

Drugs for Neglected Diseases initiative (DNDi)

Briefing note for the 79th Session of the World Health Assembly

May 2026

Overview

The Drugs for Neglected Diseases initiative ([DNDi](#)) is a not-for-profit research and development (R&D) organization, in official relations with the World Health Organization (WHO), that discovers, develops, and delivers new treatments for neglected patients. Since our creation in 2003 by public research institutions in Brazil, France, India, Kenya, and Malaysia, Médecins Sans Frontières (MSF), and WHO TDR, we have developed 14 new and improved treatments for six deadly diseases that have saved millions of lives – utilizing an alternative, collaborative, not-for-profit R&D model.

In partnership with WHO, DNDi jointly established the Global Antibiotic Research and Development Partnership (GARDP), now an independent organization playing an essential role in its work with Member States to deliver on the Global Action Plan on Antimicrobial Resistance. DNDi is also a member of the Global Accelerator for Paediatric Formulations Network (GAP-f), which promotes innovation of and access to quality, safe, efficacious, and affordable medicines for children.

This briefing note sets out DNDi's comments for consideration by the World Health Assembly on the following agenda items:

- **Agenda item 12.3: Road map for neglected tropical diseases 2021–2030**
- **Agenda item 12.6: Health in the 2030 Agenda for Sustainable Development**
- **Agenda item 12.10: Harmonization of regulatory approaches, governance and standards for data, digital health and artificial intelligence in the health sector**
- **Agenda item 13.3: Update on the Intergovernmental Working Group (IGWG) Negotiations on the WHO Pandemic Agreement**
- **Agenda item 15.5: Economics of health for all**
- **Agenda item 20.1: Reform of the global health architecture and the UN80 Initiative**

Agenda item 12.3: NTD Progress Report

DNDi welcomes the Director General's progress [report](#) and the Global [report](#) on the WHO Road Map for Neglected Tropical Diseases 2021–2030. The report notes areas of important progress, such as nine countries eliminating one NTD in 2025. The DG's report also describes areas of progress, including a reduction to only 37 reported cases of r-HAT and a 58% decrease in visceral leishmaniasis cases in 2024 compared to 2014. However, the report highlights significant concerns about the lack of progress in reducing deaths from vector-borne NTDs, as well as the need to expand access to water and sanitation and to improve the completeness and gender-disaggregation of NTD data.

In 2023, an estimated 1.495 billion people still required interventions against NTDs. The report highlights insufficient progress toward the 2030 Road Map targets, including only a 32% reduction in the number of people requiring NTD interventions against the 90% target and a 66% rise in deaths from vector-borne NTDs since 2016. **Renewed, focused, and collaborative efforts are urgently needed to enable and hasten progress towards the sustainable elimination of NTDs.**

Closing the R&D gap for NTDs

The development of new health tools remains a fundamental pillar for achieving NTD control and elimination goals. Sustained commitment and partnership have enabled the development of simpler, safer, more effective new treatments – such as acoziborole, a one-day, single-dose oral treatment for sleeping sickness that can play a pivotal role in the final push towards elimination. However, current health tools for many NTDs are inadequate for achieving and sustaining elimination. For example, dengue currently has no treatment, despite its classification as a Grade 3 emergency by WHO. In regions like sub-Saharan Africa, the few available treatments for fungal mycetoma are costly, ineffective, and toxic.

DNDi calls for finalization of the [WHO R&D blueprint for NTDs](#) to identify and prioritize research needs without further delay.¹ We need health tools that are patient-friendly, can be delivered in resource-limited settings, and limit hospitalization, thereby reducing burden on health care systems. In particular, for diseases nearing elimination – including sleeping sickness and visceral leishmaniasis – we need new, context-specific tools that meet the requirements of a sustainable elimination programme. In 2025, working with DNDi and partners such as Sanofi's Foundation S, the HAT-r-ACC research consortium,² and national health authorities, WHO delivered fexinidazole in Malawi and Zimbabwe, marking a significant milestone in making the drug available for r-HAT patients in East and Southern Africa. This major public health advancement came after decades of reliance on toxic and difficult-to-administer injectable treatments.³

Renewing focus on women and children

Women and children are disproportionately affected by NTDs, facing double neglect. At least 1.2 billion children and adolescents (<25 years) – one in six people globally – are affected by one or more NTDs.⁴ For example, in 2022, more than half of those infected with visceral leishmaniasis were less than 15 years old.⁵ School-aged children are also at higher risk of schistosomiasis due to their involvement in activities such as swimming or fishing in infected water. Children affected by NTDs face profound and long-lasting harms,

