the emphasis on sharing good practices, on cooperating at international level, and on improving understanding of the uncertainties and knowledge gaps throughout the whole life-cycle of pharmaceuticals:

- Increase awareness and promote prudent use of pharmaceuticals

[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

- Support the development of pharmaceuticals intrinsically less harmful for the environment and promote greener manufacturing
- Improve environmental risk assessment and its review
- Reduce wastage and improve the management of waste
- Expand environmental monitoring
- Fill other knowledge gaps.

Human and veterinary pharmaceutical substances may address unintended environmental health challenges. Therefore, the pharmaceutical legislation and an established practice require that companies have to produce an Environmental Risk Assessment (ERA) for new compounds. Companies perform the ERA of medicinal products during the development of new medicines. The results are submitted as part of the authorisation file of a medicinal product concerned (not as a class of substances).

The measures foreseen in the EU Strategic approach are to be discussed and further implemented by the Commission, Member States, the relevant Agencies and stakeholders. The Annex to this note lists the follow-up actions and measures that mainly fall under the competence of the Member States. EMA has also a role to implement certain actions mainly focused on the environmental risk assessment at EU level.

II. Proposed solution for the follow-up actions

It is proposed to establish *an ad-hoc group* under the Pharmaceutical Committee focused on this area to share best practices on how environmental considerations are taken into account in the life-cycle of human pharmaceuticals and potentially provide guidance/recommendations, mainly in relation to the list of actions for the Member States provided in the Annex. This ad-hoc group will deliver the outcome of its work that will be discussed and endorsed in the Pharmaceuticals Committee.

In view of this, Member States are invited to present their views and inform the Commission on their participation in this group and the willingness to take the leading role. In principle, DG SANTE will facilitate to start the work of this group in providing the possibility for a first physical meeting, while the follow-up will be organised via teleconferences.

Annex

1. **List of actions and measures in relation to human medicinal products in the relevant sections of the EU strategic Approach on pharmaceuticals in the environment that mainly fall under the competence of the Member States:**

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

- 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;

2. **List of actions and measures in relation to human medicinal products in the relevant sections of the EU strategic Approach on pharmaceuticals in the environment that mainly fall under the competence of the European Medicines Agency and in collaboration with the European Commission and the Member States:**

Section 5.3 Improve environmental risk assessment and its review

- Seek to improve the level of environmental expertise in the Committees and networks involved in the environmental risk assessment of medicinal products;
- Examine how to improve public access to the main environmental risk assessment results and relevant toxicological thresholds for medicinal products while respecting data-protection rules;
- Emphasise to applicants the importance of submitting a completed assessment by the time of the authorisation for marketing human medicinal products, so that adequate risk management measures can be established and published;
- Take stock of the results of research under the Innovative Medicines Initiative (IMI) in relation to human medicinal products;

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.