

Drugs for Neglected Diseases initiative (DNDi)

Briefing note for the 77th Session of the World Health Assembly

May 2024

Overview

The Drugs for Neglected Diseases initiative ([DNDi](#)) is a not-for-profit research and development (R&D) organization, in official relations with the 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 reached millions of people – utilizing an alternative, collaborative, not-for-profit R&D model. Furthermore, DNDi, in partnership with WHO, 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 on the following agenda items for consideration by Member States:

- **Agenda item 11.6:** Road map for neglected tropical diseases 2021–2030
- **Agenda item 11.7:** Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality
- **Agenda item 13.4:** Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response
- **Agenda item 15.4:** Climate change, pollution and health
- **Agenda 15.5:** Economics and health for all
- **Agenda 29 A:** The global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections (resolution WHA75.20 (2022))

Agenda item 11.6: Road map for neglected tropical diseases 2021–2030

The Director General’s progress [report](#) on the WHO roadmap for Neglected Tropical Diseases 2021-2030, [published before 154th session of WHO EB](#), notes and DNDI applauds areas of important progress: eight countries have eliminated one neglected tropical disease (NTD) in 2022 and six in 2023, 50 countries eliminated at least one NTD by July 2023, and Bangladesh becoming the first country in the world to eliminate visceral leishmaniasis as a public health problem. However, the report also highlights significant concerns about the lack of progress in the recovery of NTD programmes following the COVID-19 pandemic, which were the second most frequently disrupted across the spectrum of essential health services and the most affected in terms of the severity of disruptions. In 2022, 1.62 billion people still required interventions against NTDs. While this reflects a 26% decline from 2010, countries are not on track to achieve the global target of 90% reduction.¹ A continued focus and action on NTDs is needed.

Many other WHA77 agenda items provide an opportunity for action on NTDs, including agenda item 11.7: ‘Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality’ and agenda item 15.4: ‘Climate change, pollution and health’, comments for which are included in the respective sections of this briefing.

We request Member States to take note of the following issues:

1. R&D for missing health tools focusing on the needs of the most neglected supports Universal Health Coverage (UHC) and disease elimination

The recent Consolidated [report](#) by the Director General notes that at the WHO EB, Member States highlighted the need to sustain innovation for medicines and diagnostics and the need for strategic approaches, notably to tackle threats such as climate change, which can have a major impact on the geographical spread and epidemiology of NTDs, and acknowledged that challenges in accessing treatments persisted. While existing interventions such as mass drug administration have managed to curb transmission for some NTDs, **current tests and treatments for most NTDs have serious limitations that hamper the provision of life-saving medical care and impede disease control and elimination efforts.**

Progress is possible. Recent advances in research and development for new tools include the European Medicines Agency’s adoption of a positive scientific opinion for the use of the new all-oral treatment fexinidazole for *T.b. rhodesiense* sleeping sickness (the most acute form of the disease), positive results from the world’s first-ever clinical trial for eumycetoma (a neglected fungal disease), and positive clinical trial results for a shorter-duration combination treatment for visceral leishmaniasis that requires fewer injections.

Prior to these advances, people suffering from the acute form of sleeping sickness had to receive intravenous injections of a toxic drug, and those suffering from visceral leishmaniasis had to receive two painful daily injections and required hospitalization for the entirety of a 17-day treatment period.

In the ‘Global Report on Neglected Tropical Diseases 2024’, the Director General also states that further research is needed to develop diagnostics, drugs, and vaccines for NTDs. Despite progress for some NTDs, new and better diagnostic tests are still needed – as are safer, more effective, more affordable patient-friendly treatments that can be used in primary healthcare settings, close to affected communities. Avoiding or limiting hospitalization can reduce burden on health systems and can be critically important for

¹ World Health Organization. Global report on neglected tropical diseases 2024.

vulnerable people, including those with NTDs, who are poor or otherwise marginalized. **And 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.

The true test of universal health coverage is whether it addresses the needs of vulnerable and marginalized populations. However, these are the people whose needs are often overlooked by the current biomedical R&D system. 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 address key treatment gaps and meet the needs of the most vulnerable populations.

