# Swedwatch submission to the European Commission on a Pharmaceutical Strategy for Europe:

# Affordable Medicine for Europe Should Not Violate Fundamental Rights to a Safe, Clean and Sustainable Environment

Swedwatch is an independent, non-profit research organisation based in Stockholm that examines companies, investors, and state actors' due diligence obligations to protect and respect the human and environmental rights of workers and communities. Our vision is a world in which economic systems are just, transparent, and environmentally sustainable. Our main mission is to ensure business practices are responsible and inclusive with respect to human rights and the environment.

Swedwatch calls on the European Commission to ensure that the Pharmaceutical Strategy for Europe: Timely Patient Access to Affordable Medicines, promotes a responsible and transparent pharmaceutical sector that protects and respects fundamental human rights to a safe, clean, and sustainable environment. Affordable medicines for European citizens should not come at the cost of human lives and widespread environmental degradation, particularly in countries often outside the EU where drugs are manufactured.

## Key issues

The rights to a safe, clean, healthy, and sustainable environment is a fundamental human right, and integral to the core values of the European Union. As highlighted in the Swedwatch publication *Health Paradox: Environmental and Human Rights Impacts from Pharmaceutical Production in India and the Need for Supply Chain Transparency,*[1] pharmaceutical manufacturers need to be accountable for the widespread environmental and cumulative human health effects they incur as a result of releasing pharmaceutical effluents into the environment. The lack of transparency in the pharmaceutical supply chain is a major obstacle to addressing malpractice and corner-cutting by manufacturers. This results in widespread environmental pollution, and deterioration of human health in many communities where drugs are being manufactured. Regardless of where pharmaceutical products, including active ingredients, are being manufactured, "affordable" or cheap medicines destined for European markets should never come at the cost of human lives and widespread environmental degradation.

The Road Map of the Pharmaceutical Strategy points to the need for the EU to promote innovation in the pharmaceutical sector, ensuring access, availability, and affordability of medicine for European citizens. The subtitle of the Pharmaceutical Strategy – Timely Patient Access to Affordable Medicines – suggests a primary focus of the Commission on innovation and affordability of medicines for European citizens. This is also demonstrated by the emphasis placed on issues of innovation, accessibility, and affordability during the stakeholder workshop on the Pharmaceutical Strategy for

[1] https://swedwatch.org/publication/report/time-to-hold-pharmaceutical-polluters-to-account/

Europe held on 14 and 15 July 2020.[2] This is highly concerning as several organisations, including the Organisation of Economic Cooperation and Development (OECD), have highlighted the high concentrations of pharmaceuticals that contaminate the environment, and called for a life-cycle approach to medicines and reducing the environmental footprint of pharmaceutical products.[3]

It is imperative that the Commission ensures that the Pharmaceutical Strategy for Europe and its five-year action plan promotes a toxic free environment in line with the overarching goals of the European Green Deal and the New Industrial Strategy. To achieve this, enforcement of the environmental and human rights due diligence obligations of pharmaceutical companies and state actors must be an integral part of the new strategy. Furthermore, the Commission must consider key principles governing a responsible and transparent pharmaceutical sector that protects and respects the fundamental human right to a safe, clean, and sustainable environment.

## Recommendations

1) **Improve transparency of the supply chain to ensure accountability of pharmaceutical companies regarding environmental and human rights risks**
   Public disclosure of information is particularly important in maintaining accountability of companies and state actors in the pharmaceutical sector. It is essential for pharmaceutical companies to publicly disclose information regarding human rights and environmental risks of all pharmaceutical products and active pharmaceutical ingredients that have been approved for sale and use in the European Union. This should include full names of authorised production units, processing facilities and the list of sub-suppliers.

2) **Impose mandatory environmental risk assessments that extend to risks incurred by manufacturing discharges**
   Environmental risk assessments (ERAs) in the market authorisation process must include environmental risks associated with manufacturing discharges and cumulative impact assessment of areas surrounding manufacturing facilities. This requirement should also be applied retrospectively to pharmaceutical products and active pharmaceutical ingredients that have already been granted market licences in the EU.

3) **Strengthen the regulatory framework to control and mitigate release of pharmaceutical effluence in the environment**
   Pharmaceuticals in the environment present critical risks for human health. High concentrations of pharmaceutical effluence have been found near manufacturing facilities around the world, and it is therefore essential for manufacturers to control and mitigate its release into the environment. It is imperative for the EU to develop a stringent regulatory framework on environmental quality standards based on precautionary principles to regulate the release of pharmaceutical effluence such as antibiotics and anti-infectives. This

[2] https://ec.europa.eu/health/sites/health/files/human-use/docs/stakeholders_sum_workshop_en.pdf
[3] https://www.oecd.org/environment/resources/Pharmaceuticals-residues-in-freshwater-policy-highlights-preliminary-version.pdf

should include amendments to the EU principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (2003/94/EC).

4) **Promote green public procurement that encourages responsible production and consumption of pharmaceuticals**
Public health care providers must leverage their purchasing power to promote responsible production and consumption of pharmaceuticals. The European Union must promote institutions that support green public procurement to stimulate responsible pharmaceutical production and consumption.

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