¹ As of January 2026, the World Health Organization (WHO) has not yet published the final R&D Blueprint for Neglected Tropical Diseases originally expected in 2025. A WHO planning document notes that the publication is expected in Q1–Q2 2026, indicating a shift from the earlier target: https://apps.who.int/gb/mspi/pdf_files/2025/12/Item1_10-12.pdf

² HAT-r-ACC Consortium partners involved in clinical research that supported the evidence base for fexinidazole included Malawi Ministry of Health and Uganda National Health Research Organization, Makerere University (Uganda), Epicentre (France), Lisbon Institute of Hygiene and Tropical Medicine (Portugal), Institut de Recherche pour le Développement (France) and Swiss Tropical and Public Health Institute

³ <https://www.who.int/news/item/07-02-2025-who-delivers-fexinidazole-to-malawi-and-zimbabwe---a-long-awaited-safer-treatment-for-rhodesiense-human-african-trypanosomiasis>

⁴ <https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642%2824%2900022-1>

⁵ <https://pmc.ncbi.nlm.nih.gov/articles/PMC11628699/>

including disfigurement, stunted growth, chronic pain, malnutrition, and premature death. There is a notable absence of child-friendly formulations or paediatric dosing guidelines for several NTDs. Only 22 of the 47 medications available for NTDs are labelled for paediatric use.⁶ There is a need to incentivize R&D for child-friendly formulations (e.g., chewable tablets, dispersible formulations) and point-of-care diagnostics. Furthermore, we encourage Member States to support the WHO Global Accelerator for Paediatric Formulations (GAP-f) [2025–2030 strategy](#), which aims to fast-track the development of child-friendly formulations by strengthening the global R&D ecosystem for paediatric medicines.

Many NTDs also disproportionately affect women. For example, the risk of death due to dengue is nearly four times higher in pregnant women than in non-pregnant women of reproductive age. Female genital schistosomiasis affects women exclusively, causing reproductive organ damage, infertility, increased risk of HIV, anaemia, and cervical cancer. NTDs such as cutaneous leishmaniasis cause skin lesions, often leading to heightened social stigma. There is also a lack of gender-disaggregated data for NTDs, which is reported by only 13% of countries endemic for at least one NTD. Additionally, biological females, especially those who are or may become pregnant or who are lactating, are often excluded from clinical trials due to concerns that drugs could harm foetuses.

We encourage Member States to **implement the resolution ‘Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality in order to achieve SDG targets 3.1 and 3.2’**, which outlines commitments to support R&D to address the unmet needs of children and pregnant and lactating women.

Securing political will and sustainable financing to drive progress in challenging times

A significant and persistent funding gap remains a critical barrier to achieving NTD Road Map targets. The report notes that official development assistance (ODA) for NTDs declined by 41% between 2018 and 2023, a trend exacerbated by the COVID-19 pandemic.⁷ Funder pullback is not just affecting service delivery but undermining essential research: R&D for improved drugs and diagnostics, surveillance platforms, and validation of new tools are all at risk. To address the gaps, Member States should explore alternative models and financing mechanisms, such as non-profit R&D models, incentives such as the Priority Review Voucher programme for NTDS (currently only available in the US), and pooled funding. NTD endemic countries should also expand domestic financing for health R&D and NTD programmes by integrating them into national health budgets and UHC packages, in line with the principles of the Lusaka Agenda.⁸

Addressing the impact of climate change on NTDs

The report highlights climate change as a key driver intensifying and expanding NTD threats by worsening outbreaks in endemic areas and enabling vector-borne diseases to spread to new regions. Changes in temperature, rainfall, and humidity are expanding the geographical range of vectors like mosquitoes, sandflies, and snails, leading to the emergence of diseases like dengue, leishmaniasis, chikungunya, and schistosomiasis in new, previously non-endemic areas.

Dengue is cited as the NTD ‘most affected by the impact of climate change.’ Last year saw 14.6 million reported cases of dengue, with South America accounting for a significant share of the global burden, signalling a growing population at-risk of vector-borne NTDs. A WHO-led scoping review⁹ acknowledges gaps in understanding the impact of climate change on NTDs and emphasizes the need for investment in additional modelling studies to predict these shifts. **Additionally, investing in R&D for health tools to prevent, test, and treat climate-sensitive diseases, including NTDs, must be a core component of adaptation strategies.** This includes developing treatments for diseases likely to be exacerbated by climate

⁶ <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007111>

⁷ <https://www.who.int/news/item/04-06-2025-neglected-tropical-diseases-further-neglected-due-to-oda-cuts>

⁸ https://futureofghis.org/follow_ups/lusaka-agenda-overview/

⁹ <https://academic.oup.com/trstmh/article/118/9/561/7656506>

change, more resilient diagnostic platforms for use in outbreak settings, and prevention strategies such as vaccination and vector control.

