DNDi
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Drugs for Neglected Diseases initiative (DNDi)

Briefing note for the 78th Session of the World Health Assembly

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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 13 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 13.3:** Universal health coverage
- **Agenda item 13.4** Communicable diseases – Skin diseases
- **Agenda item 13.9:** Global Strategy for Women's, Children's and Adolescents' Health
- **Agenda item 16.2:** Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response
- **Agenda item 18.3:** Climate change and health

Agenda item 13.3: Universal health coverage

DNDi welcomes the Director General's Report on universal health coverage (UHC). We ask Member States to take note of the following issues while preparing for the high-level meeting on UHC in 2027.

1. R&D can support the achievement of UHC

Access to appropriate, affordable health tools is key to achieving UHC. Yet, despite some progress in recent decades, too many patients still lack access to adequate treatment, diagnostics, and vaccines – across numerous diseases.

The true test of UHC is the extent to which it reaches and addresses the needs of vulnerable populations – for example, communities affected by neglected tropical diseases (NTDs), a diverse group of 21 diseases that cause substantial illness for 1.62 billion people globally, mostly in vulnerable and marginalized communities. For many of these diseases, existing treatments are ineffective, unsafe, unavailable, or unaffordable. In some cases, treatments have never been developed at all. Too often, existing health tools for neglected diseases have serious limitations that hamper the provision of care, cause catastrophic health expenditure, and impede disease control and elimination. Countries are off track to meet the 90% reduction target for all NTDs by 2030.

Research and development can support UHC by delivering safe, effective, affordable health tools adapted to patient needs and **designed from the start to be used 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.**

Oral treatments and simpler diagnostic tests are such examples. DNDi and its partners have developed the first all-oral treatment for sleeping sickness, which eliminates the need for systematic hospitalization and treatment requiring injections. DNDi and its partners have also developed safer, shorter treatments for visceral leishmaniasis using existing drugs. Previously, patients had to endure two painful daily injections and remain hospitalized for almost three weeks. Avoiding or limiting hospitalization can be critically important, as in many settings, all expenses related to hospitalization must be paid out of pocket, often representing a catastrophic expense that feeds vicious cycles of poverty. Household income lost from out-of-pocket health expenditures and lost wages due to NTDs is estimated to be at least USD 33 billion per year.[1]

For diseases that are on the cusp of elimination, diagnostics and medicines that are specifically developed to reflect the requirements of a sustainable elimination programme will be critical to avoid backtracking on hard-won successes. These should be highly effective, safe, and suitable for deployment in remote areas with limited public health infrastructure.

Therefore, in addition to ensuring access to existing medicines, support for UHC must include support for medical innovation and the delivery of missing health tools needed to address unmet needs and ensure no one is left behind.

[1] World Health Organization. Ending the neglect to attain the Sustainable Development Goals A rationale for continued investment in tackling neglected tropical diseases 2021–2030. Available from: https://iris.who.int/bitstream/handle/10665/363155/9789240052932-eng.pdf

2. Integration and cross-cutting approaches are necessary across health priorities

People are often faced with multiple health challenges. For example, the risk of developing active visceral leishmaniasis is more than 100 times greater in people living with HIV. In addition to maximizing financing, **Member States should look for opportunities for synergies, shared services, and integration of R&D and access programmes across diseases** such as HIV, TB, and malaria and noncommunicable diseases such as diabetes, hypertension, and mental health conditions – for example, by developing better tools for testing and treatment programmes that bring transformational benefits for patients and health systems alike.

To prepare for and provide surge capacity to respond to pandemics, for example, much of the infrastructure needed for the timely development and delivery of health tools for pandemics must be 'kept warm': supported, and therefore utilized, during inter-crisis periods. This includes clinical trial infrastructure, manufacturing capacity, and procurement mechanisms and platforms. The 2027 UNGA high-level meeting on UHC should reflect on how investments in pandemic preparedness and response and other disease areas can support UHC. This could include mutualizing manufacturing needs across disease areas, where feasible, and pooling demand and exploring common delivery and access mechanisms for health tools.