R&D for NTDs must address the needs of populations that are traditionally neglected in research, including children, women who may become or are pregnant, and those who breastfeed. Children comprise 34% of the 20 million DALYs resulting from NTDs. Yet less than half of WHO-recommended medicines for NTDs are approved for children.²

To start to address this R&D neglect, in November 2023, the [WHO published a list of priority paediatric formulations](#) for five NTDs to target research to address the specific needs of infants and children. Successful implementation requires support from Member States. Women of childbearing potential and pregnant and lactating women have also historically been excluded from clinical trials due to concerns that drugs could have potentially harmful impacts on foetuses or breastfeeding babies. Greater effort and support are needed to identify, implement, and advocate for solutions that ensure that biomedical R&D meets the needs of women and children.

To be successful, solutions must centre the active engagement of affected communities through a transparent and meaningful participatory process – at all stages of R&D for health tools – to better understand and address peoples’ needs and expectations.

2. Increasing political and financial commitment for NTDs while simultaneously identifying opportunities for integration and cross-cutting approaches across disease areas

The EB [report](#) states that the rapid decrease in funding for NTDs since 2020 is the primary barrier to achieving NTD road map targets. Redirection of funding to other emergencies should not come at the expense of programmes that address the needs of some of the most neglected and vulnerable populations. The costing exercise being undertaken by the WHO together with the work proposed to expand sustainable financing for NTDs need to be supported and accelerated.

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. **Mutualizing manufacturing needs across disease areas where feasible, pooling demand, and exploring common delivery and access mechanisms for health tools should also be explored.**

² 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. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6368333/>

3. Addressing the impact of climate change on NTDs

In a recent [communique](#), WHO highlighted that NTDs are particularly sensitive to climate change. Almost half of WHO-classified vector- and water-borne diseases that are likely to be climate-sensitive are also classified as NTDs. Climate change can create favourable conditions for the spread of NTDs such as dengue, thereby threatening progress against NTDs and hampering the ability of health systems and communities to prepare for the effects of climate change on these diseases. **While further research is needed to form a deeper understanding of the likely impacts on specific NTDs, there is a need to develop adaptation strategies that include investing in R&D for health tools to tackle these diseases.** Additional comments and suggested actions are included in the Agenda Item 15.4 'Climate change, pollution and health' section, below.

We urge Member States to:

- **Commit to sustainably investing in R&D for effective health tools for use at the primary healthcare level by supporting not-for-profit R&D models that centre on patient needs and by:**
 - Supporting the development of the NTD R&D blueprint, which is being led by the WHO
 - Addressing key treatment gaps, such as those for children and women, including women of childbearing potential and pregnant and lactating women, and addressing the need for shorter, simplified regimens that can avoid the need for hospitalization and support UHC;
 - Supporting the priorities identified in the WHO-published list of paediatric formulations for NTDs to target R&D to address the specific needs of infants and children; and
 - Supporting South-South R&D collaboration models, where countries most affected by NTDs lead R&D priority-setting and development of health tools.
- **Mobilize substantial additional resources** to make significant and sustained investments in NTD programmes, including by **aligning domestic funding strategies and expanded donor resources.**
- **Ensure that investments in climate adaptation address and account for climate-sensitive NTDs.**
- **Identify opportunities for synergies, shared services, and integration of R&D and access programmes across disease areas,** including establishing mechanisms or modifying existing mechanisms to accelerate access and ensure that tools developed reach healthcare workers, communities, and patients.
- **Ensure coherence between policy processes** where actions aligned with the NTD Roadmap could be implemented. We welcome the Brazilian Presidency's inclusion of neglected and socially determined diseases in the Health Track of the G20 and urge G20 members to support initiatives to develop and produce new health tools for neglected and climate-sensitive diseases, including the Global Alliance for Local and Regional Production and Innovation.

Agenda item 11.7: Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality

Many of the challenges and critical areas for action that remain in prioritizing women's and children's health needs are outlined in the [resolution](#) 'Accelerate progress towards reducing maternal, newborn and child mortality in order to achieve SDG targets 3.1 and 3.2' and [report](#) 'Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality', published before the 154th session of WHO EB.

DNDi's comments are focused on how a lack of R&D for health tools to address the health requirements of women and children, whose specific medical needs are often neglected, is a barrier to achieving the SDG targets.