The current global health landscape – characterized by shifting funding streams and climate-related health threats – **risks widening disparities unless Member States adequately finance and prioritize NTD control and elimination.** Prioritizing NTDs is therefore not only a public health imperative but also a strategic investment in health system strengthening and global health security.

We urge Member States to demonstrate strong political will and commitment to support the goals of the NTD Road Map – including sustainable investment in needs-driven R&D – by:

- Supporting the **finalization and implementation of the WHO NTD R&D Blueprint;**
- Supporting **inclusive clinical research** that ensures that women, pregnant and lactating women, and children are included in NTD clinical trials, in line with Member States' commitments under resolution 77.5;
- Investing in the **routine collection and reporting of sex- and age-disaggregated NTD data;**
- Exploring **new funding models to mobilize additional resources** and align domestic and international financing to close the widening NTD R&D funding gap and ensure the sustainability of national programmes;
- Institutionalizing **national innovation pathways for NTDs** that systematically review the need for the development of NTD treatments, diagnostics, and vaccines; assess their relevance to epidemiology; and provide clear guidance on their adoption – including through linkages with national and regional scientific experts and regulatory authorities and, where relevant, WHO prequalification processes; and
- Prioritizing **actions to address climate-sensitive diseases**, including developing a list of climate-sensitive diseases and investing in R&D for new tools to prevent, test, and treat infectious diseases **as outlined in the Global Action Plan on Climate Change and Health and Belem Health Action Plan.**

Agenda item 12.6: Health in the 2030 Agenda for Sustainable Development

DNDi welcomes the [report](#) on Health in the 2030 Agenda for Sustainable Development. We note with concern that despite some measurable advances, the world remains far off track in achieving the health targets of the Sustainable Development Goals (SDGs). Critical gaps persist in improving maternal and child health, infectious disease control, and universal health coverage (UHC), with many countries projected to miss 2030 targets if current trends continue.

Innovating for control and elimination of NTDs

Target 3.3 explicitly calls for ending the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases by 2030, highlighting NTDs as a global health priority. Target 3.b complements this goal by focusing on the research, development, and accessibility of vaccines and medicines for diseases that primarily affect developing countries.

As noted for agenda item 8, above, NTDs continue to affect approximately 1.5 billion people worldwide. The global [report](#) on the WHO Road Map for Neglected Tropical Diseases 2021–2030 notes some progress made in the control and elimination of NTDs. However, progress remains substantially off track. The report confirms that current trajectories are insufficient to achieve the 90% reduction target by 2030. **Without deliberate action, millions of people will continue to be left behind.**

Access to appropriate, affordable health tools is key to achieving UHC. SDG target 3.8 calls for specific prerequisites for achieving UHC, including financial risk protection, access to quality essential health-care services, and access to safe, effective, quality and affordable essential medicines and vaccines for all. Despite some progress in recent decades, too many patients still lack access to adequate treatment, diagnostics, and vaccines, across numerous diseases, including for NTDs.

We are particularly concerned that R&D gaps for NTDs continue to undermine progress. Market-driven innovation systems have consistently failed to deliver sufficient affordable, adapted, and effective health tools for populations in greatest need. DNDi underscores that achieving the SDGs will require needs-driven, patient-centred R&D for health tools, guided by public health priorities rather than commercial incentives alone. R&D can support UHC by delivering safe, effective, affordable health tools adapted to patients' needs and designed from the start for use at the primary healthcare level, close to the affected communities – reducing the need for specialist intervention in hospital settings. This reduces complexity and cost, not only for patients and families but also for health systems. Household income lost from out-of-pocket health expenditures and lost wages due to NTDs is estimated to total at least USD 33 billion per year.¹⁰ Along with strengthening early diagnosis, integrated case management, vector control, and access to safe water and sanitation, the development of new treatments, diagnostics, and vaccines is essential to advancing the control and elimination of NTDs.

