Towards a greener pharmaceuticals' regulatory highway

A framework for regulators as enablers of decarbonization

World Health Organization

Towards a greener pharmaceuticals' regulatory highway

A framework for regulators as enablers of decarbonization

World Health Organization

Towards a greener pharmaceuticals' regulatory highway: a framework for regulators as enablers of decarbonization

ISBN 978-92-4-012437-0 (electronic version)
ISBN 978-92-4-012438-7 (print version)

Suggested citation. Towards a greener pharmaceuticals' regulatory highway: a framework for regulators as enablers of decarbonization. Geneva: World Health Organization; 2026. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://iris.who.int.

Sales, rights and licensing. To purchase WHO publications, see https://www.who.int/publications/book-orders. To submit requests for commercial use and queries on rights and licensing, see https://www.who.int/copyright.

Contents

Acknowledgements

WHO gratefully acknowledges the many individuals who contributed to the development of this framework.

The framework was prepared under the overall coordination and technical guidance of Rogerio Gaspar and Christine Guillard (Department of Regulation and Prequalification, WHO headquarters).

The lead writers for this framework were: Kevin Klein (Exon Consultancy, Netherlands [Kingdom of the]) and Pieter Stolk (Exon Consultancy, Netherlands [Kingdom of the]), with substantial contributions to evidence review, analysis and drafting from Siddhanth Kedhagae (Collaborate Project Management, Germany), Jaime Redondo Pedraza (Collaborate Project Management, Germany) and Carl Steinbeisser (Collaborate Project Management, Germany).

Special thanks are due to the experts who participated in the scoping interviews, stakeholder consultations and targeted follow-up discussions, providing critical insights that informed the horizon scanning and analysis: Hebatullah M. AbdulAziz (Egyptian Drug Authority, Egypt), Fatima Abubakr (National Agency for Food and Drug Administration and Control, Nigeria), Sumaila Abu (Food and Drugs Authority, Ghana), Sarah Adam (International Federation of Pharmaceutical Manufacturers and Associations, Switzerland), Camilla Felicio Agostinho (The Global Fund, Switzerland), Jean-Pierre Amorij (United Nations Children's Fund [UNICEF], Netherlands [Kingdom of the]), Kayode Amuda (National Agency for Food and Drug Administration and Control, Nigeria), Muhammadjon Azimov (Centre for Pharmaceutical Products Safety, Uzbekistan), Janis Bernat (International Federation of Pharmaceutical Manufacturers and Associations, Switzerland), Clement Bingen (MSF Belgium, Belgium), Jennifer Bonnah (Food and Drugs Authority, Ghana), Robert N. Bream (European Medicines Agency, Netherlands [Kingdom of the]), Kathleen Buckingham (United States Pharmacopoeia, United States of America [USA]), Sérgio Cavalheiro Filho (International Federation of Pharmaceutical Manufacturers and Associations, Switzerland), Indiana Castro (Medicines for Europe, Belgium), Seonmi Choi (The Global Fund, Switzerland), Jesusa Joyce Cirunay (Food and Drug Administration, Philippines), Carlotta Cogoni (International Generic and Biosimilar medicines Association, Portugal), Ellen Connorton (Lancet Countdown, USA), Monica da Luz C. Soares (Agência Nacional de Vigilância Sanitária, Brazil), Rittika Datta (Drugs for Neglected Initiative , India), Alexander Nii Oto Dodoo (African Medicines Agency, Rwanda), Feruza Djalilova (Centre for Pharmaceutical Products Safety, Uzbekistan), Admire Dube (University of the Western Cape, South Africa), Matthew Eckleman (Lancet Countdown, United Kingdom of Great Britain and Northern Ireland [United Kingdom]), Helerin Eiche (State Agency of Medicines, Estonia), Ana Gaunt (International Generic and Biosimilar medicines Association, Switzerland), Janet Ginnard (Unitaid, Switzerland), Thomas Gradel (Unitaid, Switzerland), Akif Görgülü (Médecins Sans Frontières International, Belgium), Wesal Haqaish (Jordan Food and Drug Administration, Jordan), Martin Harvey Allchurch (European Medicines Agency, Netherlands [Kingdom of the]), Colette Nkem Ifudu (National Agency for Food and Drug Administration and Control, Nigeria), Terseer Igbawua (National Agency for Food and Drug Administration and Control, Nigeria), Veronika Jekerle (European Medicines Agency, Netherlands [Kingdom of the]), Akhmadjonov Kamronbek (Centre for Pharmaceutical Product Safety, Uzbekistan), David Karenye (The Global Fund, Switzerland), Daniel Karimi (United States Pharmacopoeia, Kenya), Kamola Khakimova (Centre for Pharmaceutical Product Safety, Uzbekistan), Carina Klebl (European Medicines Agency, Netherlands [Kingdom of the]), Chaitanya Koduri (United States Pharmacopoeia, USA), Daisuke Koga (Pharmaceuticals and Medical Devices Agency, Japan), Melchior Kuo (International Federation of Pharmaceutical Manufacturers and Associations, Switzerland), Barnabas Kwangise (National Agency for Food and Drug Administration and Control, Nigeria), Clarisse Lamy (Drugs for Neglected Initiative , Switzerland), Lale Lee (UNICEF, Denmark), Adam Liddle (BSI, United Kingdom), Kristina Lorensen (UNICEF, Denmark), Nancy Martin (Gates Foundation, USA), Teresa Meneses Leonardo Alves (Dutch National Institute for Public Health and

the Environment, Netherlands [Kingdom of the]), Ann-Lise Mikolajczak (International Federation of Pharmaceutical Manufacturers and Associations, Switzerland), Ian Milimo (UNDP, Thailand), Caroline Moermond (Dutch National Institute for Public Health and the Environment, Netherlands [Kingdom of the]), Nkaelang Modutlwa (African Medicines Agency, Rwanda), Hasan Mohajeri (Swissmedic, Switzerland), Mohamed Mohamed (Egyptian Drug Authority, Egypt), Maja Flønes Monsen (Norwegian Hospital Procurement Trust, Norway), Kevin Moore (United States Pharmacopoeia, USA), Ahmad Mukhtar (National Agency for Food and Drug Administration and Control, Nigeria), Clariator Mvurume (African Medicines Agency, Rwanda), Marasi Mwencha (The Global Fund, Switzerland), Shimaa Nasr Eldeen (Egyptian Drug Authority, Egypt), Mai Nassar (Egyptian Drug Authority, Egypt), Takayuki Okubo (Ministry of Health, Labour and Welfare, Japan), Kwabena Frimpong Manso Opuni (Food and Drugs Authority, Ghana), Sarah Ouanhnon (Greener National Health Services England, United Kingdom), Mónica Perea-Vélez (GSK, Belgium), Lowik Pieters (Dutch National Institute for Public Health and the Environment, Netherlands [Kingdom of the]), Julien Pouille (Unitaid, Switzerland), Luca Prosdocimo (Medicines for Europe, Belgium), Mohammad A. Naiem Qutob (Egyptian Drug Authority, Egypt), Alicia Regodon (UNOPS, Denmark), Stephen Robinson (Drugs for Neglected Initiative, Switzerland), George Sabblah (Food and Drugs Authority, Ghana), Lourdes Sanchez Aparicio (Unitaid, Switzerland), Parantap Sarkar (Drugs for Neglected Initiative, India), Clare Scully (Lancet Countdown, United Kingdom), Vishakha Sharma (UNICEF, Denmark), Jodi Sherman (Lancet Countdown, United Kingdom), Mae Shieh (Drugs for Neglected Initiative, Switzerland), Hariadi Soleh (Indonesian Food and Drug Authority, Indonesia), Courtney Soulsby (British Standards Institution, United Kingdom), Yenny Suarez (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, Colombia), Rajinder Suri (Developing Countries Vaccine Manufacturers Network International, Switzerland), Andrej Szijjarto (Novartis, Switzerland), Madeleine Szeluch (Medicines and Healthcare products Regulatory Agency, United Kingdom), Sébastien Taillemite (Ecovamed, France), Dalia Taha (Egyptian Drug Authority, Egypt), Kevin Tetteh (FIND, United Kingdom), Rene Thuermer (Federal Institute for Drugs and Medical Devices, Germany), Perrer Tosso (United States Pharmacopoeia, USA), Victoria Tozer-Brown (Greener National Health Services England, United Kingdom), Putri Wiyana Utami (Indonesian Food and Drug Authority, Indonesia), Yasmin Vargas (UNICEF, Denmark), Leigh Verbois (United States Pharmacopoeia, USA), Claudia Vincenzi (European Medicines Agency, Netherlands [Kingdom of the]), Georgia Vivian (Greener National Health Services England, United Kingdom), Kristin Willemsen (Canadian Generic Pharmaceutical Association, Canada), Juergen Wieland (Novartis, Switzerland), Vanja Wylie (UNOPS, Denmark) and Nia Yuniarti (Indonesian Food and Drug Authority, Indonesia).

Special thanks are due to the regulatory authorities who participated in the external institutional peer review process: Agence sénégalaise de Réglementation pharmaceutique (Senegal), Therapeutic Goods Administration (Australia), Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (Cuba), Egyptian Drug Authority (Egypt), European Medicines Agency (Netherlands [Kingdom of the]), Federal Agency for Medicines and Health Products (Belgium), Medicines Control Authority of Zimbabwe (Zimbabwe), MHLW (Japan), Medicines and Healthcare products Regulatory Agency (United Kingdom), National Agency for Food and Drug Administration and Control (Nigeria), Norwegian Medical Products Agency (Norway), State Agency of Medicines (Estonia), Swissmedic (Switzerland) and Thai Food and Drug Administration (Thailand).

