RECOMMENDATIONS FOR GREENER HUMAN MEDICINES

IN THE REVISION OF THE EU GENERAL PHARMACEUTICALS LEGISLATION

Health Care Without Harm

ABBREVIATIONS USED IN THIS PUBLICATION

AMR	Antimicrobial Resistance
API	Active Pharmaceutical Ingredient
BREF	Best Available Technique Reference Document
CWW BREF	Best Available Techniques Reference Document for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector
EMA	European Medicines Agency
EPPP	Environmentally Persistent Pharmaceutical Pollutant
EPR	Extended Producer Responsibility
ERA	Environmental Risk Assessment
EU	European Union
GMP	Good Manufacturing Practice
HCWH	Health Care Without Harm
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IED	Industrial Emissions Directive
MRI	Magnetic Resonance Imaging
NHS	National Health Service
OFC BREF	Best Available Techniques Reference Document for the Manufacture of Organic Fine Chemicals
OTC	Over-the-counter
PSCI	Pharmaceutical Supply Chain Initiative
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAICM	Strategic Approach to International Chemicals Management
WGC BREF	Best Available Techniques Reference Document for Common Waste Gas Management and Treatment Systems in the Chemical Sector
WHO	World Health Organization

INTRODUCTION

In this position paper, Health Care Without Harm (HCWH) Europe presents policy recommendations to improve the sustainability of human medicines on the EU market and pharmaceutical supply chains in line with the EU zero-pollution ambition for a toxic-free environment.

The European Commission is currently revising the EU general legislation on medicines for human use to ensure a future-proof and crisis-resistant medicines regulatory system. This revision is also an opportunity to draw lessons from the COVID-19 pandemic, which has put a heavy strain on Europe's healthcare sector.[1]

The *Pharmaceutical Strategy for Europe*, published by the European Commission on 25 November 2020, paved the way for this revision.[2] The subsection "High quality, safe and environmentally sustainable medicines" describes a series of actions intended to improve the quality and environmental sustainability of medicines for human use in the EU.

In this area, the Pharmaceutical Strategy includes two flagship initiatives, which involve improving transparency of the pharmaceutical supply chain and strengthening the environmental risk assessments (ERAs) of human medicine. It also provides for other actions, notably related to the production of quality and sustainable medicines and the decarbonisation of value chains.

On 24 November 2021, the European Parliament adopted a resolution on the Pharmaceutical Strategy, which calls on the European Commission to adopt additional measures that strengthen the sustainability of medicines and to respond to the previous demands made in the European Parliament's 2020 resolution on a Strategic Approach to Pharmaceuticals in the Environment.[3,4]

It is in this context that HCWH Europe has developed 30 policy recommendations for the European Commission to adopt in its proposal for a regulation planned for Q4 of 2022.

There is an urgent need for ambitious legislative and non-legislative measures throughout the life cycle of medicines to minimise the entry of pharmaceutical residues into the environment and reduce risks for human, animal, and environmental health. This paper focuses on source-directed and use-orientated actions in line with the scope of the on-going legislative revision.

IMPROVING THE TRANSPARENCY AND SUSTAINABILITY OF THE PHARMACEUTICAL SUPPLY CHAIN

Drug manufacturing can be a source of pharmaceutical discharges into the environment in concentrations that can be significantly higher than toxic thresholds.[5] These emissions can have devastating impacts on ecosystems and can contribute to the development of antimicrobial resistance (AMR), which threatens local populations and global health.[6]

In the EU, there are no specific rules regulating the emissions from pharmaceutical production into the environment; active pharmaceutical ingredients (APIs) are not covered by the REACH regulation. The pharmaceutical industry falls under the Industrial Emissions Directive (IED) and its respective OFC, CWW, and WGC Best Available Technique Reference Documents (BREFs), which do not set emission limits for APIs.

Many pharmaceutical plants supplying the EU market are located outside Europe in countries with weaker environmental and regulatory systems, particularly in the case of antibiotics.[7] In addition to stronger EU regulation, there is a need for a global response through strengthened international cooperation and dialogue to address this problem across entire supply chains.