Addressing the needs of children

The report recognizes stagnation – and even reversal – in child health indicators. SDG target 3.2 calls for ending preventable deaths of newborns and children under 5 years of age by 2030, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births. **Gaps in the treatment of childhood illnesses are also a major barrier to achieving UHC, particularly in low- and middle-income countries.** Historically, children's treatment needs have been overlooked in profit-driven drug development, as paediatric medicines represent smaller and less lucrative markets. As a result, medicines are typically developed for adults first, with paediatric formulations delayed or never developed. **Improving child health outcomes requires**

¹⁰ <https://iris.who.int/bitstream/handle/10665/363155/9789240052932-eng.pdf>

prioritizing the development and delivery of paediatric medicines as an integral part of health system and research agendas.

Achieving target 3.2 also requires **urgent action on antimicrobial resistance (AMR)**, which disproportionately affects children and neonates. One in five AMR-related deaths occurs in children under five, 99% of whom live in low- and middle-income countries. Children die from drug-resistant infections due to high vulnerability to infection compounded by poor infection prevention and control, limited treatment options, insufficient research and development, regulatory and clinical trial challenges, and inadequate access to antibiotics. Recent initiatives, including the WHO Paediatric Drug Optimization Priority List and investments by the Global Antibiotic Research and Development Partnership, represent important progress. However, significantly greater urgency and investment are still needed.

Importance of partnerships in achieving SDG targets

Effective partnerships between governments, international organizations, civil society, academia, research institutes, communities, and the public and private sectors are key drivers of health research and innovation, critical to achieving SDG 3. Product development partnership (PDP) models, including DNDi's, are reshaping the traditionally market-driven research ecosystem to deliver essential health tools for diseases such as HIV, malaria, and NTDs. Since 2010, these organizations delivered 79 new health technologies, reaching an estimated 2.4 billion people worldwide and helping save millions of lives.¹¹

But progress is at risk. While partnerships with pharmaceutical companies have been important to advancing infectious disease research, this foundation is eroding. Large pharmaceutical firms are continuing to withdraw from R&D for infectious disease therapeutics, shifting to more profitable markets or outsourcing expertise that once fuelled in-kind collaborations. Our partnerships with major companies have dropped by over 50% in the past decade, compounded by deep funding cuts and withdrawal from infectious diseases research by traditional funders.¹² This trend threatens progress toward SDG 3, just as the need for better health tools for vulnerable populations is greater than ever. Countries like China, Brazil, India, South Africa, and Thailand are investing in neglected disease research, but many others lack the capacity to do so. Collaborative efforts have delivered life-saving treatments for neglected diseases, but to meet all the needs requires urgent action. Bold, coordinated investment and partnerships are needed to develop the medicines and other health tools communities need to address priority infectious diseases.

With only five years remaining to meet the 2030 targets, renewed and accelerated efforts are urgently needed. This period must be used to strengthen needs-driven R&D, address persistent access barriers, and ensure that innovation translates into affordable and equitable access for all populations, particularly those that have been historically neglected.

We urge Member States to:

- **Reprioritize NTDs and the SDG agenda**, ensuring sustainable funding and political commitment;
- Commit to **sustainably invest in the development of effective health tools** that can be used at the **primary healthcare level** by supporting not-for-profit R&D models that centre on patient needs;
- **Include children in research and innovation** and encourage the **rapid and coordinated development of age-appropriate treatment formulations** for diseases that affect children, including NTDs, through sustained political commitment, mobilization of adequate financing, and strengthened regulatory frameworks;

¹¹ <https://www.keepingthepromisereport.org/>

¹² <https://www.ft.com/content/7e9bd070-a99e-4f1f-bff9-3709007104e1>

- **Invest in R&D Infrastructure** to build and strengthen human and physical research capacity in high-burden countries;
- **Support both local production and innovation**, as manufacturing is necessary, but funding must also drive discovery and development of new diagnostics, medicines, and vaccines;
- **Foster inclusive, equitable partnerships**, not only with industry, but also academia, non-profits and public R&D actors, geographically diverse start-ups and SMEs to accelerate innovation in the infectious disease landscape; and
- **Ensure sustained national, regional, and global funding across the R&D continuum** to develop and deliver vaccines, diagnostics, treatments, and other essential health tools.

Agenda item 12.10: Harmonization of regulatory approaches, governance and standards for data, digital health and artificial intelligence in the health sector

Digital technologies, such as AI, can be applied across all elements of the health system, including the discovery and development of health tools such as medicines, vaccines, and diagnostics. As an R&D organization, DNDi has been employing new technologies to improve efficiency and accelerate the pace of the R&D process, including AI-driven drug discovery tools; novel imaging, diagnostic, and clinical trial design and operations technologies; and AI-driven data analysis.

