Ms. Sandra Gallina,
Director-General,
European Commission,
Directorate-General for Health and Food Safety,
1049 Brussels

06 September 2022

RE: 'Monograph' system for environmental risk assessment of medicinal products

Dear Director-General Gallina,

We strongly support establishing an active substance-based review ('monograph') system for the environmental risk assessment of human and veterinary medicinal products.

The Veterinary Medicinal Products Regulation requires the European Commission to present a report on a feasibility study of a monograph system and other potential alternatives for the environmental risk assessment of veterinary medicinal products to the European Parliament and the Council by 28 January 2022.

In October 2021, a study commissioned by the European Commission concluded that a monograph system would be justified, proportionate, and probably affordable in the long term. It would support the EU Strategic Approach to Pharmaceuticals in the Environment and the European Green Deal's 'one substance - one assessment' approach, as well as other EU strategic approaches.

The monograph system would optimise and consolidate hazard data for environmental risk assessments, improve knowledge of relevant environmental risks, avoid test duplication, and align with the 3 Rs principle of Replacement, Reduction, and Refinement. The study also determined that the administrative burden on authorities would be reduced in the long run.

The European Commission missed the 28 January 2022 deadline and seven months later there is still no clear timeline for when this will take place. We call on the European Commission to meet its legal obligation and present their report as soon as possible to address uncertainties regarding the level of environmental protection in the current system.

The European Commission is revising the regulatory framework for human medicine with a regulation proposal expected at the end of 2022. We believe it would be timely to consider the value of the monograph system in a wider policy context and also consider using it for the environmental risk assessment of human medicinal products to avoid different systems.

We remain at your disposal should you have any questions and we would very much welcome any opportunity to meet with you or a member of your staff to discuss the content of this letter in more detail.

Yours sincerely,

Will Clark,
Executive Director – Health Care Without Harm (HCWH) Europe

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Agriculture Senior Expert - Deutsche Umwelthilfe

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