3. Achieving UHC through digital health

Digital technologies, such as AI, can have application for all elements of the health system, including the development of necessary health tools. As an organization that works to bring the best science to the most neglected, DNDi is collaborating with partners to apply new technologies to old diseases – for example, by partnering 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. A project in Brazil has explored how 'deep-learning'-based AI can facilitate diagnosis of cutaneous leishmaniasis (CL) lesions and has the potential to differentiate CL from lesions caused by other skin diseases, thereby improving the provision of timely, appropriate treatment.[2]

Digital technologies, including AI and big data, hold great promise for efforts to accelerate the R&D process while reducing costs. But that promise is not guaranteed to be realized – especially for the most neglected. Attention is needed to ensure that successful technologies are not locked away for the benefit of only certain populations. Ensuring that digital technologies are truly transformative for all requires investment to generate missing data in neglected areas. It requires policies that encourage the creation of digital public goods, promote open collaboration and sharing, and allow for affordable and equitable access to new health tools.

We urge Member States to:

- **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;
- **Identify opportunities for synergies, shared services, and integration of R&D and access programmes across disease areas,** including establishing mechanisms or modifying existing

[2] Leal JFC, Barroso DH, Trindade NS, Miranda VL, Gurgel-Gonçalves R. Automated Identification of Cutaneous Leishmaniasis Lesions Using Deep-Learning-Based Artificial Intelligence. Biomedicines. 2023 Dec 20;11(12):3598. Available from: https://doi.org/10.3390/biomedicines11123598

mechanisms to accelerate access and ensure that tools developed reach healthcare workers, communities, and patients;

- **Support policies to encourage the creation of digital public goods** that allow for equitable access and promote collaboration and sharing; and
- **Acknowledge the role R&D can play in supporting UHC by including R&D in national, regional, and global UHC action plans** and including monitoring the development of and access to health tools as part of national UHC action plan indicators and international UHC efforts or roadmaps.

Agenda item 13.4: Communicable diseases – Skin diseases

DNDi welcomes the resolution on 'Skin Diseases as a Global Public Health Priority' and supports its adoption. We ask Member States to consider the following issues when adopting the resolution.

1. The impact of skin neglected tropical diseases

Skin diseases are a leading contributor to the global burden of disease and are the fourth leading contributor to non-fatal disease burden worldwide.[3] Skin diseases rank among the top reasons for outpatient visits and often lead to long-term disability, stigmatization, and mental health issues. Overall, skin conditions are estimated to affect 1.8 billion people at any point in time.

Out of all the skin diseases, over 10% are NTDs[4]. At the same time, skin NTDs make up half of all NTDs[5], disproportionately impacting people in underserved communities in low- and middle-income countries. Four of the most debilitating skin NTDs – cutaneous leishmaniasis, post-kala-azar dermal leishmaniasis, river blindness, and mycetoma – have particularly detrimental effects on affected communities.

According to WHO, up to 1 million people contract cutaneous leishmaniasis each year, leading to permanent scars, disability, stigmatization, and mental health issues.[6] Further, an estimated 50,000 to 90,000 new cases of visceral leishmaniasis occur annually worldwide, although only 25–45% of cases are reported. In Eastern Africa, 30-50%, and in South Asia, 10% of people treated for visceral leishmaniasis develop the disfiguring and stigmatizing post-kala-azar dermal leishmaniasis.[7,8] Mycetoma affects not only the skin but can spread to muscle, bone and connective tissue, leading to deformities and disabilities.

Although rarely fatal, skin NTDs have the potential to cause chronic ill health and long-term disability, resulting in a significant number of lost disability-adjusted life years.[9] They cause painful, disfiguring scars and can lead to disability and permanent deformities. Skin NTDs are particularly damaging because they are noticeable, rendering affected individuals vulnerable to discrimination. Diagnoses often occur too late for timely treatment at health facilities. Access to treatment is frequently hindered by a lack of nearby health facilities and by complex, lengthy treatments that require patients to spend extensive periods away from work and family. Most skin NTDs cannot be prevented by mass drug administration (MDA) and require individual care and treatment.

Despite their severe toll, many skin NTDs remain underreported and under-researched. For diseases like mycetoma, the global burden remains unknown and largely unreported in endemic countries across Africa, Asia, Europe, and Latin America. Increased investment in mapping skin NTDs in countries

[3] Alderton DL, Ackley C, Trueba ML. The psychosocial impacts of skin-neglected tropical diseases (SNTDs) as perceived by the affected persons: a systematic review. PLoS Negl Trop Dis. 2024;18(8):e0012391. Available from: https://doi.org/10.1371/journal.pntd.0012391

[4] World Health Organization. WHO first global meeting on skin NTDs calls for greater efforts to address their burden. 2023. Available from: https://www.who.int/news/item/31-03-2023-who-first-global-meeting-on-skin-ntds-calls-for-greater-efforts-to-address-their-burden

[5] Ibid.