For example, in 2020, DNDi collaborated with Fundación MEDINA and Institut Pasteur Korea to leverage Institut Pasteur Korea's whole-cell phenotypic and innovative image-based screening technologies to identify compounds from MEDINA's extensive microbial natural products libraries with promising antiparasitic activity and novel mechanisms of action. DNDi has also partnered with Benevolent AI to identify a repurposed drug candidate that could be effective in treating dengue. AI can also be used to aid in the diagnosis of some NTDs, such as a recent project conducted by University of Brasília that explored how 'deep-learning'-based AI can facilitate the diagnosis of cutaneous leishmaniasis lesions.

In providing guidance on the development of the 2028-2033 draft global strategy on digital health, we request Member States to consider the following.

Digital technologies, including AI and big data, hold great promise for accelerating R&D while reducing costs and increasing the likelihood of successful trials and therapies. But that promise is not guaranteed – especially for the most neglected. The effectiveness and fairness of digital technologies depend on how they are developed, deployed, and governed. **Attention is needed to ensure that successful technologies, particularly those that are publicly funded, are not locked away for the benefit of only certain populations.**

The DG's [report](#) stresses that **equity must be central to the digital transformation of health**. Proprietary algorithms and high access costs risk restricting the use of AI technologies, potentially preventing their benefits from reaching underserved populations and reinforcing existing inequities. Policies should actively encourage the creation of digital public goods, enabling equitable access and broader sharing and collaboration. It is critical that patient needs, especially those of the most vulnerable, are at the centre of any technological innovation or advancement. This requires training and sensitization of those involved in developing and deploying digital solutions.

The application of AI for neglected patients and diseases faces several challenges. AI models are typically trained on datasets reflecting pharmaceutical priorities, such as oncology, and specific populations, making them poorly representative of neglected diseases and neglected populations. Data on NTDs, when available, are often limited in size and quality, reducing their usefulness for AI development. Health data used to train AI models must be representative of key populations affected by specific health conditions, or it can entrench existing bias and lead to poor health outcomes.

Sharing of research knowledge and data across the innovation life cycle is also critical. While using digital tools to strengthen data collection and sharing processes, privacy and protection of patients and personal data need to be managed. Legal frameworks must be in place to address issues related to data ownership, consent, availability, and security. Policymakers must strike the right balance between protecting the individual while minimizing costs and delays in data sharing and strengthening data access.

We urge Member States to:

- Invest in **data generation for neglected diseases and underserved populations** to ensure AI models are built on representative and sufficient datasets;

- Adopt policies that promote the **application and optimization of AI tools for neglected infectious diseases and marginalized populations**, alongside commercially profitable areas;
- Support policies that **encourage the creation of digital public goods** that enable equitable access, collaboration, and data sharing. These tools should have utility across different geographies and populations, and AI models developed with public funding should remain accessible for public benefit; and
- Establish **strong regulatory, ethical, and governance frameworks for data use**, particularly to protect privacy and personal data while balancing the need for access to data to advance science and to prevent AI systems from exacerbating health inequalities or reinforcing existing biases related to age, race, ethnicity, gender identity, or health status.

Agenda item 13.3 Update on the Intergovernmental Working Group (IGWG) Negotiations on the WHO Pandemic Agreement

DNDi welcomes the continued efforts of Member States to advance negotiations on the Pandemic Agreement and its Pathogen Access and Benefit-Sharing (PABS) annex through the Intergovernmental Working Group (IGWG) process. While recent negotiating sessions resulted in some technical progress, Member States were ultimately unable to conclude negotiations on the outstanding PABS annex and agreed to extend deliberations beyond the original timeline. Discussions continue to reflect significant political and technical differences, particularly regarding the operationalization of benefit-sharing obligations, legal certainty around pathogen and sequence sharing, transparency provisions, and the differentiation of obligations between commercial and non-commercial actors. The decision to continue negotiations underscores both the complexity of the issues under discussion and the continued recognition by Member States that an effective and equitable PABS system remains essential to the broader implementation of the Pandemic Agreement. While important differences remain between Member States on core political and technical matters, there continues to be broad recognition that a workable agreement must balance rapid pathogen sharing with fair, predictable, and enforceable benefit-sharing arrangements.

