"Greener Pharmaceuticals' Regulatory Highway"
(a call for action on regulatory support for introduction of more sustainable products and services)

As the pace of climate change and environmental degradation accelerates, climate change emerges as one of the major threats to human health in the 21st Century, jeopardizing progress in development, global health, and poverty reduction, and creating new health risks disproportionately affecting the most vulnerable. Known avoidable environmental risks cause about one quarter of all deaths and disease burden worldwide. Resolution WHA 77.14 on Climate and Health (2024) informs that modern health systems contribute to environmental pollution and approximately 5% of global carbon emission, including through the end-to-end supply chain from product manufacturing, procurement, distribution, use, waste creation and disposal, thereby underscoring the need for mitigation and adaptations to make health systems more environmentally sustainable.

There is growing awareness among Member States of the interconnections between climate change, pollution and health, as mirrored by the Declaration of the 28th Conference of the Parties to the UN Framework Convention on Climate Change (COP28, December 2023), signed by over 140 Member States, committing to promote climate resilient and low carbon health systems, including steps to curb emissions and reduce waste in the health sector and set procurement standards including supply chains. The 14th WHO General Programme of Work (GPW) 2025-2028 presents climate change and health as its top strategic objective, emphasizing the interlinkages between health and other sectors and the need for cross-sectoral cooperation.

WHO actions in the area of health and climate are guided by the WHO Global Strategy on Health, Environment and Climate Change (2020); the WHO Operational Framework for building climate resilient and low carbon health systems (2023)[1]; World Health Assembly resolution 76.17 The impact of chemicals, waste and pollution on human health (2023)[2]; the adopted UN Global Framework on Chemicals (September 2023) addressing chemical production and use along the value chain[3], and the most recent World Health Assembly resolution WHA77.14 Climate change and health (2024[4]). WHO draws on existing, well-established health guidance, technical and standard-setting mechanisms, expert advisory groups, networks and working groups in relation to health products, assessment of health risks, management of health waste and initiatives to reduce carbon and toxicity and increase the sustainability in the health supply chain. New partnerships are being established to address emerging health and climate priorities, and more than 90 Member States have now joined the Alliance for Transformative Action on Climate and Health (ATACH) launched during the 26th Conference of the Parties to the UN Framework Convention on Climate Change (COP26, November 2021). As a voluntary network, ATACH serves as a platform for coordination, exchange and networking for tackling challenges, and monitoring global progress on health and climate priorities. This work supports building of climate resilient and sustainable low carbon health systems including health supply chains.

In March 2022, the UN Environment Assembly adopted a historic resolution, requesting the UN Environment Programme to convene an Intergovernmental Negotiating Committee (INC) on Plastic Pollution[5] to develop a

[1] https://www.who.int/publications/i/item/9789240081888

[2] Resolution WHA 76.17 The impact of chemicals, waste, and pollution on human health (2023) (who.int)

[3] Global Framework on Chemicals - For a Planet Free of Harm from Chemicals and Waste | UNEP - UN Environment Programme

[4] Resolution WHA 77.14 Climate change and health (2024) (who.int)

[5] Intergovernmental Negotiating Committee on Plastic Pollution | UNEP - UN Environment Programme

legally binding instrument addressing the full life cycle of plastic, including its production, design, and disposal, i.e., the Plastic Treaty. WHO recognizes plastics have various health and environmental impacts. WHO has proposed a dedicated programme of work to support the implementation of the Treaty in the health sector. Instead of an exemption for medical and health products, this could include delayed prohibitions on plastics and polymers of concern that are essential for access to affordable health services, allowing time for the development and regulation of sustainable alternatives. The fifth and final session of the INC was held in Busan, Republic of Korea, in December 2024 to review the advanced version of the compilation draft text[6].

Addressing climate and health is a key priority in Unitaid's 2023-2027 Strategy[7], speaking to the promotion of practices and products that make the provision of healthcare more sustainable, i.e., reducing the impact on the climate and on the environment of product manufacturing and supply. Furthermore, the Unitaid Climate and Health Strategy[8] focuses on mitigation, adaptation, and reducing the carbon footprint, speaking to climate smart health products that enable sustainable and equitable access to health for all, to be implemented through three specific objectives: 1) accelerate the introduction and adoption of key health products; 2) create systemic conditions for sustainable, equitable access and 3) foster inclusive and demand-driven partnership for innovation. Unitaid's Climate and Health Strategy aligns with WHO's comprehensive approach to climate resilient health systems.