[6] WHO fact sheet: leishmaniasis https://www.who.int/news-room/fact-sheets/detail/leishmaniasis

[7] Sheikh SS, Amir AA, Amir BA, Amir AA. Leishmaniasis. In: Bastidas Pacheco GA, Kamboh AA, editors. *Parasitology and Microbiology Research*. London: IntechOpen; 2020. p. [pages unknown]. Available from: https://www.intechopen.com/chapters/70698

[8] World Health Organization. Leishmaniasis [Internet]. Geneva: World Health Organization; 2023. Available from: https://www.who.int/news-room/fact-sheets/detail/leishmaniasis

[9] World Health Organization. Ending the neglect to attain the sustainable development goals: a strategic framework for integrated control and management of skin-related neglected tropical diseases 2021–2030. Geneva: World Health Organization; 2020. Available from: https://www.who.int/publications/i/item/9789240051423

where the disease burden is not yet known is necessary as a precursor for control, treatment, and management interventions.

Skin NTDs can have significant mental health and social impacts on affected individuals and their families.[10] They affect individuals' emotional well-being, contributing to depression, anxiety, low self-esteem, and suicidal thoughts that often go unaddressed due to inadequate access to mental healthcare. As a result, children are frequently unable to attend school. The visible symptoms of skin NTDs lead to social stigma, with women being more likely to face exclusion and discrimination in communities and families. Women may experience intimate partner violence, social avoidance, and abandonment by partners and relatives. Social stigma and physical discomfort associated with skin NTDs can also limit employment opportunities for women and educational opportunities for girls.

Delays in diagnosis and detection of skin NTDs pose obstacles to prompt treatment, due to a lack of trained healthcare professionals, limited access to healthcare facilities and high costs for treatments Expanding expertise especially among primary healthcare workers to diagnose and treat or refer patients suffering from skin NTDs is also essential for improving early detection and improve access to timely affordable care and treatment in affected communities. As disease prevalence decreases, the expertise of healthcare professionals may also decline, increasing the risk of misdiagnosis and jeopardizing sustained progress toward the control and elimination of NTDs.

In 2024, nine East African countries, in collaboration with WHO, launched the Strategic Framework for VL Elimination in Eastern Africa (2023–2030). To strengthen cross-regional efforts, the countries are considering signing an MoU to formalize regional collaboration and demonstrate their commitment to VL elimination. We support this effort to apply a united and common policy framework to address VL in the region.

2. R&D for missing health tools – focusing on the needs of the most neglected – supports universal health coverage

There are wide-ranging gaps in innovation for the health tools needed to prevent, diagnose, and treat skin NTDs effectively. Many treatments, should they exist at all, are decades old and toxic. Antifungal treatments for fungal mycetoma (eumycetoma), such as ketoconazole and itraconazole, are among the few available treatments,[11] particularly in sub-Saharan Africa. These medications are costly, have limited effectiveness, and can cause serious side effects. In advanced cases, patients may face amputation or even death due to delayed or inadequate treatment. Treatment for cutaneous leishmaniasis still mainly relies on medicines that are 60 years old, costly, and often require weeks of painful injections of toxic, heavy metal-based drugs that cause severe side effects. While advancements have been made with the development of a combination treatment of miltefosine and paromomycin, the need for hospital visits for injections of paromomycin continues to hinder access for many patients.

The draft resolution urges Member States to promote research on skin diseases and calls for international collaboration, including with industry, to achieve equitable access to treatments and diagnostics. This is encouraging. However, the needs of poor and marginalized people most often affected by skin NTDs are frequently overlooked by the current biomedical R&D system, resulting in limited treatment options.

[10] Lancet Infect Dis. Mycetoma: a unique neglected tropical disease. Lancet Infect Dis. 2016;16:100-101. Available from: https://pubmed.ncbi.nlm.nih.gov/26738840/

Progress in developing new health tools for neglected populations depends on sustainable investments in R&D and political leadership to drive such investment. Without specific interventions by governments, unmet medical needs linked to a lack of commercial return on innovation will not be addressed by the profit-driven biomedical R&D system. **Alternative financing mechanisms, partnership models, and incentives that do not depend on the profit-seeking model are needed to overcome urgent treatment gaps and meet the needs of the most vulnerable populations. They should be promoted in the implementation of the resolution.**

We urge Member States to:

- **Support the retention and prioritization of research, innovation, and access elements currently included in the draft resolution;**
- **Commit to sustainably investing in R&D** for effective health tools to treat and diagnose skin NTDs at the primary healthcare level;
- **Support the establishment and engagement of patient and community organizations, as referenced in the resolution,** to ensure that patient needs and perspectives are adequately reflected and integrated into R&D, healthcare strategies, and programme design and implementation;
- **Support not-for-profit, collaborative, and open R&D models that centre on patient needs** to ensure equitable access to treatments and diagnostics and to achieve the resolution's aim to foster collaborations between international organizations, Member States, and industry;
- **Encourage research aimed at more accurately estimating the economic burden, mental health impact, and stigma** experienced by patients with skin NTDs as a means of addressing mental and social issues highlighted in the resolution; and
- **Support community empowerment** through training of health extension workers to ensure early screening for skin NTDs in communities for referral for management in health centres.

We urge WHO to:

- **Continue convening global meetings on skin NTDs,** as recently held in March 2025, to encourage continued collaboration and momentum toward the 2030 goals, leading to opportunities for funding, prioritization, and inclusion of skin NTDs in national health plans; and
- **Support Member States in developing the Global Action Plan for skin diseases** in consultation with all relevant stakeholders and assist countries in implementation.

Agenda item 13.9: Global Strategy for Women's, Children's and Adolescents' Health

DNDi welcomes the report by the Director General on the 'Global Strategy for Women's, Children's and Adolescents' Health'. The report rightly acknowledges that 'commodities that are quality-assured are critical to provide high-quality and respectful maternal, newborn and child healthcare.' DNDi would like to highlight the need for R&D of health tools to address the health requirements of populations whose specific medical needs are often neglected.

Member States have made a commitment to support R&D to address the unmet needs of children and pregnant and lactating women via 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' adopted at WHA77. The resolution urges Member States to '*enable access to essential quality medicines for pregnant women, lactating women, mothers, newborns and children through accelerating implementation of the actions laid out in resolutions WHA69.20 (2016) and WHA75.8 (2022) and by promoting, supporting and financing accelerated investigation, development, manufacturing, registration and supply of age-appropriate, quality-assured formulations of medicines for diseases that affect mothers, newborns and children*.'

The resolution also calls on to '*strengthen and expand collaborative efforts such as those promoted by WHO technical departments and the Global Accelerator for Paediatric Formulations (GAP-f) network for securing better access to medicines for children, including antiretroviral therapy for HIV and report to the Seventy-eighth World Health Assembly, and subsequently as appropriate, on progress achieved, remaining gaps and specific actions needed to further promote better access to age-appropriate, quality assured, affordable medicines and commodities for pregnant and lactating woman, and for maternal, adolescent, child and newborn health services.'*

1. Impact of poverty-related and neglected diseases on women and children

At least 1.2 billion children and adolescents (<25 years) – one in six people globally – are affected by one or more NTDs.[12] Children represent 34% of the 20 million DALYs that result from NTDs. Some NTDs disproportionately impact children, leading to profound and long-lasting harms, including premature death, disfigurement, stunted growth, chronic pain, and malnutrition. For example, in 2022, more than half of those infected with visceral leishmaniasis were less than 15 years old.[13] Children account for over a quarter of the new cases of Chagas disease,[14] and infants are at a higher risk of developing severe dengue. School-aged children are also at higher risk of schistosomiasis due to their involvement in activities such as swimming or fishing in infected waters. In children, schistosomiasis can lead to anaemia, stunting, and reduced cognitive abilities. **The impact of NTDs on children extends beyond health: they can impact cognitive development, prohibit school attendance, and lead to social stigma and mental health consequences.**

In some cases, women are also disproportionately affected by NTDs. For example, dengue can cause severe complications that only affect women, such as vaginal bleeding. For pregnant women, dengue leads to a threefold increase in maternal death. Dengue haemorrhagic fever increases the risk of

[12] The Lancet Child & Adolescent Health. A vote for childhood NTD elimination. Lancet Child Adolesc Health. 2024;8(3):161. Available from: https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(24)00022-1/fulltext

[13] World Health Organization. Global leishmaniasis surveillance, 2022: assessing trends over the past 10 years. Weekly Epidemiological Record. 2022;97(40):471-487. Available from: https://www.who.int/publications/i/item/who-wer9840-471-487

[14] World Health Organization. Chagas disease in Latin America: an epidemiological update based on 2010 estimates. Weekly Epidemiological Record. 2015;90(6):33-44. Available from: https://iris.who.int/handle/10665/242316

maternal death by 450 times,[15] and overall, the disease increases maternal mortality to 15.9%.[16] In the Americas, Chagas disease is highly prevalent in women of childbearing age and pregnant women and can be transmitted from mother to child during pregnancy. Women who engage in domestic chores such as washing clothes are at a higher risk of developing female genital schistosomiasis due to contact with infested waters.