The recent detection of hantavirus cases on a cruise ship arriving from Argentina has once again activated international health coordination mechanisms among several countries and the WHO. Situations such as this highlight the need to maintain sustained international cooperation to prevent and respond to potential health emergencies, particularly in a context shaped by the climate crisis, biodiversity loss, global mobility, inequalities between health systems, and insufficient investment in tools to prevent and respond to these threats.

From DNDi's perspective, a strong and workable PABS system is essential not only for facilitating timely pathogen sharing, but for correcting long-standing inequities in who benefits from health innovation during outbreaks and pandemics. Past experiences, including COVID-19, have shown that rapid scientific progress does not automatically translate into equitable access to diagnostics, therapeutics, or vaccines, particularly for low- and middle-income countries. A robust PABS system must therefore ensure that benefit-sharing is predictable, enforceable, and explicitly linked to access outcomes, including affordable pricing, non-exclusive licensing, technology transfer, and geographically diversified manufacturing. Without such guarantees, pathogen-sharing arrangements risk reproducing extractive innovation models that rely on global cooperation while concentrating benefits among a limited number of actors and markets. For DNDi, PABS should function as a mechanism to align innovation incentives with public health needs and equity objectives, ensuring that the sharing of pathogens and data effectively translates into access to life-saving tools for all.

DNDi also strongly emphasises the importance of early and proactive implementation of Article 9.5 on public-interest conditions attached to publicly funded R&D. This provision represents a critical opportunity for countries to begin reshaping innovation systems by embedding equity, affordability, transparency, and knowledge-sharing requirements into public investments. Importantly, countries do not need—and should not wait for—the conclusion of negotiations on the PABS annex to take action under Article 9.5. Governments can already start operationalizing this article through existing policy levers, including funding conditions, licensing policies, procurement rules, and support for technology transfer and data sharing. Early implementation would help build the practical and normative foundations for a more equitable innovation ecosystem, strengthen coherence between national R&D policies and the objectives of the Pandemic Agreement, and reduce the risk that future benefit-sharing commitments remain purely

aspirational. Acting now would also demonstrate political commitment to ensuring that public funding delivers public value ahead of the next pandemic.

DNDi also notes the important contributions made by non-state actors during the IGWG process, including proposals related to equitable licensing approaches, non-exclusive technology transfer, and governance safeguards to ensure that public health objectives remain central to the operation of the PABS system. These contributions demonstrate the value of maintaining meaningful and inclusive stakeholder participation throughout the negotiation and implementation phases.

The coming negotiating period will therefore be critical in determining whether Member States can bridge remaining divides and establish a system capable of supporting both global health security and equity objectives in future pandemics.

Agenda item 15.5: Draft Global Strategy on the economics of health for all

DNDi thanks WHO for developing the global strategy on the economics of health for all. Implementation of this draft strategy would require multisectoral collaboration across health, science and technology, education, labour, and industrial policy.

Innovating for public health priorities

We particularly encourage Member States to direct ‘innovation towards public health priorities’, as described in the [report](#) under Strategic Direction 1. DNDi was established to address chronic challenges in ensuring that medical R&D meets the needs of neglected populations. As such, we support the call for governments to shape science policies and health innovation ecosystems to address public health priorities. Market-based approaches alone will not be sufficient to discover, develop, and ensure access to all necessary health tools, particularly for poor and marginalized communities. Persistent innovation gaps continue to impact millions of people who are affected by diseases that do not represent a lucrative market for the pharmaceutical industry – including people affected by neglected tropical diseases, pandemic threats, drug-resistant infections, and other diseases that predominantly or exclusively affect poor and marginalized communities.

Progress in developing new health tools for neglected populations depends on sustainable investments in R&D and on political leadership to drive such investment. While the private sector can play an important role in innovation, **governments must leverage incentives and public investment to ensure that resulting innovations are aligned with public health priorities.** Without specific government interventions, unmet medical needs will not be addressed by the profit-driven biomedical R&D system. **Alternative financing mechanisms and partnership models, including not-for-profit models, are also needed.**

Building public interest goals into the innovation process itself

The report by the independent WHO Council on the Economics of Health for All (2021–2023), ‘[Health for All: Transforming economies to deliver what matters](#)’,¹³ highlights longstanding failures of the R&D system that countries and communities have confronted for decades, most notably the struggle for access to HIV treatment in low- and middle-income countries. The COVID-19 pandemic exposed these failures once again: despite unprecedented scientific advances, the system failed to ensure equitable access to vaccines, diagnostics, and therapeutics. As the Council noted in its brief, ‘Governing health innovation for the common good,¹⁴ these inequities were ‘not just a moral failure’ but a ‘health and economic catastrophe.’ Addressing this requires **end-to-end R&D and manufacturing ecosystems that embed public-interest objectives, including equitable access, from the outset.** The draft strategy must therefore articulate how equity and affordability can be integrated into core innovation design principles that support open science, guiding priority-setting, partnership models, pro-access intellectual property and technology transfer arrangements, and the development and delivery of health products.