The need for more sustainable products challenges a targeted response to critical areas with impact on climate.

In November 2023, UNITAID published a study "From milligrams to megatons: A climate and nature assessment of ten key health products. Six medicines/regimens were included in the study: Heat stable Carbetocin, Longacting injectable Cabotegravir, Dolutegravir-based first line regimen, Bedaquiline, Pretomanid, Linezolid regimen (BPaL) and Artemisinin-based combination therapy all of which are invited for WHO prequalification.

From the study, it was reported that materials acquisition, pre-processing, and manufacturing activities account for around 95 percent of the selected products" total GHG emissions. Other findings in the report were that: Active Pharmaceutical Ingredients used in medicine manufacturing account for most of these emissions (≈70%); Finished Pharmaceutical Product manufacturing is responsible for ≈ 10% of selected health products value chain emissions (with electricity being the main driver); share of emissions in the supply chain is only 1% of total emissions in the current scenario with mixed use of sea, road, and air transportation (with the assumption that all 10 products will be deployed at sufficient volume to be transported to user-countries by sea, although around 60% of heat stable Carbetocin will continue to rely on air freight); the dolutegravir-based regimen, accounting for ≈ 76% of greenhouse gas emissions from the 10 products, has high emissions due to all three factors: its API preparation is highly emissive, the synthetic process with low yield; the amount of dolutegravir required for the treatment regimen requires high annual doses of API; and demand for treatment is projected to be high with 32 million people living with HIV. The approach builds upon key synthesis metrics, including solvent usage, yield rate, and synthesis steps to estimate APIs emissivity.

[6] Reference from Lancet in 2024 https://doi.org/10.1016/S0140-6736(24)01822-1

[7] Unitaid_Strategy_2023-2027.pdf

[8] Unitaid-Climate-and-Health-Strategy-2023-2027.pdf

Other examples could be quoted, but evidence collected suggest the need to insist in specific areas like manufacturing of APIs, general approaches for more sustainable manufacturing processes, packaging, transportation, sustainable procurement standards and greater transparency and accountability of sustainable product criteria and materiality of products, increased collaboration and capacity building with private sector.

Many of them will require new standards and/or new regulatory guidance to enable quick and supported transformation in the sector towards a more sustainable sector. The reduction of environmental and carbon footprint in the medical products sector, will require the quick adoption of innovative approaches at R&D and manufacturing and a different positioning of regulators, both in setting adequate standards and guidance and in adopting relevant changes in streamlining evaluation procedures.

In this context the Department of Regulation and Prequalification of WHO (Division on Access to Medicines and Health Products) launches a call for action by the regulatory community and stakeholders to address the challenges for the medical products health sector, and specifically targeting the pharmaceuticals sector. The path for innovation in this area requires the engagement of regulators with active measures that will enable adequate timelines for adoption of relevant approaches. Without reducing the standards or the time for regulatory evaluation that will call for earlier dialogue between regulators and manufacturers.

As such, we propose to the regulatory community the adoption of initiatives that will consider:
1) The establishment of new standards and guidance documents supporting innovative approaches in the manufacturing, distribution, and usage of medical products, contributing to significant reductions in the environmental and carbon footprint of these products, and to better sustainability within the health sector and mitigation of impact on the environment that also demonstrate health co-benefits of these interventions and health sector lead by example.
2) A digital transformation of all services involved in regulatory systems, establishing standards for adequate reliance mechanisms between regulators on the exchange of relevant regulatory information, including a strong support programme for capacity building in LMICs.
3) The adoption of innovative regulatory procedures that allow for earlier involvement of regulators in considering innovative approaches, supporting streamlining of regulatory reviews for new innovative products, contributing to a reduction of the impact on the environment.

WHO will engage with stakeholders in developing a white paper to be discussed in a global summit in Q4 2025 with participation of relevant stakeholders from the regulatory, public health and industrial areas, including end users and procurement agencies.

We ask all regulatory authorities for medical products to engage in this call for action, contributing decisively within the specific context of your activities.

11 November 2024