Special thanks are due to the experts from the Global Regulators Summit who participated in discussions and helped shape the final recommendations: Omnia Abdullah (Egyptian Drug Authority, Egypt), Pramote Akarapanon (Thai Food and Drug Administration, Thailand), Joan Aprilla Arland (Indonesian Food and Drug Authority, Indonesia), Tomas Boran (State Institute for Drug Control, Czechia), Carlos Bravo (Agencia Nacional de Medicamentos, Chile), Robert N. Bream

(European Medicines Agency, Netherlands [Kingdom of the]), Vincent Bretin (Unitaid, Switzerland), Anna Chioti (Ministry of Health, Luxembourg), Monica da Luz C. Soares (Agência Nacional de Vigilância Sanitária, Brazil), Charles Denonne (Federal Agency for Medicines and Health Products, Belgium), Serigne Abdou Khadre Diagne (Agence sénégalaise de Réglementation pharmaceutique, Senegal), Admire Dube (University of the Western Cape, South Africa), Helerin Eiche (State Agency of Medicines, Estonia), Kenneth Ezekwem (National Agency for Food and Drug Administration and Control, Nigeria), Torild Halvorsen (Norwegian Medical Products Agency, Norway), Martin Harvey Allchurch (European Medicines Agency, Netherlands [Kingdom of the]), Hamidreza Inanloo (Food and Drug Administration, Iran [Islamic Republic of]), Guntars Kaspars (State Agency of Medicines, Latvia), Gerald Sambu Kulwa (Tanzania Medicines and Medical Devices Authority, United Republic of Tanzania), Zivanai Antony Makoni (Medicines Control Authority of Zimbabwe, Zimbabwe), Dovile Marcinke (State Medicines Control Agency, Lithuania), Humberto Martins (National Authority Of Medicines and Health Products, Portugal), Grace Matimba (Medicines Control Authority of Zimbabwe, Zimbabwe), Munyaradzi Maunge (Medicines Control Authority of Zimbabwe, Zimbabwe), Dina Puspita Mayasari (Indonesian Food and Drug Authority, Indonesia), Naiem Mohammad (Egyptian Drug Authority, Egypt), Ibrahim Mujammami (Saudi Food and Drug Authority, Saudi Arabia), Mario Cesar Muniz Ferrer (Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos, Cuba), Nathaniel Kwabena Nkrumah (African Medicines Agency, Rwanda), Wiwin Wisma Prihatin (Indonesian Food and Drug Authority, Indonesia), Christelna Reynecke (South African Health Products Regulatory Authority, South Africa), George Sabblah (Food and Drugs Authority, Ghana), Caroline G. Samatanga (Medicines Control Authority of Zimbabwe, Zimbabwe), Lourdes Sanchez Aparicio (Unitaid, Switzerland), Yenny Suarez (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, Colombia), Madeleine Szeluch (Medicines and Healthcare products Regulatory Agency, United Kingdom), Ikrar Taruna (Indonesian Food and Drug Authority, Indonesia), Monika Trojan (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland), Rajka Truban Žulj (Agency for Medicinal Products and Medical Devices, Croatia), Putri Wiyana Utami (Indonesian Food and Drug Authority, Indonesia), Claudia Vincenzi (European Medicines Agency, Netherlands [Kingdom of the]), Zhang Ying (National Medical Products Administration, China), Nia Yuniarti (Indonesian Food and Drug Authority, Indonesia) and Pavle Zelic (Serbian Agency for Medicines and Medical Devices, Serbia).

WHO headquarters in Geneva:
Elena Villalobos Prats, Megha Rathi (Department of Environment, Climate Change, Migration and One Health); Deirdre Dimancesco, Keiko Fukuta, Luther Gwaza, Deus Mubangizi, Kylie Shae (Department of Medicines and Health Products Policies and Standards); Mohamed Refaat Abdelfattah, Mustapha Chafai, Antony Fake, Alan Fauconnier, Alireza Khadem Broojerdi, Sunday Kisoma, Rutendo Kuwana, Shanthi Pal, Irena Prat, Carmen Rodriguez, Dominic Schuler, Hiiti Baran Sillo, Marie Valentin, Wondiyfraw Worku (Department of Regulation and Prequalification).

WHO regional offices:
Alexandra Mata Espinoza (WHO Regional Office for the Americas, Innovation, Access to Medicines and Health Technologies), Joseph Kabatende (WHO Regional Office for Africa, Health Systems and Services), Houda Langar (WHO Regional Office for the Eastern Mediterranean, Access to Medical Products Health Systems and Life Course), Dorina Pirgari (WHO Regional Office for Europe, Access to Medicines and Health Products), Adrien Inoubli (WHO Regional Office for South-East Asia, Regulation of Medicines and Health Products), Anil Kuman Chawla (WHO Regional Office for South-East Asia, Vaccine Regulation, Safety and Management).

WHO gratefully acknowledges the financial support of Unitaid, Switzerland under grant number 2028-28-WHO RHT, towards the development and publication of this framework.

Abbreviations

API	active pharmaceutical ingredient
ATACH	Alliance for Transformative Action on Climate and Health
BPOM	Indonesian Food and Drug Authority
BSI	British Standards Institution
COP	Conference of the Parties
EMA	European Medicines Agency
GHG	greenhouse gas
GMP	good manufacturing practices
GWP	global warming potential
GPW14	Fourteenth WHO General Programme of Work 2025–2028
ICH	International Council for Harmonisation
ICMRA	International Coalition of Medicines Regulatory Authorities
ISO	International Organization for Standardization
LLIN	long-lasting insecticidal net
LMICs	low- and middle-income countries
NHS	National Health Service
NRAs	national regulatory authorities
PAS	publicly available specification
PEF	product environmental footprint
pMDIs	pressurized metered-dose inhalers
TLD	tenofovir, lamivudine and dolutegravir
UNHCR	Office of the United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
WHA	World Health Assembly
WHO	World Health Organization

Executive summary

This framework is a follow-up to the WHO Call for Action on a greener pharmaceuticals' regulatory highway (December 2024). It examines how regulatory systems can enable innovation that reduces the climate impact of pharmaceuticals for human use, while maintaining the standards of safety, quality and efficacy and supporting timely, affordable and equitable access to innovation by patients.

Call to action

The 2024 call for action set out three priority directions for regulatory engagement:

- establishing new standards and guidance to support innovation in the manufacturing, distribution and use of pharmaceutical and medical products;
- advancing the digital transformation of regulatory services and reliance mechanisms between regulators, including capacity-building in low- and middle-income countries (LMICs);
- adopting innovative regulatory procedures that enable earlier involvement of regulators and contribute to more streamlined regulatory processes, without compromising the standards of evaluation.

Context

Over the past 15 years, the intersection of climate and health has moved from an emerging concern to settled priority of global health governance through a succession of World Health Assembly (WHA) resolutions, the Conference of the Parties (COP) declarations and operational frameworks, culminating in the *Fourteenth WHO General Programme of Work* identifying climate change and health as a top strategic objective. Because regulatory levers shape how pharmaceuticals are developed and managed across their life cycle, regulators are central to enabling the innovations that a lower-carbon, more sustainable health sector will require.

Modern health systems contribute approximately 5% of global greenhouse gas emissions; within those systems, pharmaceuticals are the largest single driver. The National Health Service (NHS) England has estimated that pharmaceutical products account for approximately a quarter of the emissions associated with the goods and services it procures.

The pharmaceutical sector contributes to greenhouse gas emissions across the product life cycle, from material extraction and manufacturing to distribution and use. A substantial share arises upstream, although the distribution of impacts varies by product type, underscoring the importance of targeted and context-specific approaches to decarbonization.

Regulatory role

Pharmaceutical regulators can enable innovation by providing scientific guidance, setting standards, interacting and giving advice to stakeholders, supporting reliance arrangements, harmonizing requirements and offering regulatory flexibility.

The framework does not propose expanding the pharmaceutical regulators' mandate to include climate assessment. It focuses on how existing tools and processes can be applied to support sustainability-driven change while preserving core regulatory functions. The framework regards continued access, affordability and secure supply chains as critical considerations that should not be adversely impacted by actions to reduce climate impact. Climate-impact considerations should not be viewed as an additional regulatory burden but as an opportunity to use existing regulatory tools and processes to support innovation that delivers both public health and environmental benefits. The intent is to bridge environmental and pharmaceutical regulation, not to merge them.

A framework for action: three pillars

The framework for action proposed is organized around three pillars.

Pillar 1. Awareness and capacity-building. Strengthen understanding within regulatory authorities of climate-related concepts, including life cycle approaches and emissions accounting, and build capacity to identify and prioritize key sources of emissions across national product portfolios. Awareness extends to the impact of climate change on health care and on the products patients are likely to need over the coming decades, including shifts in disease patterns and the evolving demand profile that regulators may face. Existing regulatory training and capacity-building programmes can be expanded to integrate these elements and embed climate considerations into routine regulatory practice rather than leaving them as standalone activities. Capacity-building can be reinforced by knowledge-sharing platforms that let regulators exchange experience, data and hotspot analyses across jurisdictions, building on existing mechanisms rather than creating new ones.

Pillar 2. Guidance, tools and standards. Strengthen standards and guidance to support innovation by promoting global alignment on methodologies, data standards and reporting approaches related to greenhouse gas emissions. Aligned approaches enable comparability across jurisdictions and consistent identification and prioritization of carbon hotspots. Efforts should build on existing guidance and standards while improving coherence, visibility and practical usability. Voluntary data-sharing mechanisms can strengthen the regulatory community's capacity to engage with climate-related information without creating undue burden.

Pillar 3. Innovation and innovative regulatory pathways. Support the adoption of innovative regulatory procedures that enable earlier involvement of regulators in the assessment of innovative approaches, including those with potential environmental benefit, while maintaining standards of safety, quality and efficacy. The framework examines three areas of current regulatory innovation that are particularly relevant for pharmaceutical decarbonization:

- digital transformation of regulatory activities;
- early and iterative scientific advice, and leveraging existing regulatory pathways for sustainability-driven changes;
- joint piloting between regulators on specific decarbonization questions, drawing on the European Medicines Agency (EMA)–WHO post-approval reliance pilot and other reliance mechanisms, including existing WHO post-approval pilots;
- global consultation and alignment across jurisdictions.

Implementation and next steps

The work proposed will not be carried out by any single organization. A coordinated, multistakeholder effort that operates across institutional boundaries will be essential to enable sustainable transformation of the pharmaceutical sector while safeguarding public health objectives. WHO and existing international regulatory platforms can serve as convening mechanisms to support collaboration and align approaches. Whichever approach is chosen, it will rely on sustained stakeholder engagement and on building on existing regulatory frameworks rather than creating new ones.

1 Climate change and health systems

The seventy-seventh World Health Assembly (WHA), in adopting resolution WHA77.14 on Climate Change and Health in June 2024, recognized climate change as "one of the major threats to global public health" and called for urgent global action to build climate-resilient and sustainable health systems *(1).* WHA77.14 notes that modern health systems generate approximately 5% of global carbon emissions, including emissions arising "through the end-to-end supply chain from product manufacturing, procurement, distribution, use, waste creation and its disposal" *(1).* Additionally, health systems themselves are also impacted by climate change. For example, climate change is expected to increase the occurrence of weather extremes such as heatwaves and droughts (recognized health hazards) and raise the incidence of infectious diseases such as dengue, leishmaniasis and tick-borne diseases *(2).*

Over the past 15 years, the intersection of climate and health has moved from an emerging concern to a settled priority of global health governance. The foundations were laid by resolution WHA61.19 on climate change and health (2008) *(3)* and the *WHO Global strategy on health, environment and climate change* (2020) *(4).* Momentum has since built through the COP26 Health Programme and the launch of the Alliance for Transformative Action on Climate and Health (ATACH) *(5);* the *WHO Operational framework for building climate-resilient and low-carbon health systems* (2023) *(6);* resolution WHA76.17 on chemicals, waste and pollution (2023) *(7);* and the adoption of the *United Nations Global Framework on Chemicals* (2023) *(1).* In parallel, the *COP28 Declaration on Climate and Health* (December 2023) *(8),* signed by more than 140 Member States, committed signatories to promote climate-resilient and low-carbon health systems. Most recently, the *Fourteenth WHO General Programme of Work 2025–2028* has identified climate change and health as a top strategic objective *(9).* Because regulatory levers shape how pharmaceuticals are developed and managed across their life cycle, regulators are central to enabling innovations that a lower-carbon, more sustainable health sector will require.