Conditionalities for public investment to maximize public value

While we agree with the strategy’s recommendation that ‘When health innovation is backed by significant public investments, as is often the case, governments may be able to use existing policy instruments to ensure public value’, we emphasize that it is critical to do so. This would entail not only using existing policy tools but also strengthening or creating new ones that better serve public health priorities. **One such policy approach is to include conditionalities on public funding of R&D to ensure the development of and**

¹³ <https://www.who.int/publications/m/item/health-for-all-transforming-economies-to-deliver-what-matters>

¹⁴ <https://www.who.int/publications/m/item/governing-health-innovation-for-the-common-good>

equitable access to health technologies, an option also endorsed by the WHO Council on the Economics of Health for All in its report.

One immediate action is to implement Article 9.5 of the Pandemic Agreement, which commits countries to develop policies regarding public-interest conditions to publicly funded research. Experience from COVID-19 shows that failing to include or enforce access conditions, despite major public investments, led to inequities in the availability and affordability of vaccines, diagnostics, and treatments. When implemented effectively, it gives governments the leverage to ensure that publicly financed R&D aligns with health needs and supports equitable access. These conditions should include transparency and open sharing of knowledge, research inputs, processes, and outputs. Applying such terms and conditions for public funding is critical to enabling continuity of research, avoiding duplication, and ensuring that the fruits of research reach those in need.

Unless specific contractual commitments, binding rules, and enabling policies are proactively established to ensure development and equitable global access, the very same challenges we have witnessed for COVID-19 and countless other diseases will also hinder availability, affordability, and access for future health tools.

In implementing this strategy, we urge Member States to:

- **Actively shape the science and health innovation ecosystem, including by designing and leveraging public financing and incentive mechanisms** to ensure that R&D is driven by public health needs;
- **Implement Article 9.5 of the Pandemic Agreement by establishing policies to attach access conditions on public R&D investments;**
- **Require publicly funded research inputs, outputs, and processes to be shared in the public domain and/or licensed non-exclusively;**
- **Promote and invest in alternative financing mechanisms, partnership models, and incentives** that do not depend on the profit-seeking model to address key gaps in essential health tools and meet the needs of the most vulnerable populations;
- **Promote and safeguard open knowledge ecosystems** by enacting supportive legislation, investing in the infrastructure needed for data sharing and open access, and ensuring that policies and regulations, including those on data protection, clinical trial transparency, and procurement, actively enable rather than hinder open science approaches to knowledge management;
- **Commit to sustainable and predictable financing** of end-to-end R&D that supports open, collaborative approaches to the discovery and development of essential health tools, with clear priority given to areas most likely to be neglected by the market; and
- **Strengthen global governance structures and frameworks** to ensure that health innovations developed to respond to key public health priorities are treated as **global public goods**.

Agenda item 20: Reform of the global health architecture and the UN80 Initiative

DNDi would like to thank the Secretariat for conducting consultations on the process for the development of the proposal for global health architecture (GHA) Reforms. As an organization working at the intersection of innovation, access, and public-interest R&D, we focus our comments on how reforms can better deliver needs-driven innovation and equitable access for neglected populations.

Focus on the role of biomedical innovation in the GHA

We support the inclusion of product innovation and access as core functions of the GHA. These must be addressed across all three working groups: Functions, Mandates & Capacities; Coordination & Inclusive Decision-Making; and Financing. The development and delivery of health technologies are shaped not only by science, but also by governance arrangements, coordination mechanisms, and financing models.

COVID-19 and current global health challenges, including emerging and re-emerging infectious diseases, and the persistent neglect of diseases disproportionately affecting neglected populations in low- and middle-income countries, have shown that market forces alone will not address the most pressing public health needs. For example, the absence of a specific treatment for dengue remains a critical challenge to countering the disease's rapidly increasing global impact. Medicines for cutaneous leishmaniasis are more than 60 years old, costly, and often require weeks of painful injections of toxic, heavy metal-based drugs that cause severe side effects. **These gaps underline a central lesson: commercial incentives alone are insufficient to deliver timely, needs-driven innovation or to ensure equitable, affordable, and sustained access to health technologies of public health importance.** In addition, withdrawal of large pharmaceutical companies from the infectious disease landscape, compounded by funding cuts, risks reversing hard-won gains at a time when unmet health needs are increasing.