There are several industry-led initiatives, such as the AMR Industry Alliance or the Pharmaceutical Supply Chain Initiative (PSCI), that seek to promote responsible supply chain management in the pharmaceutical sector. Whilst these are welcome developments, to date private and voluntary initiatives have had a limited effect on reducing pharmaceutical manufacturing emissions.[8]

One particular problem is that these initiatives often lack effective action or transparency. The AMR Industry Alliance's antibiotic discharge targets, for example, focus only on surface waters, where dilution can reduce drug concentrations, as opposed to targeting manufacturing wastewater, which would be much more effective.

Furthermore, pollution levels under this initiative are not directly measured in water samples but estimated from internal data, and the lack of access to key data hampers oversight.[9]

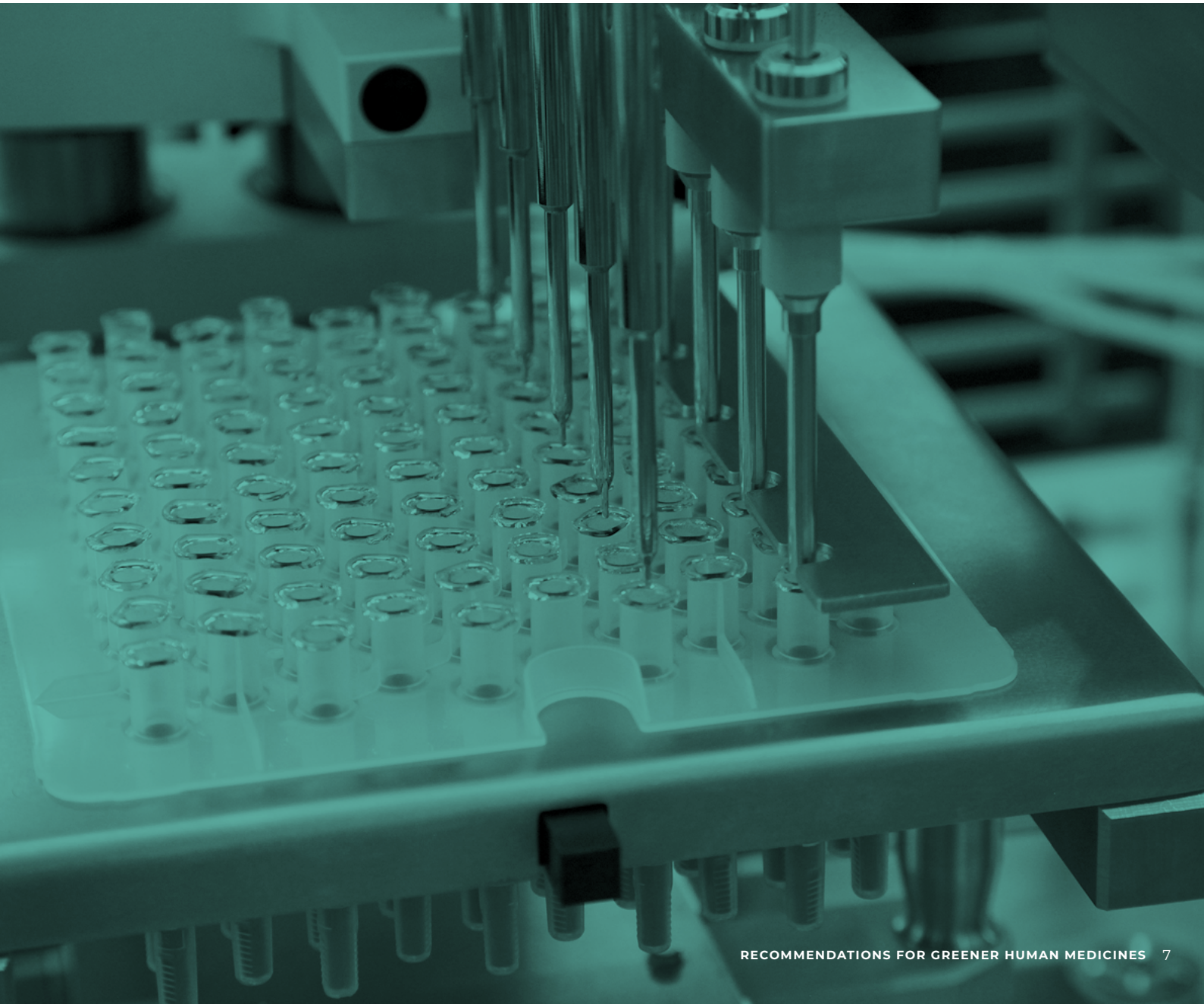
Overall, there is a lack of transparency in the pharmaceutical supply chain that makes the origin of APIs challenging or impossible to trace. Without open access to supply chain information, it is difficult to hold the pharmaceutical industry accountable for the emissions of pharmaceutical residues that can occur during their manufacturing processes.[7]