Social and cultural factors also exacerbate the disproportionate impact that NTDs have on women. For example, cutaneous leishmaniasis (CL), which manifests in the form of skin lesions and ulcers, places an outsized burden on women. Depending on the severity of the scars or disfiguring skin pathology, CL can lead to lasting social stigma that influences quality of life and psychological well-being.[17] In many contexts, women are more vulnerable to skin diseases and suffer greater social stigma than men.[18] Stigmatization can affect all aspects of women's lives, particularly interpersonal relationships, social activities, work capacity, and marriage.

2. The need to include underserved populations in research

The Director General's report (EB156/17) finds that 64 countries are off track to meet the Global Strategy's neonatal mortality target, and 54 countries are off track to meet the target for the under-five mortality rate. **Each year, millions of children's lives are cut short or debilitated by diseases that are largely treatable – but for which child-adapted treatment formulations are often not developed. Children's specific treatment needs have long been an afterthought in profit-driven drug development, given that they represent lower-volume markets.**[19,20] Medicines are generally first developed for adults, and the development of paediatric formulations starts only after, if at all. The needs of children living with HIV illustrate this neglect, where the development of optimal paediatric antiretroviral treatment formulations lagged 20 years behind that of adults. Despite the burden of NTDs in children, only 22 of the 47 medications available for NTDs are labelled for paediatric use.[21]

Children are excluded from the vast majority of clinical trials to assess the safety and efficacy of medicines and determine dosing. A 2019 study of clinical trials for neglected diseases found that across more than 360 late-stage clinical trials, only 17% included people younger than 18 years of age. **As a result, children are more often than not left without safe, effective medicines approved for paediatric use.** In addition, a lack of harmonized regulatory guidance for including paediatric populations in research also hinders drug development for children.

We welcome the ongoing work of the Global Accelerator for Paediatric Formulations Network (GAP-f), of which DNDi is a member, to address this unacceptable imbalance between the burden of disease for NTDs in children and the R&D dedicated to addressing their health needs. Via the

[15] Paixao ES, Teixeira MG, Costa DN, Harron K, de Almeida MF, Barreto ML, et al. Dengue in pregnancy and maternal mortality: a cohort analysis using routine data. Sci Rep. 2018;8(1):9938. Available from: https://doi.org/10.1038/s41598-018-28387-w

[16] Brar R, Sikka P, Suri V, Singh MP, Suri V, Mohindra R, et al. Maternal and fetal outcomes of dengue fever in pregnancy: a large prospective and descriptive observational study. Arch Gynecol Obstet. 2021;304(1):51-58. Available from: https://doi.org/10.1007/s00404-020-05930-7

[17] Bennis I, De Brouwere V, Belrhiti Z, Sahibi H, Boelaert M. Psychosocial burden of localised cutaneous leishmaniasis: a scoping review. BMC Public Health. 2018;18:1236. Available from: https://doi.org/10.1186/s12889-018-5260-9

[18] Al-Kamel MA. Impact of leishmaniasis in women: a practical review with an update on my ISD-supported initiative to combat leishmaniasis in Yemen (ELYP). Int J Womens Dermatol. 2016 Jun 16;2(3):93-101. Available from: https://doi.org/10.1016/j.ijwd.2016.04.003

[19] US Food & Drug Administration. Drug Research and Children. 2016. Available from: https://www.fda.gov/drugs/information-consumers-and-patients-drugs/drug-research-and-children

[20] Watts G. WHO launches campaign to make drugs safer for children. BMJ. 2007 Dec 15;335(7633):1220. Available from: https://doi.org/10.1136/bmj.39423.581042.DB

[21] Rees CA, Hotez PJ, Monuteaux MC, Niescierenko M, Bourgeois FT. Neglected tropical diseases in children: an assessment of gaps in research prioritization. PLoS Negl Trop Dis. 2019;13(1):e0007111. Available from: https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007111

Paediatric Drug Optimization (PADO) process, the initiative has prioritized a portfolio of paediatric formulations that are most needed across several disease areas. To target research to address the specific needs of infants and children, WHO, via the PADO process, has published lists of priority paediatric formulation needs for HIV, TB, hepatitis C, antibiotics, and five NTDs. **Addressing these priorities requires political, technical, and financial support from Member States.** We congratulate GAP-f on developing a five-year strategy to be launched in May 2025, which will help accelerate the investigation, development, and introduction of better medicines for children.