1.1 Greener pharmaceuticals' regulatory highway: a call for action

In December 2024, the WHO Department of Regulation and Prequalification published a call for action on the *Greener Pharmaceuticals' Regulatory Highway (10).* This call for action was addressed to the regulatory community and to stakeholders across the pharmaceutical value chain. It identified several areas in which standards-setting and regulatory practice could potentially be decisive levers, and it clearly emphasized that enabling decarbonization must not come at the expense of regulatory standards, the timeliness of regulatory evaluations or patient access. The call for action proposes three priority directions for regulatory engagement (Fig. 1):

- **Establishing new standards and guidance** to support innovation in manufacturing, distribution and usage of pharmaceutical and medical products, which contribute to significant reductions in the environmental and carbon footprint of these products;
- **Advancing digital transformation of regulatory services** and reliance mechanisms between regulators, including capacity-building in LMICs;
- **Adopting innovative regulatory procedures** that allow early involvement of regulators for technologies that contribute to a reduction of the impact on the environment.

Member States have endorsed the commitment to address the environmental footprint of health systems, including pharmaceutical supply chains, while protecting access to safe, effective, quality-assured pharmaceuticals and other medical products *(1,11)*. While the current initiative focuses specifically on pharmaceuticals, some underlying principles may also be relevant to other health products. However, applying these principles in those contexts would require dedicated analyses to address product-specific considerations that are beyond the scope of this framework.

Fig. 1. The three priority directions proposed by the call for action

Call for action

Priority directions for regulatory engagement

Establishing new standards and guidance to support innovation in the manufacturing, distribution and use of pharmaceutical and medical products, which contribute to significant reductions in the environmental and carbon footprint of these products

Advancing digital transformation of regulatory services and reliance mechanisms between regulators, including capacity-building in low- and middle-income countries

Adopting innovative regulatory procedures that allow early involvement of regulators for technologies that contribute to a reduction in environmental impact

1.2 Regulatory system as an enabler of innovation for environmental sustainability

Pharmaceutical regulators can enable innovation by providing scientific guidance, setting standards, interacting and giving advice to stakeholders, supporting reliance arrangements, harmonizing requirements and offering regulatory flexibility. Environmental considerations should not be viewed as an additional regulatory burden but rather as an opportunity to use existing regulatory tools and processes to support innovation that delivers both public health and environmental benefits. Realizing this may require proportionate, risk-based decision-making approaches to ensure that sustainability-driven changes can be implemented without adding unnecessary complexity while maximizing impact.

The *Greener pharmaceuticals' regulatory highway* call for action recognized that the regulatory dimension of the pharmaceutical value chain has not yet been adequately mobilized to drive decarbonization of pharmaceutical products across their life cycle.

This framework is, therefore, a follow-up to this call and will focus deliberately on pharmaceuticals, recognizing that they are among the fastest-growing and most carbon-intensive sources of greenhouse gas (GHG) emissions within the health care value chain *(12,13).* It examines how regulatory systems can enable innovation that reduces the climate impact of pharmaceuticals, while maintaining the standards of safety, quality and efficacy on which they are founded and supporting timely, affordable and equitable access to innovation by patients.

The following sections will assess the carbon footprint of the pharmaceutical value chain, the specific levers available to regulators across the lifespan of products, the type of actions required from the wider ecosystem (industry, procurement agencies, funders, technical partners and Member States) and a proposed framework for coordinated action that will support decarbonization across the whole value chain.

2 Scope of the framework

This framework focuses on pharmaceuticals for human use, ranging from small molecules to biopharmaceuticals and vaccines, where these fall within the remit of national regulatory authorities (NRAs) or the WHO Prequalification Programme. Medical devices, including in vitro diagnostics, vector control products and other regulated health technologies, are not the primary focus of this framework, although the regulatory tools and approaches discussed in later sections may be relevant for those health products. Such products may have distinct emission profiles and regulatory challenges, and future steps arising from the call for action could provide opportunities for dedicated discussions on medical devices and other health products.

The pharmaceutical value chain is part of the health care supply chain, which is defined as "the flows of goods and services needed from production to distribution, and ultimately to final consumption (or use) of a medical product – medicine or medical device – by patients, health professionals or health care institutions" *(14).* WHO considers the pharmaceutical value chain, from raw material sourcing and active pharmaceutical ingredient (API) manufacture through formulation, packaging, distribution and use, to end-of-life disposal. Section 3 describes each stage in more detail.

Research and development, including clinical trials, are considered where regulatory authorities have an established role in shaping their conduct. The carbon footprint of clinical trials, the role of animal models and the application of the 3R principles (replacement, reduction and refinement of animal use in research) all sit at the edge of this scope. Consequently, the framework does not attempt a full treatment of research-stage emissions.

Broader health system operations, such as hospital energy use, clinical waste management, prescribing patterns and health care delivery, are being addressed through the work of initiatives such as ATACH, Greener NHS and others. This complements the focus of this framework on pharmaceutical products.

Procurement bodies, United Nations supply agencies and the wider supply chain community are advancing carbon requirements on aspects such as the manufacturing, transportation and use of pharmaceuticals and vaccines *(16).* This framework aims to draw on that work without duplicating it.

This framework focuses on climate-related impacts, expressed in terms of GHG emissions and carbon footprint, within the broader set of measures addressing the environmental impacts of pharmaceuticals. It does not, however, seek to address climate-related risks, such as the vulnerability of pharmaceutical supply chains to disruptions arising from heat, flooding or water stress. While these dimensions are interrelated, as both resilience and emissions reduction can reinforce one another, they involve distinct analytical approaches, evidence bases and policy responses. Climate risk and supply chain resilience are therefore the subject of separate WHO work *(11)* and are not covered here.

More broadly, this framework does not aim to comprehensively address the full range of environmental sustainability and risk considerations associated with pharmaceuticals. These include, for example, issues related to antimicrobial resistance, the use of hazardous solvents and the wider chemicals and waste agenda, which are closely linked to but extend beyond the climate focus of this analysis. It is nevertheless recognized that carbon footprint considerations should not be viewed in isolation from these wider environmental impacts. Several related policy processes are advancing in parallel, including the expansion of environmental risk assessment within the new European Union pharmaceutical legislation and the ongoing international negotiations towards a binding instrument on plastic pollution.

3 Pharmaceuticals and their contribution to climate change

The pharmaceutical sector contributes to GHG emissions across the product life cycle, from material extraction and manufacturing to distribution and use. A substantial share of emissions arises upstream, although the distribution of impacts varies by product type. This underlines the importance of targeted and context-specific approaches to decarbonization.

3.1 Current evidence on pharmaceuticals and climate impact

Modern health systems contribute to approximately 5% of global carbon emissions *(1).* The NHS England has estimated that pharmaceutical products account for approximately a quarter of the emissions associated with goods and services it procures from national and global suppliers *(11).* While pharmaceuticals are generally small in volume and weight, their contribution to the carbon footprint is significant due to increasing global pharmaceutical consumption, combined with energy-intensive and complex manufacturing processes of the API and downstream supply chain activities. In 2025, Hagenaars et al. presented the first comprehensive global assessment of GHG emissions related to pharmaceutical production and consumption from 1995 to 2019 *(13).* During this period, the global pharmaceutical GHG footprint grew by 77%, far outpacing the 49% increase in global consumption-related GHG emissions.

Current literature increasingly focuses on identifying "carbon emission hotspots" across the pharmaceutical value chain. These hotspots refer to specific stages, processes, locations or components within a pharmaceutical supply chain that are disproportionately associated with carbon emissions and have the greatest environmental impact *(17).* Understanding these emission hotspots within the pharmaceutical value chain, particularly for specific products or product classes, can help target interventions where they are most likely to achieve meaningful and sustained reductions in carbon emissions.

The 2023 Unitaid assessment *From milligrams to megatons: A climate and nature assessment of 10 key health products* provided one of the most granular analyses to date of the climate and environmental impacts of pharmaceutical value chains *(12).* The assessment examined 10 strategic products and quantified their GHG emissions across the value chain. For the 10 key health products analysed, it found that materials acquisition, preprocessing and manufacturing together account for a significant share of total value chain emissions, with API manufacturing alone contributing roughly 70% of emissions. Similar findings have emerged from pilot case studies applying publicly available specification (PAS) 2090:2025, a specification that provides a framework for measuring the environmental impact of pharmaceutical products. These studies quantified emissions of individual products across their life cycle, including API manufacturing, distribution and storage *(18,19).* Similarly, a report codeveloped by NHS England, WHO and ATACH, *Decarbonizing the healthcare supply chain: strategic actions for health systems (16),* describes how certain pharmaceuticals generate high emissions in manufacturing but require little energy in storage, while others have lower carbon footprints associated with manufacturing but demand continuous refrigeration during transport and storage.

However, current literature also shows large variations of carbon emission hotspots between different product classes across the different stages along the value chain. For example, for tenofovir, lamivudine and dolutegravir (TLD), a fixed-dose HIV treatment, the hotspot sits firmly upstream, with more than 95% of emissions across the TLD value chain coming from API manufacturing, which involves a complex synthesis process with low yield (Case study 1) *(12).* By contrast, for vaccines, the hotspot shifts downstream into distribution. The United Nations Children's Fund (UNICEF) identified air freight as a major contributor, as vaccines are often dispatched in temperature-controlled systems to LMICs. A different emission profile is observed for pressurized metered-dose inhalers (pMDIs), where the primary source of carbon emissions occurs during product use rather than manufacturing or distribution due to the release of propellants (Case study 2) *(16).*

Based on the available evidence from literature, different steps in the value chain can be distinguished for contributing separately to carbon emissions of pharmaceuticals (and other health care products), from raw material sourcing to manufacturing (including packaging), distribution (including storage), use and disposal.

Case study 1. Dolutegravir-based HIV treatment: an unintended climate dividend

The transition from efavirenz-based to dolutegravir-based first-line antiretroviral therapy is a well documented case of a new pharmaceutical delivering a substantial, unintended climate dividend at scale. The dolutegravir-based regimen, known as TLD, contains 650 mg of API per daily dose against efavirenz's 1200 mg and emits approximately 223 g CO_2-equivalent per person per day against efavirenz's 595 g, a factor 2.6 reduction driven principally by the lower API mass and almost entirely from upstream manufacturing.

Over 2017–2027, the global transition to dolutegravir-based regimen is estimated to have prevented 26 million tonnes of CO_2-equivalent that would otherwise have been emitted under continued efavirenz use, approximately 0.3–0.4% of the entire LMIC health sector footprint, from a single transition. Unitaid further estimates that up to 40% of dolutegravir's remaining footprint could be abated at net cost savings through process optimization and energy efficiency, with another ~50% addressable through green energy and bio-based or recycled materials.