We request Member States to take note of the following issues:

1. The need for R&D for children

The EB [report](#) mentions 'treatment of childhood illnesses' as one gap that hinders the achievement of UHC, particularly for low- and middle-income countries. **It is important that the needs of children affected by illnesses not specific to childhood, but for which child-adapted treatment formulations are often not developed, are also included.**

Each year, millions of children's lives are prematurely cut short or debilitated by diseases that are largely treatable – yet child-adapted treatment formulations are often not developed as the treatment needs of children have long been an afterthought in profit-driven drug development, given that they represent lower-volume markets.^{3,4} 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. Children represent 34% of the 20 million DALYs that result from NTDs. For example, in 2022, more than half of those infected with visceral leishmaniasis were less than 15 years old.⁵ Children account for over a quarter of the new cases for Chagas disease,⁶ and infants are at a higher risk of developing severe dengue.

Some NTDs disproportionately impact children, leading to profound and long-lasting harms, including premature death, disfigurement, stunted growth, chronic pain, and malnutrition. And 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. Despite the burden, only 22 of the 47 medications available for NTDs are labelled for use in children.⁷

³ 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>

⁴ Watts G. WHO launches campaign to make drugs safer for children. BMJ. 2007 Dec 15. Available from: <https://dx.doi.org/10.1136%2Fbmj.39423.581042.DB>

⁵ World Health Organization. Global leishmaniasis surveillance, 2022: assessing trends over the past 10 years. Available from: <https://www.who.int/publications/i/item/who-wer9840-471-487>

⁶ World Health Organization. Chagas disease in Latin America: an epidemiological update based on 2010 estimates," Weekly Epidemiological Record 6, February 2015. pp. 33-343

⁷ 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. Available from: <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007111>

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, the 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. GAP-f represents an important step toward identifying gaps, setting priorities, removing barriers, and accelerating development of and access to quality, safe, efficacious, and affordable medicines for children. The initiative has prioritized a portfolio of the paediatric formulations that are most needed across several disease areas via the Paediatric Drug Optimization (PADO) process, and the WHO has published these lists of priority paediatric formulation needs for HIV, TB, hepatitis C, antibiotics, and five NTDs to target research to address the specific needs of infants and children. **Addressing these priorities requires political, technical, and financial support from Member States.**

2. The need to support the inclusion of pregnant and lactating women in research and clinical trials

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.

These gaps became all the more evident during the COVID-19 pandemic, with women and children under-represented in clinical trials. A report from the Director General to WHA76⁸ 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.’ This underrepresentation also results in delays in availability of medicines. Proposals to ensure responsible strategies for gender-responsive drug development should be integrated into the actions needed to meet the SDG targets and into the Global Strategy for Women’s, Children’s and Adolescents’ Health 2016-2030.

We welcome and support the resolution’s reference to the need for development of and access to essential medicines for children and pregnant and lactating women and the need for Member States to promote, support, and finance the development, manufacturing, registration, and supply of age-appropriate, quality-assured formulations of medicines for diseases that affect mothers, newborns, and children. Importantly, the resolution also calls for WHO to strengthen and expand the work of the GAP-f network in identifying gaps, setting priorities, removing barriers, and accelerating the development of and access to quality, safe, efficacious, and affordable medicines for children. We suggest Member States to consider the minor addition of the word ‘children’ in OP 3.6 to say “.... and report to the 78th 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 children**, and for maternal, adolescent, child and newborn health services”, to ensure consistency with OP 1.14.

⁸ A76/5 [Global Strategy for Women’s, Children’s and Adolescents’ Health \(2016–2030\)](https://www.who.int/publications/m/item/global-strategy-for-women-s-children-s-and-adolescents-health-2016-2030) (who.int)

We urge Member States to:

- **Support prioritization of and investment in the development of age-appropriate formulations for children with NTDs**, including support for the PADO list of priority NTD treatment formulations for children, undertaken by GAP-f.
- **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 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.
- **Promote the collection, utilization, and reporting of sex- and age-disaggregated information** in ongoing and future programmes and research.