Women's health continues to be underprioritized in R&D decision-making. Across disease areas, there are widespread knowledge gaps in understanding the impact of medicines on biological females, especially those who may become or are pregnant or who are lactating – often leading to exclusion from clinical trials due to concerns that drugs could have harmful impacts on foetuses.

A report from the Director General to WHA76 on the Global Strategy for Women's, Children's and Adolescents' Health 2016-2030 states that '…poor inclusion of women, children and adolescents in early COVID-19 research, testing and surveillance activities hampered a definitive understanding of the direct effects of COVID-19 on them.'

While health tools such as medicines, vaccines, and diagnostics offer the potential to reduce mortality and morbidity among women who may become or are pregnant or who are lactating, lack of data on the safety and efficacy of drugs and vaccines for this neglected group at the time of product approval limits women's access to safe and effective treatments, leading to preventable illness and death. Therefore, **proposals to ensure gender-responsive drug development – from the early phases of research – should be considered in implementing the Global Strategy**.

We urge Member States to:

- **Encourage the rapid and coordinated development of age-appropriate treatment formulations** through public health-focused collaborations between academic institutions, key paediatric networks, product development partnerships, and public and private R&D organizations;
- **Support implementation of the GAP-f five-year strategy** to ensure that safe, effective, quality, and affordable paediatric formulations are developed and made available to children
- **Support implementation of 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';**
- **Support and implement strategies to include women** – including women of childbearing potential and pregnant and lactating women – **and children as soon as possible in the drug development process** to close evidence gaps and better meet their health needs when affected by poverty-related, neglected, and other diseases;
- **Ensure that regulatory requirements are streamlined and harmonized** to support the inclusion of groups currently underrepresented in research, including children and pregnant and lactating women, in a way that is ethical and appropriate;
- **Support research to understand sex- and gender-based barriers in accessing healthcare services,** including diagnosis and treatment, and promote interventions that address these barriers; and
- **Promote the collection, utilization, and reporting of sex- and age-disaggregated information** in ongoing and future programmes and research.

Agenda item 16.2: Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response

DNDi supports the formal adoption of the Pandemic Agreement at the World Health Assembly.

The consensus text represents a significant step forward, and DNDi congratulates all Member States for their leadership and collaborative spirit in reaching this important milestone. This is a crucial achievement in the global effort to build a more equitable and robust framework for preventing, preparing for, and responding to pandemics.

While the text reflects the outcome of extensive negotiations and compromise, it nonetheless contains important elements that merit recognition – particularly those related to research and development and production of health products. The inclusion of strong R&D-related provisions - and a recognition of the need for investment – lays the groundwork for action toward global readiness and equity in future health emergencies.

The agreement includes commitments that, if implemented, have the potential to strengthen the global R&D landscape. These include promoting the inclusion of representative populations in clinical trials, facilitating the use of pandemic-related products as comparator tools across studies, and ensuring access to resulting products for both trial participants and their communities.

We particularly welcome the groundbreaking progress made on Article 9.5 of the agreement, which addresses conditionalities on public funding for R&D. If implemented effectively, this provision can underpin critical progress toward ensuring that public investments in pandemic-related R&D are tied to clear commitments on equitable access – with governments giving themselves the power to guarantee that R&D spending ultimately meets public health needs.

Moving forward: Building on the consensus

We look forward to the entire agreement's successful ratification and implementation. However, Member States should not wait for the agreement's full ratification to act. This can—and should—start now. We call on governments to act now and use their public investments to drive innovation and deliver equitable access for all who need it.

The real test lies in whether governments take swift, concrete steps to develop ambitious national-level policies that translate their commitments into meaningful impact.

Agenda item 18.3: Climate change and health

We commend Member States and WHO for adopting the resolution 'Climate Change and Health' at WHA77 and committing to develop a Global Plan of Action (GPoA) on Climate Change and Health. We support the commitment made by Member States in the resolution to promote R&D to respond to climate-sensitive diseases and support its inclusion in the GPoA. While the GPoA focuses on many aspects of adaptation, mitigation, leadership, and advocacy, **DNDi focuses its comments on the proposed action area under Evidence and Monitoring, Objective A, on responding to climate-sensitive diseases through research and development and equitable access to health tools.**