An Access to Medicine Foundation report found that of the pharmaceutical companies analysed, *"very few companies publicly report any level of detail on either the number of manufacturing sites audited, or on how many of these sites report compliance with safe levels. No company publicly reports on the actual levels of antibacterial residue entering local soil and water, and no company publishes its audit results."*[10]

RECOMMENDATIONS

- Make it compulsory for pharmaceutical companies to publicly disclose supply chain information, including names and locations of suppliers, production units, and processing facilities, in an online public database to ensure the traceability of all pharmaceutical products. The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) database provides a good case example of this.[11]
- Include mandatory environmental criteria that address discharges of pharmaceutical residues into the environment, e.g. emission limit values, in the EU Good Manufacturing Practice (GMP) legislation.
    - Directive 2003/94/EC lays down the principles and guidelines of good manufacturing practice for human medicines, further specified in EudraLex Volume 4.[12] These guidelines aim to ensure the quality and safety of the manufacturing process, but do not currently address discharges of pharmaceutical residues into the environment. As an existing system to control pharmaceutical production, the GMP provides a good framework for new environmental protection measures.
- Develop environmental standards for drug production that will create a level playing field for drug manufacturers. These standards could be derived from Environmental Risk Assessment (ERA) data and be used to update the OFC BREF, strengthening the link between pharmaceutical legislation and the IED. Such standards would also support pricing and reimbursement agencies and procurers, who could use them as a benchmark to reward companies that have invested in greening their supply chain.
- Develop guidelines to help purchasing authorities use procurement policy to promote greener pharmaceuticals and sustainable production with clear environmental criteria and performance indicators based on the Public Procurement Directive.

- Advocate for a revision of the WHO GMP framework that includes mandatory environmental criteria addressing the discharges of pharmaceutical residues into the environment.
    - In 2020, the WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted guidance for manufacturers and inspectors on how the GMP should be implemented in waste and wastewater management in antimicrobials production.[13] The final guidance document was narrowed in scope compared to the ambitious first draft, but this draft could still be a source of inspiration for the proposed revision of the WHO GMP framework.[14] This revision must address all drug categories, not just antimicrobials. This would be aligned with the European Parliament's resolution of 24 November 2021 urging the European Commission to include environmental standards, especially on waste and wastewater management, in the GMP guidelines at international level.
- Strengthen international cooperation and dialogue with manufacturing countries, develop a global research agenda, and advocate for global solutions. This can be carried out through the WHO, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Strategic Approach to International Chemicals Management (SAICM) in which the EU should take a leading role to address Environmentally Persistent Pharmaceutical Pollutants (EPPPs).



STRENGTHENING ENVIRONMENTAL RISK ASSESSMENTS FOR HUMAN MEDICINE

Environmental Risk Assessments (ERAs) aim to evaluate and limit potential adverse effects of medicines on the environment. This ensures that potential effects are studied and that precaution measures are taken if a risk is identified. ERAs must be performed by pharmaceutical companies and submitted to the EMA during the marketing authorisation process.[15]

The guideline on ERA for human medicines came into force on 1 December 2006, but it was not applied retroactively, which meant medicines for human use that entered the EU market through the centralised procedure before this date often lack an adequate ERA and for many there are no data on potential environmental impact.[16]

In Germany, it is estimated that environmental fate and effect data are only available for less than a third of the active substances of potential environmental concern.[17] Furthermore, there are comprehensive environmental data available for only about 40% of the active pharmaceutical substances monitored in surface water.[18]

Unlike veterinary medicines, environmental risks are not criteria in the benefit-risk assessment for human medicines in the regulatory review of marketing applications. This means that environmental aspects are not taken into account when the EMA decides on its marketing recommendations for new medicine.

The pharmaceutical industry tends not to prioritise ERAs during the development of new drugs as environmental risks are not considered in the benefit-risk assessment for human medicines. In 2011-2012, 37% of ERAs analysed in a paper were submitted after the deadline and 83% of these had missing studies or were of unsatisfactory quality.[19]

For the same reason, environmental risks are not considered in the pharmacovigilance system, which means that environmental effects are not reported after use and referral procedures are not possible in case of environmental risks.