Agenda item 13.4: Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response

In December 2021, through decision SSA2(5) (2021), the World Health Assembly established, in accordance with Rule 41 of its Rules of Procedure, an intergovernmental negotiating body (INB) open to all Member States and Associate Members.

Pursuant to decision SSA2(5): The INB was established to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, with a view to adoption under Article 19, or under other provisions of the WHO Constitution as may be deemed appropriate by the INB.

DNDi welcomed the establishment of the INB and identified the negotiation process as a vital opportunity to operationalize the lessons we have learned from past health crises into concrete norms and measures that can enable a more equitable biomedical R&D system – in particular, norms and measures that embed the principles of access, affordability, and equity into the R&D process itself, including by articulating specific, globally agreed standards for the critical actions that governments can take to ensure that their public investments in R&D are designed to deliver equitable access.

DNDi has closely followed and participated in the process and at meetings of the INB from the start. The comments and suggestions we have made throughout (details of which can be found [here](#)) are rooted directly in our firsthand experience as an R&D organization that undertakes research in the public interest and seeks to secure globally equitable access to the fruits of medical innovation. We therefore focused on how an international instrument can best ensure investment in the discovery and development of – and equitable access to – essential health tools as global public goods in order to prepare and respond to outbreaks and pandemics.

As Member States continue negotiations to finalize the text of the Pandemic Agreement for consideration at WHA77, we urge member States to ensure that it contains concrete measures that States can and should take, to ensure equity in pandemic prevention, preparedness and response. One such measure is to include conditionalities on public funding of R&D to ensure the development of and equitable access to health technologies.

Agenda item 15.4: Climate change, pollution and health

Climate change will impact the epidemiology and geographical range of climate-sensitive infectious diseases, including the most neglected tropical diseases, many of which lack safe, effective, and affordable health tools for prevention and treatment. **DNDi focuses its comments on how Member States and the WHO can best respond to the current inadequate level of preparedness to tackle the spread of climate-sensitive infectious diseases, and why R&D for new health tools to prevent and treat them must feature prominently in climate adaptation efforts.**

1. Impact of climate change on climate-sensitive infectious diseases

Despite ongoing global coordination to mitigate the impacts of climate change, progress to date has been insufficient. Data shows that climate change is affecting the spread of infectious diseases in three ways: the changing incidence and geographical spread of vector-borne and water-borne climate-sensitive infectious diseases, climate-related migration, and the increased risk of new emerging zoonotic diseases.^{9,10} The proportion of annual global deaths due to climate-sensitive diseases is estimated to be 69.9%.¹¹

As a [recent WHO communique](#) states, many NTDs are climate-sensitive. In fact, nearly half (11 out of 25) of the vector or waterborne diseases listed by the WHO, which might be impacted by climate change, are also classified as NTDs. These diseases affect 1.62 billion people – mostly in the least developed economies and most impoverished communities. They can bring financial devastation to those affected, feeding vicious cycles of ill-health and poverty.¹²

Climate change is currently threatening progress towards the control and elimination of numerous infectious diseases. Additionally, climate change-induced morbidity and mortality from infectious diseases are expected to rise globally in the future. For example:

- **Dengue** is the most prevalent mosquito-borne viral disease in the world, recognized by WHO as one of the top ten threats to global health in 2019. Facilitated by the impact of rising temperatures, dengue outbreaks are now occurring worldwide with an 85% increase in the number of cases globally between 1999 and 2019 and yearly infection rates now estimated to be as high as 390 million¹³. Dengue-related deaths increased by 27% in 2022 compared to 2016.¹⁴ The disease is now endemic in more than 100 countries, with the Latin America, South-East Asia, and Western Pacific regions most seriously affected. Endemic countries are facing longer outbreaks along with increased incidence.
- **Leishmaniasis** is also climate-sensitive, as ambient temperature directly affects the vector's development and geographical distribution. The epidemiology of leishmaniasis will therefore be affected by rising temperatures and changing rainfall patterns, and transmission might spread to previously non-

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

¹⁰ The report by Director General mentions '...climate change is already having observable adverse impacts on human health and well-being through heat, malnutrition, **infectious diseases**, mental health and displacement, both at the global level and in the majority of the specific regions assessed.' The Lancet Countdown report on climate and health states that climate change is putting more populations at risk of contracting infectious diseases such as dengue, West Nile virus, malaria etc. IPCC's sixth assessment report mentions 'the incidence of vector-borne diseases has increased from range expansion and/or increased reproduction of disease vectors.'