Climate change-induced morbidity and mortality from infectious diseases are expected to rise globally as a result of 1) the changing incidence and geographical spread of vector-borne and water-borne climate-sensitive infectious diseases due to changing temperatures and rainfall patterns, 2) climate-related migration, and 3) the increased risk of new emerging zoonotic diseases.[22] Take the example of neglected tropical diseases (NTDs), which affect 1.65 billion people living mainly in the least developed economies and most impoverished communities. Nearly half (11 out of 25) of the vector- or water-borne diseases listed by WHO that might be impacted by climate change are also classified as NTDs. In addition, while many diseases once labelled as 'tropical' are now spreading to non-endemic regions, **countries in the Global South will continue to carry a disproportionate burden of the impacts of climate change on infectious diseases**. For example, the region of the Americas faced its largest outbreak of dengue, a climate-sensitive disease, last year. Dengue is also endemic in the Southeast Asia and Western Pacific regions.

Health services and tools are needed to protect people from the impacts of climate variability and change. **For many climate-sensitive infectious diseases, the world lacks simple, safe, and effective tools for diagnosis and treatment that can be easily integrated into primary healthcare systems.**

Current tests and treatments for many climate-sensitive NTDs, when they exist at all, have limitations that hamper the provision of life-saving medical care and impede disease control and elimination efforts. For example, no specific treatment for dengue exists. With infections now doubling every year[23], preventive measures alone, such as vaccination and vector control, will not be sufficient to address dengue's rising threat. Appropriate treatments are urgently needed to prevent progression to severe disease and to decrease the overall burden on public health systems.

DNDi provides suggestions for how Member States can put commitments made in the resolution and GPoA into practice by integrating them into their National Adaptation Plans, Health National Adaptation Plans, and Adaptation Communications. In addition, certain commitments will require prioritization and coordinated action at both the regional and global levels.

1. Developing a list of climate-sensitive diseases

As a first step in operationalizing the R&D commitment in the GPoA based on the available evidence, a list of climate-sensitive diseases should be developed. The list should be tailored to regional and national contexts and also be relevant at the global level.

[22] The Lancet Infectious Diseases. Twin threats: climate change and zoonoses. Lancet Infect Dis. 2022 Dec 8;22(12):1777. Available from: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00817-9/fulltext

[23] World Health Organization. WHO launches global strategic plan to fight rising dengue and other Aedes-borne arboviral diseases. Geneva: World Health Organization; 2024 Oct 3. Available from: https://www.who.int/news/item/03-10-2024-who-launches-global-strategic-plan-to-fight-rising-dengue-and-other-aedes-borne-arboviral-diseases

WHO first published a Bacterial Priority Pathogens List in 2017 to guide investment in R&D, and it formed the basis for activities around surveillance and response to antimicrobial resistance. WHO has also published a list of priority pathogens of epidemic and pandemic potential, by region, to enhance preparedness and accelerate the development of medical countermeasures.

With similar utility, a prioritized list of climate-sensitive diseases would serve as a vital tool for guiding research, investment, and public health strategies. Such a list would need to be maintained dynamically because the impact of climate change on infectious disease patterns can change over time. In a national context, the list of climate-sensitive diseases may vary depending on geographical features, climate variability, ecosystems, presence of vectors, and other factors. National public health priorities and policies also play a crucial role in determining which diseases are prioritized for surveillance, control, and prevention efforts.

2. Understanding the impact of climate change on infectious diseases, including NTDs

A scoping review found that, while studies were available for some NTDs such as dengue, leishmaniasis, and chikungunya, for many NTDs, gaps remain in knowledge on how climate change may affect transmission, particularly for non-vector-borne NTDs. Further research is needed to understand and establish the link between climate change and infectious diseases, including NTDs. **Research to understand and predict the influence of climate change on pathogen survival and disease virulence, transmission, and spread should also be prioritized under WHO's Research for Action on Climate Change and Health (REACH) agenda, and other national, regional, and international research agendas.**

3. Continuing to innovate as an adaptation strategy for climate-sensitive diseases

Availability of and access to health tools to prevent, detect, test, and treat climate-sensitive diseases will be vital to minimizing the impact of climate change, particularly on vulnerable communities, and to staying ahead of emerging challenges to prevent illness and save lives.

Advances in new treatments show that innovation plays a critical role in disease control and that innovative treatments play a key role in disease control and elimination. For example, affordable, shorter, and more effective therapies for leishmaniasis—developed and implemented in Africa and South Asia—have reduced pressure on health systems and will be essential as climate-driven disease burdens rise. Such success stories underpin the need for investments in biopharmaceutical innovation for health tools for climate-sensitive diseases.