The dividend was delivered through a new product pathway. Dolutegravir was authorized as a new molecular entity in the USA and the European Union in 2013–2014; the TLD fixed-dose combination required its own new authorization. The voluntary licensing through the Medicines Patent Pool enabled rapid generic introduction across more than 110 LMICs. This case illustrates that climate benefits at this magnitude can sit beyond the reach of post-approval change instruments and that the carbon footprint of a candidate pharmaceutical remains invisible to regulators and procurers unless product-level emissions are systematically estimated. | Sources: *(12,27)*

Case study 2. Pressurized metered-dose inhalers

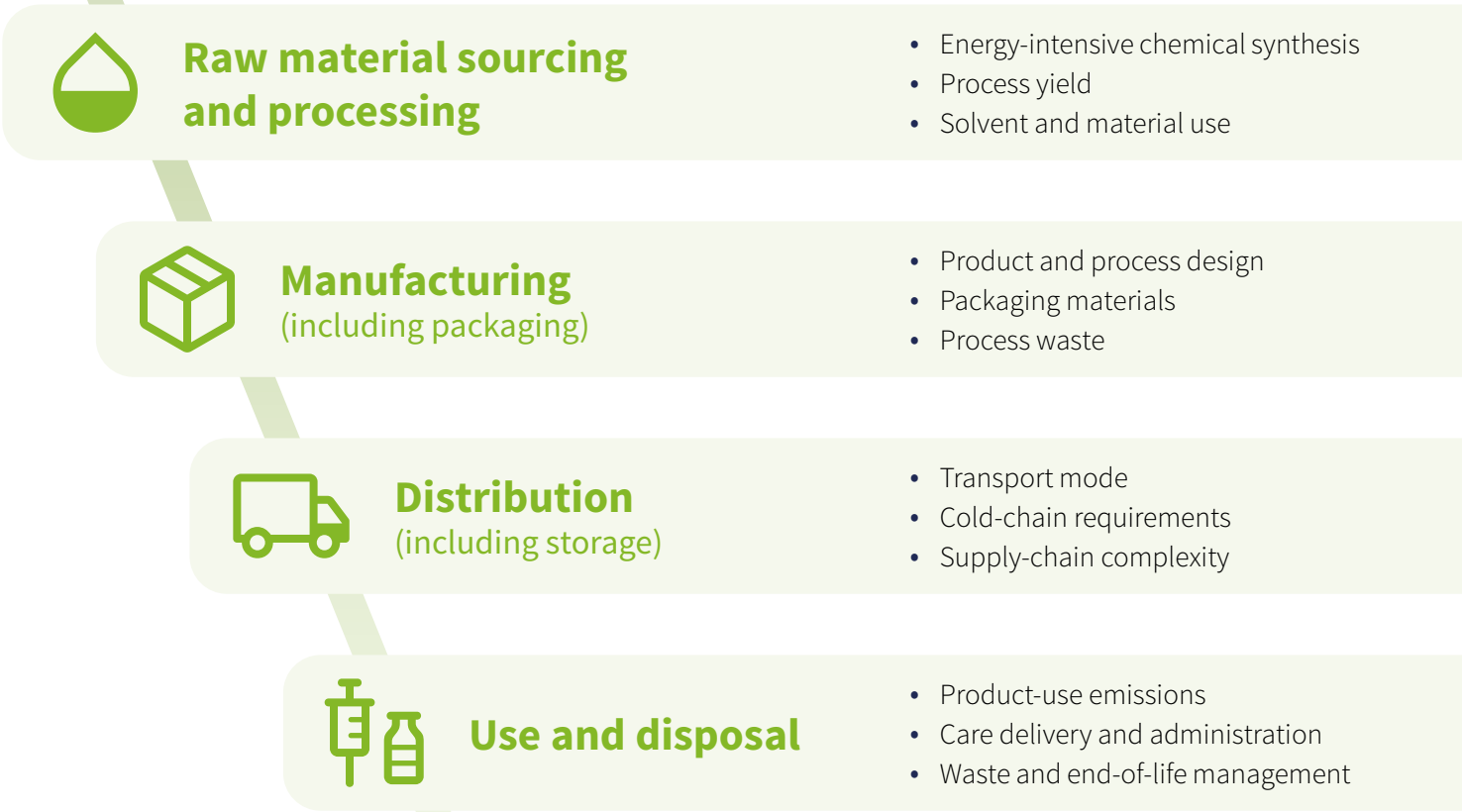
Transitioning away from high-GWP propellants in pMDIs

pMDIs are the most common type of inhaler used to treat asthma and chronic obstructive pulmonary disease worldwide. The hydrofluorocarbon propellants used in these inhalers are major GHGs, which have a GWP roughly 1300–3350 times that of carbon dioxide *(30).* Changing a propellant is considered a major pharmaceutical change, requiring demonstration of therapeutic equivalence, for example, comparison of the aerodynamic particle size distribution and other properties of the emitted cloud.

The revised European Union Fluorinated Greenhouse Gases Regulation (Regulation [EU] 2024/573), adopted in February 2024, placed medical inhalers within the European Union's hydrofluorocarbon phase-down quota system for the first time. The regulation was built in such a way that it incentivized reformulation for pMDIs without disrupting patient supply and allowing industry time to complete the relevant clinical programmes, obtain approvals from regulatory agencies and scale up manufacturing of the new propellants *(31).* To facilitate this, EMA published a Q&A document on therapeutic equivalence and clinical safety requirements when transitioning to low-GWP propellants in oral pMDIs *(32).*

This led to the successful reformulation and subsequent regulatory submission and approval of one pMDI (and its duplicate) where the high-GWP propellant was replaced with propellant that has a 90–95% reduced carbon footprint. The reformulated product is therapeutically equivalent to the original product *(33,34).* For patients and clinicians, this ensures a continuity of treatment, thus addressing a concern that has historically slowed environmentally driven device changes *(30,42).*

Fig. 2. Major sources of GHG emissions across the pharmaceutical value chain



3.2 Pharmaceutical value chain

Raw material sourcing and processing

The carbon footprint of pharmaceuticals begins with the extraction and processing of raw materials used to produce APIs, excipients and solvents (Fig. 2). API synthesis is often highly energy-intensive, particularly when requiring high temperatures and multiple synthesis steps. Emissions are further influenced by factors such as solvent use, process yield, the number of synthesis steps and the quantity of API required per treatment regimen *(12,16)*.

Opportunities for decarbonization include applying green chemistry principles to improve process efficiency, reduce raw material use and minimize waste. For example, the selection of less hazardous and lower-impact solvents, combined with higher-yield synthetic routes and fewer synthesis steps, can substantially reduce both energy demand and carbon emissions *(12,20)*. Transitioning to recombinant (lab-produced) or animal-free materials represents another significant opportunity to improve sustainability, including potential reductions in environmental and carbon impact through more controlled, efficient and scalable manufacturing processes.

Case study 3. Recycled polyethylene LLINs

LLINs used in malaria control are produced predominantly from polyethylene fibres with an insecticide incorporated during manufacture. The Office of the United Nations High Commissioner for Refugees (UNHCR) estimates that its annual procurement of 1.6 million LLINs accounts for more than 6500 tonnes of CO_2-equivalent and more than 800 tonnes of plastic released into the environment.

UNHCR's 2024 analysis identifies a shift from virgin to 100% recycled polyethylene as the most viable route to reduce these emissions, estimating an annual reduction of approximately 3000 tonnes of CO_2-equivalent within UNHCR's own procurement if the shift were made fully. GreenNet, a recycled polyethylene deltamethrin LLIN produced by Shobikaa Impex Private Limited, received WHO prequalification (Vector Control Products) on 16 August 2024, reference P-00320.

UNHCR identifies the regulatory process as a constraint on the wider availability of recycled LLINs, alongside the small number of suppliers currently active in this segment of the market and the relatively limited volume of UNHCR procurement, which may be too small to attract new entrants. | Sources: *(28,29)*

Manufacturing (including packaging)

Carbon emissions are also associated with the manufacturing and packaging stage of the value chain, for example, the conversion of APIs and raw materials into finished pharmaceutical products and the production of primary, secondary and tertiary packaging materials, such as glass vials and ampoules, plastics for bottle packs and aluminium for blister packs. These emissions arise from energy-intensive operations, including heating, cooling, ventilation, sterilization and other tightly controlled processes required to meet quality standards *(20).* The carbon impact at this stage in the value chain is therefore highly influenced by material choice, energy consumption, process efficiencies and the volume and complexity of packaging.

Opportunities to reduce carbon emissions include improving manufacturing efficiency, reducing material waste and redesigning products and packaging to use fewer materials and materials with a lower carbon impact *(12).* Packaging reforms are frequently mentioned in regulatory discussions, such as the use of recycled or recyclable materials, bio-based alternatives and polyvinyl chloride-free blister packs *(21).* Implementation of electronic product information (e-labelling) can similarly reduce or eventually replace paper package leaflets. Regulatory systems can support the uptake of these innovations by providing clear guidelines for managing post-approval changes, thereby enabling environmentally beneficial modifications to be implemented more efficiently. Such guidelines provide the opportunity to incorporate best evidence, for instance, in determining whether recycled materials are suitable for pharmaceutical use and free from contamination risk. A case study illustrating the climate impact of product innovation describes the transition from efavirenz-based to dolutegravir-based first-line antiretroviral therapy (Case study 1). A complementary example from the wider health products sector is the use of long-lasting insecticidal nets (LLINs) made from recycled polyethylene, which shows how the adoption of recycled materials can contribute to reducing emissions and waste (Case study 3).

Distribution (including storage)

The distribution of pharmaceuticals contributes to carbon emissions through the transportation of products from manufacturing sites to wholesalers, health care facilities, pharmacies and ultimately patients. Emissions are strongly influenced by the type of transport used, with air freight being significantly more emissions-intensive than maritime, rail or road transport. Additional carbon emissions arise from temperature-controlled logistics required for temperature-sensitive pharmaceuticals *(21).* The overall carbon footprint of distribution is further influenced by factors related to supply chain complexity, transport distances, packaging weight and volume and the geographical concentration of manufacturing sites requiring global distribution networks.

Opportunities to reduce carbon emissions include optimizing logistics routes and shifting freight from air transport to lower-carbon alternatives, such as sea, rail or road transport, where feasible *(12,17).* Improvements in cold-chain efficiency, including better insulation and storage management, can further reduce energy consumption associated with temperature control. Reducing packaging size and weight may also decrease transport-related emissions. In addition, more regionalized manufacturing and shorter supply chains could help reduce the environmental impact associated with global pharmaceutical distribution *(17).*

Use and disposal

Carbon emissions also play a role at the end of the pharmaceutical value chain during the use and disposal stages. A particular example of products that directly release GHG during administration is pMDIs with high global warming potential (GWP) propellants (Case study 2). Additional carbon emissions during this stage may arise from energy required for heating, cooling or preparing for administration, including the use of ancillary materials, such as infusion bags, syringes and solvents, as well as patient travel to health care facilities. Moreover, the disposal of pharmaceuticals may result in carbon emissions. It is generally acknowledged that, although the carbon footprint for disposing of pharmaceuticals is smaller, this stage is highly relevant to wider environmental concerns, such as plastic waste, environmental toxicity and water pollution. Case study 3 highlights a nonpharmaceutical case on insecticide-treated nets, which showcases recent analysis of the potential positive impact of using recycled polyethylene on plastic waste and CO_2 equivalent emissions while also emphasizing regulatory constraints that limit implementation.