¹¹ IPCC. Climate Change 2022: Impacts, Adaptation, and Vulnerability Contribution of Working Group II to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change.; 2022; Available from: https://www.ipcc.ch/report/ar6/wg2/downloads/report/IPCC_AR6_WGII_Chapter07.pdf

¹² World Health Organization. Global Report on Neglected Tropical Diseases 2023.

¹³ World Health Organization. Dengue and severe dengue. 2023. Available from: <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>

¹⁴ World Health Organization. Global report on neglected tropical diseases 2024.

endemic areas.¹⁵ According to one study's estimate, the number of people exposed to leishmaniasis may double by 2080.¹⁶

- Climate change is also impacting the distribution and transmission risk of **Chagas disease**, a potentially fatal parasitic illness. Climate change has facilitated geographic shifts in the distribution of the vector that transmits the disease, thus increasing risk of cases in non-endemic countries.¹⁷

In addition, while many infections once labelled as 'tropical diseases' are now leading to outbreaks worldwide – as illustrated by the recent emergence of dengue and other tropical diseases in areas such as the United States¹⁸ and Europe¹⁹ and the re-emergence of dengue in Japan²⁰ – **countries in the Global South will continue to carry a disproportionate burden of the impacts of climate change on infectious diseases.**

2. Status of adaptation measures: Lack of investment in R&D for health tools to tackle climate-sensitive diseases

As highlighted in the Director General's [report](#) published before the 154th session of the WHO EB, achieving climate-resilient health systems to address the health risks and impacts of climate change requires increased capacity for disease surveillance, epidemiological investigation, virus testing, and vector control. However, limiting investments to only these areas will not suffice. **The availability of and equitable access to tools to diagnose and treat climate-sensitive diseases are also critical to building resilient communities and health systems.**

For many climate-sensitive infectious diseases, inadequate investment in medical R&D threatens the world's ability to adapt to the effects of climate change on these diseases. Current tests and treatments for most climate-sensitive NTDs, when they exist at all, have serious limitations that hamper the provision of life-saving medical care and impede disease control and elimination efforts. **The world lacks tools for prevention, diagnosis, and treatment that are simple, safe, and effective – and that can be easily integrated into already overburdened health systems.**

For example, for dengue, treatment consists primarily of supportive care, with no specific treatment yet available to prevent progression to severe disease.²¹ 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. **With predicted increases in their incidence and geographical spread, the current state of adaptation efforts to prevent and treat climate-sensitive infectious diseases is inadequate.**

¹⁵ World Health Organization. Leishmaniasis, key facts. 2023 Jan 12. Available from: <https://www.who.int/news-room/fact-sheets/detail/leishmaniasis>

¹⁶ Short E, Caminade C, Thomas BN. Climate Change Contribution to the Emergence or Re-Emergence of Parasitic Diseases. Infectious Diseases: Research and Treatment. 2017 Sep 25. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5755797/>

¹⁷ Graves BN. Climate Change And Chagas Disease In The Americas: A Qualitative Systematic Review. Dissertations & Theses. 2019. Available from: https://digitalcommons.library.tmc.edu/uthsph_dissertopen/87/

¹⁸ Hotez PJ. The rise of neglected tropical diseases in the "new Texas". PLoS Neglected Tropical Diseases. 2018 Jan 18. Available from: <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005581>

¹⁹ Naddaf M. Dengue is spreading in Europe: how worried should we be?. Nature. 2023 Oct 31. Available from: <https://www.nature.com/articles/d41586-023-03407-6>

²⁰ Wang X, Nishiura H. The Epidemic Risk of Dengue Fever in Japan: Climate Change and Seasonality. The Canadian Journal of Infectious Diseases and Medical Microbiology. 2021 Oct. Available from: <https://pubmed.ncbi.nlm.nih.gov/34721747/>

²¹ IPCC's sixth assessment report states, '...dengue risk will increase with longer seasons and a wider geographic distribution in Asia, Europe, Central and South America and sub-Saharan Africa, potentially putting additional billions of people at risk by the end of the century.' The Lancet Countdown report states that transmission potential for dengue will increase by 36–37% by 2050.