Redesigning innovation systems with equity at the core

Closing the R&D gap requires renewed and coordinated global action, sustained investments, and strengthened partnerships. With one of the GHA reform's key principles being 'Leave no one behind', discussions must therefore move beyond alignment of mandates and capacities, efficiency, and coordination within existing models and instead address how innovation systems themselves are designed, governed, and financed to serve public health and equity objectives.

'Equity and solidarity', a key principle to guide GHA outcomes, must be operationalized. One such way is to focus discussions on how innovations of public health importance must be developed as public goods to better serve public health and equity goals. This requires deliberate choices around priority-setting, decision-making, funding mechanisms, and knowledge management and sharing – including pro-access intellectual property management, technology transfer, manufacturing, and regional and local production strategies. It also requires clarity about whether those public goods are global, regional, or national.

Clarifying roles across the architecture

The 'Functions, Mandates & Capacities' workstream should therefore clarify institutional roles for actors in the innovation space, including the normative and convening role of WHO. The 'Enhancing coordination & inclusive decision-making' workstream should address how priorities for innovation are set, whose voices are represented in those decisions, and how accountability for access outcomes is ensured. The 'Financing' workstream must explicitly consider how predictable, sustainable financing can be mobilized for needs-driven R&D and the acceleration of research.

Defining key R&D functions in the GHA

Effective support for needs-driven R&D within the future GHA requires clear articulation of complementary and differentiated roles across institutions, grounded in public health objectives. WHO has a unique normative, convening, and stewardship role to support R&D, which includes setting standards, guiding priorities, coordinating global strategies, and undertaking regulatory and ethical reviews. Governments and regional institutions, particularly in low- and middle-income countries, play the essential role of building sustainable research and development, manufacturing, and regulatory capacity, aligned with country-defined priorities. Public funders and development agencies are central to mobilizing predictable, long-term financing and attaching conditions to ensure equitable access. Product development partnerships (PDPs) and other public-interest R&D organizations translate global and regional priorities into operational R&D programmes that integrate innovation, access, and capacity strengthening. GHA reform should strengthen the linkages between these roles, ensuring that norm-setting, financing, coordination, and delivery reinforce one another.

Recognizing and strengthening public interest R&D models

Reform discussions should explicitly recognize and strengthen public-interest R&D models, including PDPs. The Keeping the Promise report¹⁵ highlights that PDPs have become a critical model for developing health technologies for diseases and health threats that are neglected by traditional commercial markets. Since 2010, PDPs have developed 79 new health tools that have reached 2.4 billion people. Recent successes made possible by the PDP model include: acoziborole, a single-dose cure developed by DNDi for sleeping sickness that will help assure sustainable elimination of the disease; Coartem Baby, the first and only malaria treatment for newborns and young infants, developed thanks to MMV; and pretomanid, a new anti-tuberculosis compound developed by TB Alliance that enables the first all-oral regimen for highly drug-resistant TB. The report also highlights a robust pipeline of nearly 300 candidates. Beyond product development, PDPs also support clinical trial sites, capacity strengthening, and research infrastructure in low- and middle-income countries. 2023 data notes PDP engagement across more than 700 sites in 98 countries.

GHA reform discussions should explicitly examine how public interest R&D models can be better supported, coordinated, and scaled within the broader architecture, rather than treated as peripheral exceptions. PDPs should be systematically and meaningfully involved in the process, as they bring operational experience in needs-driven R&D, equitable access planning, and the establishment of long-term, equitable partnerships with endemic-country institutions, which is directly relevant to GHA reform discussions. Their inclusion would help ensure that reform proposals are informed by practical, tested models that already operationalize equity, solidarity, and public interest approaches to health innovation.

We therefore urge Member States and WHO to:

- **Explicitly recognize health R&D and access to innovation as core functions of the global health architecture**, and ensure these are addressed coherently across all GHA reform workstreams; and
- **Strengthen and institutionalize public-interest R&D models**, including PDPs, as proven mechanisms to deliver innovation as public goods where market incentives are weak or absent, and ensure their systematic and meaningful inclusion in GHA reform processes.

¹⁵ <https://www.keepingthepromisereport.org/>