Follow-up mitigation actions, e.g. advertising bans or making drugs available under prescription only, cannot therefore be implemented based on post-authorisation observations.

Consequently, Member States tend not to develop appropriate resources for the evaluation of ERAs, which can vary from one country to another.[20] The EMA also has reduced capacity – its committees for human medicines do not include ERA experts and there is no permanent working party for environmental issues for human medicines.

Another issue is that ERAs have a limited scope. They do not consider the risks that manufacturing discharges and their cumulative impact can have on the environment and human health. ERAs do not consider either the risks of AMR development from production, use, and disposal, nor the risks that degradation products, metabolites, and combination effects can pose.

The EMA guideline on ERA is under revision; the current draft no longer even provides for the investigation of possible metabolites and transformation products for the aquatic compartment.[21] If this guideline is approved, there will be no information available on metabolites and transformation products, which can be transferred to groundwater and drinking water.

Finally, ERA data are not fully publicly available, which is in conflict with the Aarhus Convention. Only main ERA studies are published in (European) Public Assessment Reports, where they are categorised by products rather than by substances, making environmental information on APIs difficult to research. It is also common that ERA studies submitted post-approval are not reflected in (European) Public Assessment Reports.

RECOMMENDATIONS

- Include environmental risks in the benefit-risk assessment for human medicines (already the case for veterinary medicines). This will strengthen the importance of ERAs in the marketing authorisation process and improve risk mitigation measures, e.g. conditions on use, for the products.
  - This is also expected to incentivise the EMA and Member States to develop new resources, force pharmaceutical companies to pay a greater attention to ERAs and result in dossiers of higher quality, and encourage the pharmaceutical industry to develop greener medicines. This recommendation is supported by the European Parliament resolution of 17 September 2020, provided that marketing authorisations are not delayed nor refused solely on the grounds of adverse environmental impacts.
- Include environmental issues in the pharmacovigilance system to monitor real-world data and take into account the results of new scientific research (which would require a revision of the benefit-risk assessment).
- Establish a catch-up procedure for pharmaceuticals that have been authorised on the market before 1 December 2006 without an ERA (legacy drugs), as already provided for veterinary medicines in the Veterinary Medicinal Products Regulation, starting with a priority list of active substances.
- Make it compulsory for pharmaceutical companies to provide comprehensive and reliable environmental data at the time of marketing authorisation. In the case where this would create a major delay, introduce a compulsory mechanism to submit the ERA in a given

timeframe and, if needed, to add risk mitigation measures to the product information. This would be in line with the 'no data, no market' principle that applies to chemical substances under the REACH regulation.

- Make ERA data publicly accessible in an online database under the supervision of the EMA in line with the Aarhus Convention. This database should include all ecological and human toxicological data as well as the fate, behaviour, and ecotoxicological effect in the environment of medicines, their active ingredients, and their metabolites. This would allow the adoption of appropriate risk mitigation and management measures to reduce pharmaceutical emissions. This information would also be helpful for research purposes and for developing drug formularies.
- Replace the current product-based environmental assessment system with a substance-based review system ('monographs'), for which marketing authorisation holders would share responsibility, to reduce administrative burden, increase transparency, and reduce animal testing.
    - A recent feasibility study commissioned by the European Commission to introduce such a system for veterinary medicines concluded that this system is justified and proportionate. Whilst it would be more expensive and resource-intensive in the short term, the conclusion was that the benefits should outweigh the disadvantages in the long term.[22]
- Broaden the scope of ERAs to also address environmental risks during the production and formulation process (as considered in the European medicines agencies network strategy to 2025[23]), risks of AMR development and maintenance in the environment from production, use, and disposal for antimicrobials, as well as environmental risks of degradation products, metabolites, and combinations effects, in view of the growing evidence that mixtures of pharmaceuticals can have a greater joint toxicity.[24]
- Require a regular review of ERAs to ensure that new environmental information available can be used in a timely manner, increase collaboration between stakeholders, and improve the use of resources.
- Ensure a better link between ERA data and other regulatory frameworks such as relevant EU water and soil legislation, e.g. Water Framework Directive, and industrial emissions legislation, e.g. Industrial Emissions Directive (IED), to ensure efficient risk assessment and mitigation measures in line with the 'one substance, one assessment' principle of the Chemicals Strategy for Sustainability.