3. Part of the solution: Innovation for vaccines, diagnostics, and treatments as a core component of climate change adaptation strategies

We support the reference to the need for biopharmaceutical innovation to prevent, test, and treat climate sensitive diseases in the [resolution](#) 'Climate change and health'. The increased incidence of some climate-sensitive diseases in high-income countries may eventually spur innovation and investment by the for-profit pharmaceutical sector for diseases that are considered a sufficient threat. However, this does not guarantee R&D for health tools for climate-sensitive diseases affecting low- and middle-income countries, where the burden of climate-sensitive diseases is already real – and extensive. Furthermore, without sufficient commitment and support, equitable access to these tools would continue to remain a challenge, as highlighted during the COVID-19 pandemic.

The biomedical R&D system is already failing neglected populations in low-resource settings affected by neglected tropical and infectious diseases. Public policies are needed to shape the R&D ecosystem to ensure a focus on these populations, including by ensuring that public investments in R&D are conditioned on public benefits – and to ensure that innovation capacity in the Global South is utilized and developed further. Without progress on these critical fronts, innovation will remain the privilege of the rich and not reach populations in already burdened countries in the Global South hardest hit by climate-sensitive infectious diseases.

We urge Member States to:

- **Invest in R&D for new tools** to tackle infectious diseases, particularly for those neglected by the market.
- **Ensure that the need for health tools** required to protect populations against the rise and spread of infectious diseases **features prominently in climate adaptation discussions and strategies**, including by:
 - Supporting the inclusion of indicators on progress of action on climate-sensitive infectious diseases in the UAE-Belém work programme on the Global Goal on Adaptation framework. In this [submission](#), DNDi has proposed a selection of broad categories of indicators related to climate-sensitive diseases that Parties can consider.
 - Supporting the inclusion of strategies to address climate-sensitive diseases, including R&D of health tools, in the proposed Global Plan of Action on climate change and health and WHO's 14th General Programme of Work.
- **Ensure coherence between policy processes addressing climate and health**, where actions aligned with the resolution could be implemented. We welcome the Brazilian Presidency's inclusion of climate and health as a priority within the health track of the G20 and urge G20 members to support initiatives to develop and produce new health tools for neglected and climate sensitive diseases, including the Global Alliance for Local and Regional Production and Innovation.

Agenda item 15.5: Economics and health for all

DNDi supports the recommendations of the independent WHO Council on the Economics of Health for All (2021–2023), outlined in [‘Health for All: Transforming economies to deliver what matters’](#). When examining the actions that can best advance the establishment of an economy for health for all, we particularly encourage Member States to consider the Council’s recommendations on ‘Innovating for health for all,’ including the following:

1. Reorienting the governance of health innovation for the common good

DNDi was established to address chronic challenges in ensuring that medical R&D meets the needs of neglected populations. As such, we recognize the challenges identified by the WHO Council and agree with many of the recommendations calling for a reorientation of the governance of health innovation for the common good.

We agree that the *directionality* of R&D must be reoriented to prioritize the most pressing public health needs, not those that are most likely to maximize profits. Decisions about whether and how to discover, develop, produce, allocate, and price essential health technologies cannot be left to narrow national interests or market forces alone. As the Council states, ‘[r]edesigning the health innovation ecosystem for the common good requires a major shift from a model where innovation is seen as being driven by market forces, to a model that is collectively governed in the public interest.’

This will require end-to-end R&D and manufacturing ecosystems that are driven by and that prioritize the health needs of people in all regions of the world, and that, in addition, build public-interest goals such as equitable access into the R&D process itself.

This is not a new challenge. Many challenges of the R&D system identified by the Council are acute examples of the chronic failures countries and communities have faced, and worked to overcome, over the past three decades – the struggle for access to HIV treatment in low- and middle-income countries being a prime and perhaps the best-known example. The COVID-19 pandemic is another: while the system succeeded in accelerating scientific progress, it failed to ensure equitable access to vaccines, diagnostics, and therapeutics.