Adopting an integrated approach that includes surveillance and monitoring, early warning systems, diagnostics, treatments, vaccines, and vector control tools is vital to saving lives, protecting the vulnerable, and building resilient communities and health systems. In many cases, they are also essential to achieving disease control and elimination goals.

4. Building tools that are adapted to a changing climate and fit for use during climate emergencies

Communities most vulnerable to infectious diseases often live in areas hit hardest by extreme climate events, where health challenges are worsened by poor infrastructure and limited access to power and clean water. **We need 'climate-smart' products—vaccines, diagnostic kits, medicines, and medical devices—that are designed to function effectively and remain stable in hot, humid environments and that can be stored at room temperature and withstand power outages.**

5. Addressing inequities in access to innovation

DNDi supports the GPoA's reference to 'Create an enabling environment to facilitate equitable access to health tools by those hit hardest by climate-related health impacts'. Innovation alone is not enough: equitable access must be embedded into the innovation process from the start. The spread of infectious diseases to non-endemic regions may spur innovation and investment in developing health tools to respond to some climate-sensitive diseases. **Still, an enabling environment is needed to ensure that innovation does not remain a privilege of the rich.** Public policies are needed to shape the innovation ecosystem to ensure a focus on neglected populations in low-resource settings who are most affected by neglected tropical and infectious diseases, including policies that ensure that there are conditions on public investments in R&D that enable and safeguard equitable access.

6. Strengthening research networks in countries endemic for climate-sensitive diseases

DNDi supports the GPoA's proposal for action to ensure 'research in low- and middle-income countries is led or has significant engagement by researchers from the countries in which the research takes place to ensure localization and capacity-strengthening'. **It is important to ensure that endemic countries set the research priorities and agenda and that R&D capacity in the Global South is utilized and developed further.** Public leadership from high-burden countries is especially vital, given their deep expertise in managing climate-sensitive infectious diseases and their understanding of the unique needs of their populations and health systems. The G20 Coalition for Local and Regional Production, Innovation, and Equitable Access provides one such opportunity to focus a pilot project on R&D for a neglected climate-sensitive disease, such as dengue.

7. Keeping communities at the centre of climate action

Climate-sensitive diseases often disproportionately impact vulnerable populations, including children, pregnant women, those with pre-existing health conditions, and communities with limited resources and poor access to healthcare and proper hygiene and sanitation. Climate change exacerbates existing inequalities, and therefore, it is imperative to ensure that health interventions, products and services reach those most in need. Policies must ensure that groups most at risk from climate-sensitive diseases are included in discussions and decision-making processes and not left behind.

8. Monitoring progress in responding to climate-sensitive diseases

DNDi recommends including **indicators to track progress of action on climate-sensitive infectious diseases in the WHO General Programme of Work (GPW14), Global Goal on Adaptation, GPoA, and national monitoring efforts**. In developing these indicators, we suggest particular focus on:

- Consulting endemic countries, affected communities, and organizations involved, in adaptation tools and strategies;
- Ensuring data is inclusive and representative, especially of vulnerable and historically marginalized groups; and
- Wherever possible, leveraging existing indicators to reduce reporting burdens on countries.

We urge Member States to support the inclusion and execution of proposed actions in the GPoA related to 'Promote research and development to detect, prevent, test for, treat and respond to climate-sensitive diseases and health outcomes, including those related to climate-forcing pollutants, and support affected communities in efforts to adapt to climate impacts' and 'Create an enabling

environment to facilitate equitable access to health tools by those hit hardest by climate-related health impacts'.

We urge Member States to take steps towards operationalizing these commitments by:

- **Developing a list of region-specific yet globally relevant climate-sensitive diseases** along with national adaptation plans to support efforts to detect, prevent, prepare for, and respond to climate-sensitive diseases.
- **Promoting research to explore the connections between climate change and NTDs beyond vector-borne illnesses**, as well as the impacts of climate change on pathogen survival, disease virulence, transmission, and spread;
- **Investing in R&D for new tools to tackle infectious diseases**, particularly for those neglected by the market, **including through support for WHO's development of the R&D blueprint for NTDs**;
- **Developing 'climate-smart' medical products and health tools** that can withstand difficult conditions and environments;
- **Building research capacity and promoting collaborative partnerships** between countries endemic for climate-sensitive diseases; and
- **Supporting the development of indicators on climate-sensitive diseases as a part of the GPoA, WHO General Programme of Work (GPW14), UAE-Belém Work Programme** (within the framework of the Global Goal on Adaptation), and national monitoring plans.