Potential measures to reduce emissions include promoting the rational, responsible and efficient use of health care products and supporting clinically appropriate lower-carbon alternatives where available. In some areas, reusable or lower-impact devices and delivery systems may further reduce emissions associated with treatment and care delivery. It is also broadly recognized that health care systems need to identify environmentally sustainable low-carbon disposal pathways while also promoting waste avoidance, reusability and repairability to reduce the broader environmental impact at this stage of the value chain *(17).*

3.3 Recognized standards and methods of carbon emissions measurements

The *GHG Protocol* is the most widely used carbon accounting framework; its *Product life cycle accounting and reporting standard* (2011) provides the conventions required to measure and report the entire life cycle GHG emissions of a product or service *(22),* while the International Organization for Standardization (ISO) 14040:2006 and ISO 14044 standards provide the methodological backbone for life cycle assessment *(23,24).* In particular, ISO 14067:2018 sets out how to quantify and communicate a product's carbon footprint *(25).* The product environmental footprint (PEF) is a standardized life cycle assessment method formally recommended by the European Commission (2021) *(26);* unlike a standard carbon footprint, it assesses a product's entire supply chain across 16 different environmental impact categories. Traditionally, the pharmaceutical industry drew on guidance developed for value chains of related industries, such as the health sector and the chemical industry. However, efforts are ongoing to develop a framework that can be adapted specifically for the pharmaceutical industry. Developed by the PharmaLCA Consortium and the British Standards Institution (BSI) in October 2025, PAS 2090:2025 is a recent tool offering a framework for measuring the environmental impact of pharmaceutical products throughout their life cycle.

It is important to acknowledge that measuring carbon emissions is a complex process. It requires a holistic, life cycle-based approach that considers emissions across the entire pharmaceutical value chain, from raw material sourcing to end-of-life disposal. While a particular intervention may reduce emissions at one stage, it can inadvertently increase emissions elsewhere. Evaluating decarbonization measures in isolation therefore risks shifting, rather than reducing, the overall environmental burden. Additional complexity may arise when carbon footprint reductions are achieved at the expense of other environmental objectives, whereby increased use of hazardous chemicals, higher water consumption or greater waste and pollution may act as drivers of environmental risks, including persistence, bioaccumulation and toxicity, antimicrobial resistance, endocrine disruption and adverse ecotoxicological effects. Carbon footprint assessments should therefore be complemented by a broader evaluation of environmental impacts to ensure that interventions result in overall environmental benefits rather than unintended trade-offs.

3.4 Decarbonizing the pharmaceutical value chain: opportunities and constraints

The pharmaceutical value chain presents numerous opportunities to reduce carbon emissions, although the feasibility and impact of interventions vary considerably across life cycle stages. Some decarbonization measures may require significant upfront investment, which can limit their uptake in the short term; however, costs are expected to decrease as technologies mature and implementation scales increase. It is also important to recognize that many factors influencing emissions, such as energy generation, industrial processes and transportation fuels, fall largely outside the direct remit of NRAs. This is especially the case for NRAs in countries that are strongly dependent on imported APIs or starting materials. Such import dependence is itself a notable source of transportation-related emissions; therefore, strengthening regional pharmaceutical manufacturing and supply chain networks may reduce transportation-related emissions. Nevertheless, regulatory systems can influence a range of decisions throughout the pharmaceutical value chain, thereby acting as important enablers of decarbonization.

Decarbonization draws on several levers that recur throughout this framework. Innovation in new products encourages carbon impact to be considered during product development and lets regulators recognize products of equivalent quality, safety and efficacy but lower carbon impact, with targeted and proportional instruments, such as scientific advice and early engagement, as the primary enablers. Innovation in existing products enables sustainability-driven change across the life cycle of authorized products, such as process improvements, alternative or reused solvents and packaging or drug-delivery innovations. Because these changes often trigger resource-intensive post-approval variations, risk-based life cycle management tools, such as International Council for Harmonisation (ICH) Q12 and post-approval change management protocols, help to implement them in good time while maintaining standards of quality, safety and efficacy.

Process innovation within the regulatory system spans several fronts. These include new assessment methods, common measurement standards and ways of integrating environmental information into review workflows; collaboration mechanisms – such as reliance, harmonization and work-sharing – that improve efficiency and reduce duplication without creating new frameworks; and measures to reduce the footprint of regulatory activities themselves, such as digital submissions, remote and hybrid inspections and reliance-based recognition of decisions. Cross-cutting innovation covers material-level changes that touch many products at once, such as recycled content in primary and secondary packaging and changes in plastics use within the bounds set by direct-contact safety requirements. The framework for action that follows sets out how regulators can enable these levers, organized around three pillars: 1. awareness and capacity-building; 2. guidance, tools and standards; and 3. innovation and innovative regulatory pathways.

4 Framework for action

This section describes a framework for action based on three pillars:
1. awareness and capacity-building;
2. guidance, tools and standards; and
3. innovation and innovative regulatory pathways (Fig. 3). Together, they deliver against the three priority directions of the 2024 call for action. The actions proposed are illustrative as NRAs operate under different mandates, capacities and political contexts.

4.1 Pillar 1. Awareness and capacity-building

Pillar 1 focuses on strengthening awareness and building capacity within regulatory authorities to better understand and consider climate-related challenges, thereby enabling a more informed and effective regulatory engagement. This includes developing a solid foundation in key concepts, such as life cycle approaches and emissions accounting, as well as enhancing the ability to identify and prioritize major sources of emissions ("carbon hotspots") across national product portfolios. Such efforts should encompass both product-specific and systemwide drivers and help to direct attention to areas where the greatest emission reductions can be achieved. Awareness also includes the impact of climate change on health care and on the products that patients are likely to need over the coming decades, including shifts in disease patterns and the evolving demand profile that regulators may face.

Academia and research institutions already play an important role in identifying emission hotspots and developing assessment methodologies, and continued collaboration with the regulatory community can further enhance the evidence base and support capacity-building in this area. Existing regulatory training and capacity-building programmes can be expanded to integrate these elements and embed climate considerations into routine regulatory practice rather than leaving them as standalone activities. Opportunities for international collaboration should also be explored to facilitate knowledge exchange and harmonization of approaches.

Fig. 3. Three pillars of the framework for action

A framework for action: three pillars

Pillar 1. Awareness and capacity building

To better understand and consider climate-related challenges, thereby enabling a more informed and effective regulatory engagement

- Education and training
- Knowledge sharing and platform

Pillar 2. Guidance, tools and standards

To support innovation and promote global alignment on methodologies for measuring GHG emissions and assessing decarbonization efforts

- Create a global repository of recognized data standards and specifications
- Identifying carbon hotspots
- Voluntary reporting infrastructure

Pillar 3. Innovation and innovative regulatory pathways

To support the adoption, or better use, of regulatory procedures within the current regulatory framework

- Digital transformation of regulatory activities
- Early and iterative scientific advice, and leveraging existing regulatory tools for sustainability-driven changes
- Joint piloting
- Global consultation and alignment across jurisdictions

Education and training

A critical first step in operationalizing this pillar is to ensure visibility and familiarity with climate science and carbon emissions within regulatory agencies. Education and training should build a shared understanding of carbon and climate science across the agency. This includes introducing key concepts such as scope 1, 2 and 3 emissions, life cycle assessment and product carbon footprint, and distinguishing climate impact from the broader category of environmental impact. This also relates to creating a common understanding of the role that climate impact will play within the NRA, for example, how it will intersect with core missions, such as assuring the quality, safety and efficacy of the new pharmaceuticals, monitoring and surveillance responsibilities and the role an NRA has in supporting and stimulating innovation. Clarifying how NRAs position themselves in relation to other authorities, such as environmental protection agencies, will be an important area for further discussion and development following this framework. Awareness raising and training should take place at all levels of the organization, from senior leadership to regulatory committees and content experts. Wherever possible, existing regulatory training and educational programmes should be expanded for this purpose rather than becoming standalone initiatives. WHO could play a potential role in supporting these efforts by identifying or facilitating climate-related training programmes for regulators. An example from a recent education and training initiative by the South African Health Products Regulatory Authority (SAHPRA) (Case study 4).

Knowledge sharing platform

Promoting the regular sharing of decarbonization initiatives, outcomes and hotspot analyses can help accelerate learning across jurisdictions. A hotspot analysis carried out in one system can inform action elsewhere without being redone, provided it rests on the common methods set out in Pillar 2. In this regard, WHO could play a facilitating role by supporting a platform for knowledge and data exchange, enabling regulators and other stakeholders to share experiences and build a stronger evidence base for future action. Rather than creating new infrastructure, such an effort can build on initiatives already underway. WHO's ATACH maintains a community of practice that shares case studies and best practices across countries. Established regulatory networks, including ICH, International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Pharmaceutical Regulators Programme, offer further channels through which methods, data and experience can be exchanged.

Case study 4. SAHPRA: Building carbon literacy into regulatory capacity

SAHPRA developed a pilot programme (2027–2028) to build decarbonization capacity by extending existing systems rather than creating new ones. Under its awareness and capacity-building strand, SAHPRA is extending its existing staff-training programme, deployed across the agency in 2026, to include carbon literacy: Scope 1, 2 and 3 emissions, the basics of life cycle assessment, and the meaning of a product carbon footprint in the regulatory context. It intends to extend this training, including carbon hotspot identification, to other African regulators through the Regional Centres of Regulatory Excellence programme it will host in 2027. To address the common situation where manufacturers lack product-specific data from their API suppliers, SAHPRA is also partnering with a local academic institution to develop average emission factors by therapeutic class for use as default values. The programme is intended as a replicable model for other African authorities. | Source: SAHPRA presentation, WHO Global Regulators Summit, 19 June 2026.

4.2 Pillar 2. Guidance, tools and standards

Pillar 2 focuses on strengthening standards, guidance and data-sharing approaches to support innovation and promote global alignment on methodologies for measuring GHG emissions and assessing decarbonization efforts. Greater coherence and comparability across jurisdictions can facilitate consistent identification and prioritization of emissions hotspots while reducing unnecessary duplication. Efforts should build on existing standards while improving coherence, visibility and practical usability. Voluntary data-sharing mechanisms can strengthen the regulatory community's ability to engage with climate-related information without creating undue burden.

Global repository of recognized data standards and specification

Measuring the carbon footprint of a product must be done in a consistent and standardized manner, especially if different products or variations of a product need to be compared. A potential challenge is to determine which standards apply in which situation and how they should be interpreted. As discussed in Section 3.3, different standards already exist. ISO 14040:2006 and ISO 14044 describe the principles and requirements for life cycle assessment; ISO 14067:2018 specifies principles, requirements and guidelines for the quantification and reporting of the carbon footprint of a product. The BSI's PAS2090 specification applies this to pharmaceutical products, focusing on a broader environmental life cycle assessment, while the French government recently published a more focused standard purely for measuring the carbon footprint of pharmaceuticals *(23,24,25,35,36)*.