At almost every step during COVID-19, when there was an opportunity for both public and private actors to be more ‘purpose-driven’ and ‘mission-oriented’, political and commercial choices were made that further entrenched the status quo. As the Council stated in its brief, [‘Governing health innovation for the common good’](#), the resulting inequities were ‘not just a moral failure’, but also a ‘health and economic catastrophe’.

DNDi’s experience has shown that it is possible to build partnerships that ensure both the innovation of, and equitable access to, necessary health tools across many diseases – including HIV, hepatitis C, COVID-19, and neglected tropical diseases – provided all partners have a common vision from the beginning, agreed in advance, and embed efforts to ensure access into R&D collaboration agreements. This is also possible throughout the different stages of R&D.

Renewed public leadership and international cooperation is required to correct course and move away from a business-as-usual, ‘trickle-down’ approach to global health innovation and access towards a more effective, end-to-end biomedical innovation ecosystem that ensures the benefits of scientific progress will be equitably shared and considered global public goods, available to all.

2. Investing in alternative financing mechanisms, partnership models, and alliances, including not-for-profit models

Market-based approaches alone will not be enough to discover, develop, and ensure access to all necessary health tools. Traditional market incentives alone fail to respond to, prioritize, and ensure R&D investments where the people affected are poor, where need is uncertain, or where demand may be low. This is a daily reality for 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 the development of new health tools for neglected populations depends on sustainable investments in R&D, and on political leadership to drive such investment. **Without specific interventions by governments, these unmet medical needs will not be addressed by the profit-driven biomedical R&D system. Alternative financing mechanisms, partnership models, and incentives are needed.**

3. Conditionalities for public investment to maximize public value, sharing both risks and rewards

We agree with the Council's recommendation that governments, particularly those that fund R&D, should use their leverage to negotiate clear terms and conditions and to secure rights on the outcomes of the research they fund in order to be able to use, license, or assign those rights, if needed, to ensure the development of and equitable access to health technologies. Despite providing significant amounts of public funding for the development of COVID-19 vaccines, diagnostics, and therapeutics, public funders of R&D either did not include conditions in funding and/or procurement contracts, or chose not to exercise them, and thereby failed to use their power to ensure access and affordability globally – or even domestically.

There is considerable public and philanthropic funding for research – whether through direct R&D grants or other subsidies or pre-purchase commitments – and funders should therefore secure a public return on their public, or public interest-driven, investments to ensure not just the development of appropriate health tools but equitable access to them.

This means requiring clear and transparent terms and conditions that ensure open collaboration to accelerate research and ensure the affordability, availability, and equitable allocation of essential health tools.

These terms and conditions should ensure transparency and open sharing of knowledge, including research inputs (e.g., specimens, samples, compound libraries, and datasets with appropriate data protections), processes (e.g., protocols, clinical trial designs, and R&D costs), and outputs (e.g., study data and clinical trial results – shared openly, including through open-access publications). Applying such terms and conditions for public and philanthropic R&D funding is critical to enabling continuity of research, avoiding duplication, and ensuring that fruits of research reach those in need.

The pandemic has shown us that purely voluntary mechanisms for sharing intellectual property and know-how, even in the midst of an acute public health crisis, did not guarantee equitable access to medical countermeasures. As such, it is important that funders systematically use their leverage to ensure that more forceful pro-access IP management approaches are in place. **Unless specific contractual commitments, binding rules, and enabling policies are proactively established to ensure global equitable 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.** Many of these issues are currently under discussion in negotiations on the Pandemic Agreement, which provides a vital opportunity to operationalize

the lessons we have learned from past health crises into concrete norms to which all countries will need to adhere.

We urge Member States to:

- **Establish and attach conditions on public R&D investments** within domestic health innovation funding and **support the inclusion of a provision on attaching conditions to public funding in the Pandemic Agreement INB negotiations.**
- Address key treatment gaps to meet the needs of the most vulnerable populations by promoting and investing in **alternative financing mechanisms, partnership models, and incentives** that do not depend on the profit-seeking model.
- 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.
- Put in place measures to **improve transparency of R&D information**, as agreed in WHO resolution 72.8 'Improving the transparency of markets for medicines, vaccines, and other health products', including the cost of R&D – knowledge of which plays a critical role in incentivizing and projecting costs for further investment, ensuring fair pricing, and ensuring a public return on public investments in R&D.

