From the PlanED Prescribing Consortium
May 30, 2024

To the European Commission
CC: European Medicines Agency

Recommendations to improve environmental sustainability in EU pharmaceutical legislation

Dear European Commission,

I am writing on behalf of the Consortium of the Erasmus+ project 'Planetary Health Education in Prescribing' (PlanED Prescribing; a collaboration between eight European medical schools and the Dutch National Institute for Public Health and the Environment (RIVM), with advisory support from, among others, the European Association for Clinical Pharmacology and Therapeutics) to express our concern about the way in which environmental sustainability is included in the ongoing reform of the EU pharmaceutical legislation.

The objective of PlanED Prescribing is to integrate environmental considerations into medical education for prescribers. This aligns with the European Commission's commitment to improve the environmental sustainability of medicines. We aim to equip prescribers in Europe and beyond with the knowledge and skills needed to minimize the environmental impact of medicines while ensuring optimal patient care. Unfortunately, this objective is hindered by a lack of essential information about the environmental impact of medicines, which makes it difficult to consider green(er) choices when prescribing. We believe that the current revision of the European Commission's pharmaceutical legislation provides a window of opportunity to redress the situation, by including additional and more specific measures that could contribute to the availability of essential information, facilitating environmentally friendly choices.

We appreciate the European Commission's commitment, as outlined on its website, to making medicines more environmentally sustainable through its new legislation. However, the current proposal for new legislation falls short of addressing this issue in sufficient detail. While the proposal improves the environmental risk assessment of medicines and outlines the goal to reduce antimicrobial resistance, it lacks explicit emphasis on reducing the overall environmental footprint of treatment with medicines. Therefore, we would like to propose two key recommendations for the new legislation:

1. **Provide harmonised criteria, definitions and assessment methods for determining the overall environmental impact of medicines**
    a. Pursue consensus on the criteria needed to assess the overall environmental impact of medicines, considering all aspects of production, development, transport, use, waste and pollution. Acknowledging the dynamic nature of research and practice on this, our consortium would welcome the opportunity to be involved in ongoing discussions on these environmental criteria.
    b. Provide harmonised definitions and assessment methods to establish a standardised approach for determining the environmental sustainability of medicines. This is essential to enable regulators, prescribers, procurers and other stakeholders to make reliable comparisons between medicines. By providing harmonised methodology, data requests by regulators and other stakeholders will also be harmonised. This is in

the interest of both stakeholders and the pharmaceutical industry as it will ensure a level playing field between companies and member states. We are aware that some pharmaceutical companies already have data on the environmental impact of their products but are hesitant about publishing this information until there is a standardised approach to assessment and reporting. Regulatory guidance is needed to ensure these data become available and that the methodology used is transparent.

2. **Ensure transparency and data availability**
    a. Incorporate specific provisions in the pharmaceutical legislation to ensure that all relevant data concerning the environmental sustainability of medicines is made accessible to regulators, procurers, healthcare professionals and other stakeholders. These provisions should include mandating pharmaceutical companies to report environmental impact data on a product level.
    b. Integrate information about environmental sustainability into pharmaceutical product information. This is necessary not only for new medicines entering the market, but also for older medicines already in the market, given their widespread use and importance. We would be happy to discuss possibilities on how to include clear sustainability metrics in product information, to assist prescribers to make the most environmentally friendly choices.
    c. Publish where (human) medicinal products, and their ingredients, are produced.

We earnestly request that these recommendations be included in the new pharmaceutical legislation. This will ensure that the issue will be taken up adequately by regulators and by stakeholders within the pharmaceutical sector, which is essential for making progress. Moreover, these recommendations also comply with many other EU legislative aspects such as the Zero Pollution ambition, the Green Deal, and the Corporate Sustainability Reporting Directive.

The PlanED Prescribing Consortium will remain committed to keep you informed on relevant insights as our project progresses. We are also open to further discussions. Should you have any questions or require additional information, please feel free to contact us. In the interests of transparency and to foster a collective effort to achieve more environmentally sustainable treatment with medicines, this letter will also be made public.

We appreciate your commitment to improving the environmental sustainability of medicines and hope that by working together we can have a positive impact on the achievement of this important goal.

Yours sincerely,

The PlanED Prescribing Consortium
Prof. Dr. Jelle Tichelaar as project leader on behalf of the complete consortium
Amsterdam - May 30, 2024

Annex 1: The complete consortium of PlanED Prescribing

Partners

- Amsterdam University Medical Center
- Dutch National Institute for Public Health and the Environment (RIVM)
- Inholland University of Applied Sciences
- Maastricht University
- Radboud University Medical Center
- Transilvania University of Brașov
- University Medical Center Groningen
- University of Bologna
- University of Lisbon
- University of Zagreb

Associate partners

- Dr Amy Booth & Dr SanYuMay Tun from the University of Oxford
- Dr Marc Labriffe from the University Hospital of Limoges
- Dutch Society for Clinical Pharmacology & Biopharmacy
- European Association for Clinical Pharmacology and Therapeutics
- European Society for Medical Oncology - Climate Change Task Force
- Netherlands Federation of University Medical Centres - working group Green Deal Sustainable Healthcare 3.0 “Medications”
- CO_2-assistant
- Research & Expertise Center in Pharmacotherapy Education
- Northwest Academy Alkmaar