ENCOURAGING GREENER MEDICINES, PROMOTING RESPONSIBLE USE, AND REDUCING PHARMACEUTICAL WASTE

Pharmaceuticals are biologically active, often mobile (particularly in the case of metabolites), and not readily biodegradable in the environment.[25] They are designed to interact with living systems at low doses, which means that even low concentrations in the environment are a concern. Evidence of negative effects on ecosystems and non-target species has been demonstrated.[26]

Medicines also have a high carbon footprint and contribute to the global climate crisis. In 2020, the National Health Service (NHS) in England reported that medicines and chemicals in the supply chains made up 20% of its carbon emissions (excluding the direct use of anaesthetic gases and metered dose inhalers), and represent one of the greatest opportunity areas for carbon reduction.[27]

Several medicines known to pose environmental risks are over-the-counter (OTC) medication. These are commonly advertised to increase sales, which does not fit with the principle of responsible use. As a result, restricting advertising of pharmaceuticals, especially painkillers and lifestyle medicines, has been identified as a strategy to decrease pharmaceutical residues in the environment.[28]

The roadmap/inception impact assessment published by the European Commission after the Pharmaceutical Strategy identified this problem and proposed to *"assess how environmental considerations are taken into account in the advertising and prescription of medicinal products"*,[29] but this point is crucially missing in the Pharmaceutical Strategy itself.

Waste from unused medicine is another important problem, representing 10% of wastewater pollution.[30] Directive 2004/27/EC makes it mandatory for Member States to establish appropriate collection schemes for unused or expired drugs.

It does not, however, provide implementation guidelines and there are wide variations in the systems and their use across Member States.[31]

There are also concerns that in some EU countries pharmacies are asked to finance disposal and collection schemes on their own.[32] In order to finance collection systems, Member States such as France and Spain have established Extended Producer Responsibility (EPR) schemes for expired pharmaceutical products.[33] Countries with highest collection rates tend to have such schemes in place.[34]

RECOMMENDATIONS

- Make pharmaceuticals that can cause a harm to the environment prescription-only, based on environmental risk thresholds.
- Support the training of healthcare professionals (in particular doctors and pharmacists) on the environmental impact of medicines and the exchange of best practice to promote responsible use and proper disposal.
- Incentivise the research and development of environmentally sustainable and climate-neutral pharmaceuticals throughout the value chain through funding schemes such as Horizon Europe.
- Make pharmaceutical companies contribute to financing post-registration monitoring and water treatment costs due to pharmaceutical pollution, in line with the 'polluter pays' principle under Directive 2004/35/CE, to improve their responsibility for the pollution they generate.
- Develop guidance for healthcare institutions to reduce the discharges of pharmaceutical residues from use and disposal to municipal wastewater.
- Promote the separate collection of urine of patients administered with X-ray or magnetic resonance imaging (MRI) contrast agents.
- Make it compulsory for pharmaceutical companies to measure and consistently report (both in terms of comparability and quality) the greenhouse gas emissions of their products throughout the value chain.
- Ban advertising for OTC medicines that can pose a risk to the environment.
- Adopt stronger market conditions for medicines with high environmental risk, e.g. marketing limitations when greener alternatives exist, risk management measures to prevent environmental releases, or limitation of use in healthcare institutions with effective on-site wastewater treatment facilities.
- Classify pharmaceutical substances based on environmental criteria and create a label for OTC products that meet high environmental standards to reward and incentivise green production and development as well as to allow patients to make informed purchasing decisions. The Region Stockholm's Pharmaceuticals and Environment database provides a good case example of an eco-classification scheme.[35]

- Develop implementation guidelines on pharmaceutical collection schemes that harmonise take-back systems across the EU and collaborate with Member States to properly enforce the current regulation.
- Make it compulsory to feature disposal information for patients on the outer drug packaging and in pharmacies (in addition to patient information leaflets) to prevent disposal via the toilet or sink.
- Compel pharmaceutical companies to propose different packaging sizes and forms for their products, in particular for liquid drugs, to reduce the amount of pharmaceutical waste.
- Compel pharmaceutical companies to contribute to financing pharmaceutical collection schemes under the EPR principle of the Waste Framework Directive.
- Regulate the management of human medicinal waste beyond cytostatic and cytotoxic substances, which are the only pharmaceuticals explicitly classified as hazardous waste under the Waste Framework Directive currently.

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