Each of these standards and tools has specific application areas for which they are particularly suited. Especially for organizations that are new to the field, an overview of the different standards and their application can be challenging to reach. WHO could play a supportive role by directing regulators and manufacturers to existing reporting schemes and, together with the International Pharmacopoeia and the International Meeting of World Pharmacopoeias, facilitate the development of a single point of reference for relevant pharmacopoeia standards and methodologies. This could help build global consensus on how to measure carbon emissions from pharmaceuticals and medical products and how to measure and demonstrate the effect of decarbonization efforts.

Identifying carbon hotspots

NRAs can be responsible for tens of thousands of products. Although some of the “low-hanging fruits” are being focused on, there are many other topics that can be further addressed. Therefore, this requires a careful assessment of where current carbon hotspots occur. Regulators need not measure emissions themselves; other specialists do that. Their role is to encourage the production of data that comply with recognized standards and to focus on the hotspots that can be influenced through regulatory tools. At the scale of a national portfolio, locating these hotspots depends on consistent measurement methods and on comparable data being reported. The standards and carbon footprint metrics set out earlier in this pillar make this possible. These hotspots could be product-specific (such as the hydrofluorocarbon propellants in certain types of inhalers) or relate to groups of products (such as certain packaging materials, solvents or excipients). Hotspots also fall at different life cycle stages: upstream API synthesis for most small-molecule medicines, storage and distribution for temperature-controlled products or the use phase for inhaler propellants. When such an assessment is made, a next step could be to identify those hotspots that are most amenable to improvement, have the highest impact and are feasible from the perspective of a regulatory agency *(17)*.

Voluntary reporting infrastructure

A voluntary reporting infrastructure could be established by disclosure templates that allow manufacturers to submit environmental metrics, including energy and water consumption, solvent use, emissions and packaging materials. This could also support the development of a "carbon footprint index" for pharmaceutical products. Any voluntary reporting infrastructure must include minimum standards for data integrity and third-party verification to ensure that environmental claims submitted by manufacturers are credible, traceable and potentially auditable. Such templates do not impose compliance

obligations. They build the regulatory community's ability to receive and act on climate data as the evidence base grows, and they create a structured starting point from which firmer standards can be considered later if the evidence supports it.

WHO's ongoing work on Good Manufacturing Practice (GMP) illustrates the approach (Case study 5). The intent is to shift mindsets and generate evidence on what is feasible, with a view to more binding standards later, if the evidence supports it.

Case study 5. A standalone "points to consider" document on environmental sustainability in GMP

WHO's Norms and Standards team has developed a standalone "points to consider" document on environmental sustainability in pharmaceutical manufacturing, illustrating how environmental considerations can be introduced into existing regulatory frameworks. The WHO GMP compendium contains around 45 guidelines; rather than revising each, a scoping review and gap analysis of the existing guidelines led to a single consolidating document. The document sets out a framework for integrating environmental sustainability principles and measurable environmental performance indicators – such as energy and water consumption, solvent use, emissions and packaging materials – into the pharmaceutical quality systems of facilities operating under GMP. It is addressed to regulators, inspectors and manufacturers, and by design covers only environmental impacts within the manufacturing facility. The approach is deliberately nonbinding: the framework is framed as points to consider rather than enforceable requirements. Its purpose is to signal regulatory direction, encourage voluntary measurement and reporting, and build the evidence base, with a view to firmer standards later if the evidence supports it. A risk-based, equity-sensitive design gives manufacturers of differing capacity, from innovator to generic, room to engage. The draft was released for public consultation in 2026. | Source: Stakeholders Forum (8 May 2026), Global Regulators Summit (19 June 2026), and scoping interview (26 March 2026).

4.3 Pillar 3. Innovation and innovative regulatory pathways

Pillar 3 focuses on supporting the adoption or better use of regulatory procedures within the current regulatory framework that enable earlier and more iterative engagement with regulators to assess innovations with potential environmental benefits while maintaining the same standards of quality, safety and efficacy. Regulatory tools can support both new products and sustainability-driven improvements to existing ones, contributing to more efficient and predictable regulatory processes. Approaches that improve predictability, convergence and efficiency in the assessment of such changes (including tailored pathways, joint submissions, post-approval change management protocols and early scientific advice) can support earlier engagement, reduce implementation risk, improve planning and promote global alignment while minimizing potential supply disruptions. Seven categories of regulatory tools are relevant (Table 1): digital transformation of regulatory activities, binding regulatory measures, nonbinding measures (such as guidance), incentivization mechanisms, life cycle management and engagement tools, transparency and accountability measures and reliance and harmonization. These categories are not exclusive: most instruments combine elements of more than one category, and the regulatory system functions through the interaction of all seven rather than through any single one. Additionally, the same categories of tools also support the work in Pillars 1 and 2.
The subsections that follow examine four areas of regulatory innovation, each drawing on the tools introduced in Table 1, that are particularly relevant for pharmaceutical decarbonization: digital transformation of regulatory activities; early and iterative scientific advice and leveraging existing regulatory pathways for sustainability driven changes; joint piloting *(15);* global consultation and alignment across jurisdictions.

Table 1. Overview of regulatory tools

Tool category	What it is	Examples
Digital transformation of regulatory activities	Digital tools and shared workflows that allow regulators to act faster and more interoperable, with a smaller operational footprint.	ICMRA Pharmaceutical Quality Knowledge Management System as the digital workflow underpinning collaborative post-approval change assessment; remote inspections retained at EMA, Food and Drug Administration (FDA), Pharmaceuticals and Medical Devices Agency and Health Canada after COVID-19.
Binding regulatory measures	Enforceable requirements that directly shape behaviour. Include marketing-authorization requirements, GMP, post-approval obligations and rules on promotion.	European Union environmental risk assessment for marketing authorization applications; European Union Regulation 2024/573 on fluorinated GHGs (pMDI propellant phase-down and GWP labelling).
Nonbinding regulatory guidance	Guidelines, points-to-consider documents and best-practice notes. Deployable without legislative change, and revisable as the evidence base develops.	Guidelines on integrating sustainability into pharmaceutical development; points-to-consider documents on greener manufacturing or packaging; best-practice documents.
Incentivization mechanisms	Targeted, and proportional measures that encourage particular behaviours without making them mandatory. Including expedited reviews, including scientific advice.	Examples focusing on unmet medical need: EMA PRIority MEdicines (PRIME); FDA Breakthrough Therapy and Fast Track; National Medical Products Administration priority pathways.
Life cycle management and engagement tools	Mechanisms that support prospective planning and efficient implementation of changes across a product's life cycle. They improve predictability, reduce duplication across products and support data generation.	ICH Q12 post-approval change management protocols; platform technology approaches for manufacturing processes and analytical methods; structured early engagement through scientific advice.
Transparency and accountability measures	Mechanisms that increase visibility of environmental performance and create incentives for behavioural change. Include mandatory and voluntary disclosure regimes and benchmarking.	Disclosure obligations emerging from nonpharmaceutical regulation.
Reliance and harmonization	Not regulatory tools in their own right, but influence how the wider system functions, how change is embedded and how predictability is managed across jurisdictions.	EMA-WHO post-approval reliance pilot; ICMRA Pharmaceutical Quality Knowledge Management Collaborative Pilots; WHO Prequalification Collaborative Review Procedure, the Organisation for Economic Co-operation and Development Mutual Acceptance of Data system. Regional harmonization initiatives such as ZaZiBoNa, African Vaccine Regulatory Forum and the East African Community Medicines Regulatory Harmonisation Programme.

Digital transformation of regulatory activities

Digital transformation of regulatory activities covers tools ranging from electronic product information, such as e-leaflets (Case study 6), to digital submission and assessment systems and reliance mechanisms for exchanging regulatory information between regulators, supported by a dedicated capacity-building programme for LMICs. Several instruments are in operation. For example, the ICMRA Pharmaceutical Quality Knowledge Management System is the digital workflow underpinning collaborative post-approval change assessment across multiple authorities *(37)*. Another important example is the ICH M4Q(R2) Structured Product Quality Submissions, which further enables digitalization by standardizing and structuring quality data submissions. Moreover, remote and hybrid inspections, increasingly adopted by regulatory authorities following the COVID-19 pandemic, offer opportunities to reduce inspection-related travel while maintaining robust regulatory oversight. The growing use of digital tools and technologies, including virtual meeting platforms with audiovisual capabilities, file sharing systems and electronic document management systems, enables regulators to effectively and efficiently access inspection-related information and records remotely, reducing the need for physical transfer of records or travel to inspection sites. These approaches can contribute to both greater efficiency and reduced environmental impact. However, the benefits of remote and hybrid inspections should be realized through a risk-based approach. Remote inspections should not be presumed equivalent to on-site verification in all circumstances. For high-risk activities, such as sterile manufacturing or certain aspects of data integrity assessment, physical presence remains necessary to provide the required level of scrutiny and regulatory oversight.

From a climate perspective, this digital infrastructure supports reliance at scale, reducing duplicated regulatory activity, and cuts the travel and paper footprint of regulatory operations. At the same time, the carbon footprint of digital infrastructure itself, particularly large-scale AI compute, is nontrivial and should be accounted for.

Regulatory review pathways to support sustainability

Existing regulatory procedures could be leveraged to support applications that aim to reduce environmental and climate impacts while maintaining the same standards of quality, safety and efficacy. In particular, scientific advice mechanisms can play a key role by enabling early and iterative dialogue between developers

Case study 6. Electronic product information (e-labelling) at Indonesia's BPOM

The Indonesian Food and Drug Authority (BPOM) has piloted electronic product information, or e-labelling, as a regulatory measure with an environmental cobenefit. Product information for health care professionals and patients is made available digitally and accessed by scanning a 2D barcode, replacing printed paper leaflets to provide faster, more efficient and more environmentally friendly access to up-to-date information. The pilot was conducted from December 2023 to November 2025, under a BPOM Chairperson decree (No. 317/2023, as amended by Decrees No. 433/2024 and No. 595/2025) and a 2026 circular letter on variation registration and electronic product information. The measure works within BPOM's existing mandate and builds on digital infrastructure rather than new assessment requirements, illustrating how digital transformation of regulatory information can deliver an incidental decarbonization benefit by reducing the paper, printing and distribution footprint of pharmaceutical packaging. | Source: BPOM presentation, "The Indonesian FDA's Role and Policies in Supporting Pharmaceutical Decarbonisation," WHO Global Regulators Summit, 19 June 2026.

and regulators on sustainability-related innovations, helping to clarify evidence requirements, to identify potential regulatory challenges and to support the generation of data needed to demonstrate that proposed changes maintain product quality, safety and efficacy.

By facilitating earlier engagement and greater regulatory predictability, scientific advice can support both the development of new products and the implementation of sustainability-driven improvements to existing products. While such tools do not alter regulatory standards or provide preferential approval, they can serve as important incentives for manufacturers by reducing regulatory uncertainty, minimizing the risk of unnecessary development work and enabling more efficient planning of environmental improvement initiatives.

Climate impact-driven changes can be modifications to an authorized product but also adapting to entirely new products. Post-approval variations are frequently identified by manufacturers as barriers to implementing processes or manufacturing improvements with environmental benefits. Greater use of scientific advice, together with regulatory reliance and, where appropriate within the existing framework, streamlined variation procedures could help manufacturers design robust change packages, reduce unnecessary duplication of assessment and facilitate the timely approval of sustainability-related changes. This approach can support the adoption of environmentally beneficial innovations, while ensuring that standards of quality, safety and efficacy remain unchanged.

Joint piloting

Joint pilots are activities undertaken by two or more regulatory authorities or by an authority together with WHO Prequalification. They reduce the cost of acting alone, generate a shared evidence base, and test how reliance mechanisms function for sustainability-driven submissions. Pilots are initially undertaken at a small scale to test approaches within a safe environment and generate lessons for the future.

Within the context of decarbonization, potential topics for joint pilots include coordinated handling of post-approval changes for solvent substitution and process improvement, alignment on climate information in product dossiers and joint assessment of sustainability-driven changes (for example, secondary packaging), ensuring that the operational changes can be recognized as low-risk under existing GMP frameworks and guidelines such as ICH Q9(R1) on quality risk management.

Global consultation and alignment across jurisdictions

Scaling sustainability-driven change across the regulatory community requires alignment between authorities. This alignment has two complementary components: regulatory reliance and internationally aligned guidance.

The first component is the use of global regulatory reliance mechanisms to embed sustainability-driven changes consistently across jurisdictions. Within such a mechanism, when a change has already been assessed and approved by a reference authority, relying authorities can recognize it through an abbreviated administrative verification within a defined period rather than a full independent reassessment. Procedures such as the EMA-WHO post-approval reliance pilot, the ICMRA Pharmaceutical Quality Knowledge Management Collaborative pilots, the WHO Prequalification Collaborative Review Procedure and the Organisation for Economic Co-operation and Development Mutual Acceptance of Data system provide potential models and infrastructure.

As a second component, internationally aligned guidance and recommendations are another practical output. These can cover how to apply available standards (Pillar 2), how to apply abatement levers, case studies at product level and general recommendations on implementing decarbonization measures. Adjacent sectors that have already introduced climate standards offer useful precedent. Such guidance can stimulate voluntary action and reduce uncertainty for higher-risk, higher-impact approaches that involve regulatory approval. Organizations are encouraged to discuss potential environmental-based changes to processes and associated impact on licences and approvals with national regulators at an early stage to get regulatory support for the proposals.

Realizing the three pillars set out above will depend on coordinated action across the actors involved. The following section sets out the roles of each.

5 Implementation

Progress will require coordinated action across regulatory authorities, manufacturers, procurement bodies, multilateral organizations, standards bodies and Member States, among others (Fig. 4). WHO and existing international (regulatory) platforms can serve as convening mechanisms to support collaboration and align approaches. One possible operating mode is a coalition of interested parties willing to take collective responsibility for the agenda and to operate across the institutional boundaries that currently separate environmental and pharmaceutical regulation. Other arrangements are also possible, including working through existing fora such as ICMRA, ICH and the WHO Prequalification Programme.

Whichever mode is chosen, it will rely on sustained collaboration, stakeholder engagement and building on existing frameworks. It will also depend on the contribution of a range of actors, each with a different mandate, capacity and point of entry to the regulatory system. The list of actors below is not exhaustive. The work proposed in this framework depends on action from all of them.

5.1 Governance and regulatory oversight

Pharmaceutical regulators (national, regional). Regulators sit at the centre of the agenda by virtue of their position in the value chain, but their action is bounded by their legal mandate and by the resources available to them. National authorities in LMICs face the additional challenge of building this capability from a smaller base and stand to benefit, in particular, from reliance mechanisms and capacity-building programmes. At the same time, strengthening regulatory collaboration should be based on a global partnership of equals, recognizing all NRAs as active contributors and fostering reliance and knowledge exchange as a two-way relationship rather than a one-directional transfer of expertise.

Member States. The legal mandate within which regulators operate and the resources available to them are set by Member States. Their role in giving regulators the explicit remit to consider climate impact and in funding the capacity to do so will shape what this framework can ultimately deliver.

Environmental regulators and policy-makers. Environmental protection agencies and environmental ministries hold the mandate for much of what lies beyond the pharmaceutical regulator's remit, including energy generation, transportation fuels, waste, pollutant discharge and corporate environmental disclosure. Because pharmaceutical regulators often cannot act where another authority is already responsible, engaging these bodies is what allows the two regulatory systems to be bridged rather than duplicated and clarifies where responsibility for a given measure properly sits.

Fig. 4. Main actors in decarbonization of the pharmaceutical value chain

Main actors*

*Not an exhaustive list

5.2 Coordination and harmonization

Multilateral and international organizations. These organizations provide the convening capacity that the agenda needs. International platforms, such as ICH, ICMRA and WHO Prequalification, are established venues through which sustainability-driven measures can be brought to a wider community of authorities and could form a basis to support further dialogue and sharing of best practices between NRAs and stakeholders.

Regional economic communities and harmonization initiatives. Regional bodies are the route through which national authorities pool technical resources and align their requirements. For example, regional harmonization initiatives, such as ZaZiBoNa, African Vaccine Regulatory Forum, the Gulf Centralised Committee for Drug Registration and the East African Community Medicines Regulatory Harmonisation Programme, run joint assessments and inspections, giving a regional point of entry for several national systems.

5.3 Implementation and market shaping

Manufacturers. This includes manufacturers of APIs, raw materials, originator/innovator companies and generic/biosimilar manufacturers. The different types of organizations come to this agenda from different starting points. For example, innovator companies have more capacity to invest in process improvements and product redesign, and several have public decarbonization commitments at the corporate level. Generic manufacturers operate on thinner margins and have less room to absorb new regulatory expectations without a clear business case. Regulatory actors should take this asymmetry into consideration, especially in generic-dominated markets where access and affordability could be at risk.

Procurement bodies and supply agencies. Governments, United Nations procurement agencies and international organizations, such as the Global Fund, can leverage their collective purchasing power to drive the adoption of health products with lower climate footprints and greater climate resilience. Procurement bodies have, in some cases, moved faster than regulators on climate standards. UNICEF Supply, the Global Fund supply mechanism and some national health systems have introduced sustainability requirements in tendering, supplier carbon reduction plans and product-level disclosure expectations *(38,39,40).*

5.4 Evidence, standards and capacity-building

Academia and research institutions. Much of the measurement science that makes decarbonization quantifiable, including life cycle assessment and carbon footprint methodology, originates in academia and research institutions. Universities and research groups further train the regulatory and scientific workforce on which capacity-building depends.

Standards bodies. Bodies such as ISO, BSI and national standards organizations develop and maintain the measurement standards (e.g., ISO 14040/14044, ISO 14067, PAS 2090, the French government methodology on the carbon footprint of pharmaceuticals) that the regulatory and industrial communities rely on for credible quantification *(23,24,25,41).*

5.5 Health system stakeholders and end users

Health care professionals and patients. Engaging health care professionals and patients can further strengthen climate-sensitive procurement. By increasing awareness of the climate impact of the products they use, they can be empowered to advocate for more sustainable alternatives and support informed decision-making. More broadly, patient and end-user engagement underpins any framework of disclosure or reporting that follows. It also provides a counterweight to changes that might be perceived as compromising access or product quality.

6 Conclusion

This framework highlights that the transition towards low-carbon pharmaceuticals is both necessary and achievable within existing regulatory systems. The tools, pathways and institutional arrangements required to enable this shift are already in place. The challenge ahead lies not in creating new structures but in mobilizing and aligning what already exists towards a shared objective: safeguarding both planetary and human health.

At its core, this agenda reaffirms the fundamental mandate of pharmaceutical regulators to ensure that all health products are safe, effective, of assured quality and accessible to those who need them. Integrating environmental sustainability into this mandate does not alter its purpose; it strengthens its relevance in a world where climate change is rapidly reshaping health needs, health systems and supply chains.

Achieving this transformation will require collective leadership and sustained cooperation across the pharmaceutical value chain. Regulators, manufacturers, procurement bodies, multilateral organizations and Member States each hold essential levers of change. Through coordinated action, they can ensure that innovation serves both public health and environmental sustainability, without compromising equity or access.

While this framework focuses on pharmaceuticals, similar considerations apply to other categories of health products, including medical devices and diagnostics. These product groups present distinct climate impact profiles and regulatory considerations and therefore warrant dedicated analysis. Targeted follow-on work in these areas would complement and extend the framework presented here, contributing to a more comprehensive transformation of health product value chains.

This framework calls for a shift in perspective: from viewing environmental considerations as an additional constraint to recognizing them as a driver of innovation, resilience and long-term system sustainability. By embedding climate considerations into existing regulatory practices, the global community can accelerate progress while maintaining trust in regulatory systems.

Ultimately, the transition to a more sustainable health products sector is not only a technical or regulatory endeavour; it is a shared global responsibility. It requires a spirit of partnership grounded in mutual trust, knowledge exchange and a commitment to act together. In doing so, the international community can advance towards health systems that are not only effective and equitable but also resilient and aligned with the goals of a sustainable future.

References

1 Resolution WHA77.14. Climate change and health. Geneva: World Health Organization; 2024 (https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_R14-en.pdf, accessed 10 July 2026).

2 Romanello M et al. The 2025 report of the Lancet Countdown on health and climate change: climate change action offers a lifeline. The Lancet. 2025;406(10521):2804–57 (https://doi.org/10.1016/s0140-6736(25)01919-1).

3 Resolution WHA61.19. Climate change and health. Geneva: World Health Organization; 2008 (https://iris.who.int/handle/10665/23547).

4 WHO global strategy on health, environment and climate change: the transformation needed to improve lives and well-being sustainably through healthy environments. Geneva: World Health Organization; 2020 (https://iris.who.int/handle/10665/331959). Licence: CC BY-NC-SA 3.0 IGO.

5 COP26 Health Programme [website]. In: Alliance for Transformative Action on Climate and Health. Geneva: World Health Organization (https://www.who.int/initiatives/alliance-for-transformative-action-on-climate-and-health/cop26-health-programme, accessed 10 July 2026).

6 Operational framework for building climate resilient and low carbon health systems. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/373837). Licence: CC BY-NC-SA 3.0 IGO.

7 Resolution WHA76.17. The impact of chemicals, waste and pollution on human health. Geneva: World Health Organization; 2023 (https://apps.who.int/gb/ebwha/pdf_files/WHA76/A76_R17-en.pdf, accessed 10 July 2026).

8 COP28 UAE declaration on climate and health. Geneva: World Health Organization; 2023 (https://www.who.int/publications/m/item/cop28-uae-declaration-on-climate-and-health, accessed 10 July 2026).

9 A global health strategy for 2025–2028 – advancing equity and resilience in a turbulent world: fourteenth General Programme of Work. Geneva: World Health Organization; 2025 (https://iris.who.int/items/bb8e67b6-9a0f-42ee-9549-4ff380995add). Licence: CC BY-NC-SA 3.0 IGO.

10 Greener pharmaceuticals' regulatory highway. Geneva: World Health Organization; 2024 (https://www.who.int/publications/m/item/greener-pharmaceuticals-regulatory-highway, accessed 17 July 2026).

11 Report of the Climate Resilient and Environmentally Sustainable Supply Chains in the Health Sector Expert Consultation. Geneva: World Health Organization (https://www.who.int/publications/m/item/report-of-climate-resilient-and-environmentally-sustainable-supply-chains-in-the-health-sector-expert-consultation, accessed 10 July 2026).

12 From milligrams to megatons: a climate and nature assessment of ten key health products. Geneva: Unitaid; 2023 (https://unitaid.org/uploads/Report_From-milligrams-to-megatons_A-climate-and-nature-assessment-of-ten-key-health-products.pdf, accessed 17 July 2026).

13 Hagenaars RH, Heijungs R, de Koning A, Tukker A, Wang R. The greenhouse gas emissions of pharmaceutical consumption and production: an input–output analysis over time and across global supply chains. Lancet Planet Health. 2025;9(3):e196–206 (https://doi.org/10.1016/S2542-5196(25)00028-2).

14 Securing medical supply chains in a post-pandemic world. Paris: OECD Publishing; 2024 (https://doi.org/10.1787/119c59d9-en).

15 WHO collaborative procedure for registering medicines through reliance [website]. European Medicines Agency (https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/who-collaborative-procedure-registering-medicines-through-reliance, accessed 10 July 2026).

16 Decarbonizing the healthcare supply chain: strategic actions for health systems. Geneva: World Health Organization (https://iris.who.int/items/226a8f41-5866-41af-84bc-927b6691e0df). Licence: CC BY-NC-SA 3.0 IGO.

17 Building climate-resilient, environmentally sustainable and low-carbon health supply chains: key priorities for collective action. Geneva: Unitaid; 2025 (https://unitaid.org/uploads/Building-climate-resilient-sustainable-low-carbon-health-supply-chains.pdf, accessed 17 July 2026).

18 PAS 2090 pilot use case – Novo Nordisk. London: BSI; 2026 (https://page.bsigroup.com/l/73472/2026-02-28/2cjzgm8/73472/1772302490t2IzQP9B/BSI_PAS_2090_Pilot_Novo_Nordisk_Case_Study_final.pdf, accessed 10 July 2026).

19 PAS 2090 pilot use case – GSK. London: BSI; 2026 (https://page.bsigroup.com/l/73472/2026-02-28/2cjzgmc/73472/1772302838ZBJpFcoV/BSI_PAS_2090_Pilot_GSK_Case_Study.pdf, accessed 10 July 2026).

20 Decarbonising healthcare supply chains [website]. London: Sustainable Markets Initiative (https://www.sustainable-markets.org/health-systems-taskforce-whitepapers, accessed 10 July 2026).

21 Karliner J et al. Low-carbon, climate-resilient health care supply chains: high-level health care climate action principle #3. Manila: Asian Development Bank; 2025 (https://dx.doi.org/10.22617/WPS250466-2).

22 Bhatia P, Cummis C, Draucker L, Lahd H, Rich D, Brown A. Greenhouse Gas Protocol product life cycle accounting and reporting standard. Washington (DC) and Geneva: World Resources Institute and World Business Council for Sustainable Development; 2011 (https://www.wri.org/research/greenhouse-gas-protocol-product-life-cycle-accounting-and-reporting-standard, accessed 17 July 2026).

23 ISO 14040:2006. Environmental management – life cycle assessment – principles and framework. Geneva: International Organization for Standardization; 2006 (https://www.iso.org/standard/37456.html, accessed 10 July 2026).

24 ISO 14044:2006. Environmental management – life cycle assessment – requirements and guidelines. Geneva: International Organization for Standardization; 2006 (https://www.iso.org/standard/38498.html, accessed 10 July 2026).

25 ISO 14067:2018. Greenhouse gases – carbon footprint of products. Geneva: International Organization for Standardization; 2018 (https://www.iso.org/standard/71206.html, accessed 10 July 2026).

26 Damiani M, Ferrara N, Ardente F. Understanding product environmental footprint and organisation environmental footprint methods. Luxembourg: Publications Office of the European Union; 2022 (https://dx.doi.org/10.2760/11564).

27 The untold story of dolutegravir: when climate impact goes hand-in-hand with access to better treatments. Geneva: Unitaid (https://unitaid.org/publication/the-untold-story-of-dolutegravir-when-climate-impact-goes-hand-in-hand-with-access-to-better-treatments, accessed 10 July 2026).

28 Greening opportunities for mosquito nets [website]. Geneva: Office of the United Nations High Commissioner for Refugees (https://www.unhcr.org/media/greening-opportunities-mosquito-nets, accessed 10 July 2026).

29 GreenNet [website]. In: WHO Prequalification of Medical Products. Geneva: World Health Organization (https://extranet.who.int/prequal/vector-control-products/greennet, accessed 10 July 2026).

30 Wilkinson A, Woodcock A. The environmental impact of inhalers for asthma: a green challenge and a golden opportunity. Br J Clin Pharmacol. 2022;88(7):3016–22 (https://doi.org/10.1111/bcp.15135).

31 Regulation (EU) 2024/573 of the European Parliament and of the Council of 7 February 2024 on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 (https://eur-lex.europa.eu/eli/reg/2024/573/oj/eng, accessed 17 July 2026).

32 Questions and answers on data requirements when transitioning to low global warming potential propellants in oral pressurised metered dose inhalers: scientific guideline. Amsterdam: European Medicines Agency; 2023 (https://www.ema.europa.eu/en/questions-answers-data-requirements-when-transitioning-low-global-warming-potential-lgwp-propellants-oral-pressurised-metered-dose-inhalers-scientific-guideline, accessed 10 July 2026).

33 Trixeo Aerosphere approved in the UK as first inhaled respiratory medicine using next-generation propellant with near-zero global warming potential [press release]. Cambridge: AstraZeneca; 2025 (https://www.astrazeneca.com/media-centre/press-releases/2025/trixeo-aerosphere-approved-in-the-uk-as-first-inhaled-respiratory-medicine-using-next-generation-propellant-with-near-zero-global-warming-potential.html, accessed 10 July 2026).

34 Chiesi completes clinical development program for carbon-minimal pressurized metered-dose inhalers, paving the way for regulatory submissions [press release]. Parma: Chiesi (https://www.chiesi.com/en/media-hub/press-releases/pmdi-carbon-minimal-clinical-development-regulatory-submissions, accessed 10 July 2026).

35 Carbon footprint of medicines: assessment methodology. Paris: ECOVAMED; 2025 (https://www.entreprises.gouv.fr/files/files/Publications/2025/Guide/eng-bro-a4-methodo-dge-0128.pdf, accessed 10 July 2026).

36 First global standard for measuring the environmental impact of pharmaceuticals published [press release]. London: BSI; 2025 (https://www.bsigroup.com/en-GB/insights-and-media/media-centre/press-releases/2025/december/first-global-standard-for-measuring-the-environmental-impact-of-pharmaceuticals-published, accessed 10 July 2026).

37 Pharmaceutical Quality Knowledge Management System (PQKMS) [website]. International Coalition of Medicines Regulatory Authorities (https://icmra.info/drupal/en/strategicinitatives/pqkms, accessed 10 July 2026).

38 Delivering a net zero NHS [website]. In: Greener NHS. Leeds: NHS England (https://www.england.nhs.uk/greenernhs/a-net-zero-nhs, accessed 10 July 2026).

39 Five years of a greener NHS: progress and forward look [website]. Leeds: NHS England (https://www.england.nhs.uk/long-read/five-years-greener-nhs-progress-forward-look, accessed 10 July 2026).

40 Procedure on sustainable procurement. New York: United Nations Children's Fund (https://www.unicef.org/documents/sustainable-procurement-procedure, accessed 10 July 2026).

41 NHS England's PAS 2090 pilot use case [case study conducted in collaboration with NHS England]. London: BSI (https://www.bsigroup.com/en-GB/insights-and-media/insights/case-studies/nhs-englands-pas-2090-pilot-use-case, accessed 17 July 2026).

42 Vincenzi C, Klebl C, Sauces T, Abed I, Jekerle V. A regulatory perspective on the first approved EU application to reformulate an inhaled medicine with a gas propellant with reduced global warming potential. Br J Clin Pharmacol. 2026;1-4 (https://doi.org/10.1002/bcp.70686).

Annex. Methods

The development of this framework followed an evidence-informed and consultative approach designed to ensure transparency, methodological rigour and global relevance.

Evidence identification and horizon scanning

An initial horizon scanning phase combined a structured literature review and a series of scoping interviews. The literature review drew on peer-reviewed and grey literature sources. Searches were conducted in bibliographic databases (including PubMed and Google Scholar), and through targeted searches of organizational websites and relevant repositories. Grey literature was identified from key international organizations, regulatory authorities and technical partners. Study selection followed predefined inclusion criteria, and screening was conducted by two reviewers. Discrepancies were resolved through discussion to ensure consistency in study selection.

In parallel, a series of scoping interviews was conducted with a purposive sample of stakeholders to capture qualitative insights into current challenges, opportunities and emerging practices related to the decarbonization of pharmaceutical products. Stakeholders included representatives from regulatory authorities, industry, multilateral organizations and United Nations agencies including WHO staff, UNICEF staff, standards-setting bodies and national public health agencies across different geographical regions, including both high-income countries and LMICs.

Stakeholder consultation and validation

Findings from the horizon scanning phase informed a stakeholder consultation forum. The forum aimed to align perspectives, identify regulatory challenges and opportunities, validate and enrich the initial horizon scanning findings. Following this, targeted follow-up interviews were undertaken with selected stakeholders to explore specific issues in greater depth.

Drafting and peer review

Evidence generated through the literature review, interview and consultation processes was synthesized through an iterative drafting process. The draft was peer-reviewed by regulatory authorities operating at Maturity Levels 3 and 4 (ML3 and ML4), WHO-Listed Authorities (including transitional WHO-Listed Authorities), and Pan American Health Organization Regional Reference Authorities, representing diverse geographical and income settings, as well as WHO technical experts. Feedback was systematically incorporated to ensure accuracy, balance, feasibility considerations and alignment with evidence base. A dedicated Global Summit for regulators, with representatives from national and regional regulatory authorities was convened to review the draft and discuss proposed approaches. Inputs and conclusions from this meeting were integrated into subsequent revisions. Prior to finalization, the draft underwent an additional round of external peer review by regulatory authorities as well as internal peer review by WHO subject-matter experts to support validation and consensus.

Data management and confidentiality

Interviews were documented using a General Data Protection Regulation-compliant artificial intelligence -powered notetaking tool. Artificial intelligence-generated summaries to support analysis were reviewed by the project team to ensure accuracy. Audio recordings and transcripts were used solely for analysis and documentation purposes and were securely stored and deleted following finalization of the project.

Declarations of interest

All external experts who provided independent expert advice submitted to WHO a declaration of interest disclosing potential conflicts of interest that might affect, or might reasonably be perceived to affect, their objectivity and independence in relation to the subject matter of this publication. WHO reviewed each of the declarations and concluded that none could give rise to a potential or reasonably perceived conflict of interest related to the subjects covered by the publication.

Department of Regulation and Prequalification

World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

Email: regulation_prequalification@who.int
Website: https://www.who.int/teams/regulation-prequalification