Agenda 29. A: The global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections (resolution WHA75.20 (2022))

DNDi congratulates the WHO for the work undertaken and progress achieved in implementing the global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections. We request Member States to take note of the following issues.

1. HIV: Improving health outcomes for people with advanced HIV disease and children living with HIV

There is enhanced attention to addressing advanced HIV disease, improving access to new tools, and reducing the major causes of death among people with HIV (PLHIV) but much more needs to be done. For example, people with advanced HIV disease are highly susceptible to cryptococcal meningitis (CM), a fungal infection, because they have weakened immune systems. In 2021, CM was responsible for an estimated 19% of AIDS-related mortality and 112,000 deaths among PLHIV.²² While tools for diagnosis, prevention, and treatment such as fluconazole exist, access is extremely limited, with CM mortality rates in LMICs a staggering 70% compared to 20-30% in high-income countries. Other treatment options such as amphotericin B can be toxic to the kidneys and require intravenous administration. Flucytosine is a life-saving component of WHO-recommended treatments; however, it must be taken four times per day and is currently not registered or not available in many African countries with high burdens of CM. Efforts are underway to develop a simplified, sustained-release formulation of flucytosine while also increasing access to currently available formulations. More progress must also be made to close the gaps in access to HIV diagnosis, treatment, and care for children with HIV, only 57% of whom have access to life-saving treatment compared to 77% of adults.²³

We urge Member States to:

- Support and accelerate the **development, introduction, and scale-up of appropriate treatment options** to improve health outcomes for advanced HIV disease; and
- Rapidly **scale up access to existing paediatric antiretroviral treatment formulations.**

2. Hepatitis C: Removing barriers to testing and treatment and sustaining financing to meet SDG elimination targets

We are pleased to note from Director General's [report](#) that hepatitis C incidence and mortality rates fell by an estimated 5% and 17%, respectively, from 2019 to 2022. We also extend our congratulations to Egypt for being the first country to achieve WHO validation on the path to elimination of hepatitis C. However, despite the existence of improved diagnostics and highly effective treatments, only 36% of people living with hepatitis C have been diagnosed and only 20% (12.5 million) have received curative treatment.²⁴ Only 11 countries are on track to eliminate hepatitis C by 2030.²⁵ Getting back on track to achieve SDG targets would require curing an estimated 30 million people with hepatitis C by the end of 2026.²⁶

²² Rajasingham R, Govender NP, Jordan A, et al. The global burden of HIV-associated cryptococcal infection in adults in 2020: a modelling analysis. *Lancet Infect. Dis.* 2022. Available from: <https://pubmed.ncbi.nlm.nih.gov/36049486/>

²³ UNAIDS. Factsheet. Available from https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

²⁴ <https://www.who.int/news/item/09-04-2024-who-sounds-alarm-on-viral-hepatitis-infections-claiming-3500-lives-each-day>

²⁵ Katherine Heath, Andrew Hill. WHO hepatitis C elimination targets: the global equity challenge. *The Lancet Gastroenterology & Hepatology.* 2024. Available from: [https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(23\)00408-9/fulltext](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(23)00408-9/fulltext)

²⁶ World Health Organization. Global Hepatitis Report 2024.

While antivirals are available for treatment, serious barriers remain for access to affordable direct-acting antiviral treatments, particularly in high-burden countries. The price of 12-week treatment sofosbuvir/daclatasvir (SOF/DAC) varies greatly between countries – from the lowest reported price of approximately USD 33 for a generic course of treatment in Pakistan to the highest reported price of approximately USD 10,000 in China, where prices are similar for generic and originator products²⁷. Actions to remove barriers to scaling up diagnosis and treatment, including using TRIPS flexibilities to allow generic competition, are urgently needed.

In addition to the exorbitant price of treatments in many high-burden countries, there must be increased attention to the danger of rising resistance of the hepatitis C virus to NS5A inhibitors, a class of antivirals that target the NS5A protein essential for the replication of the hepatitis C virus within host cells. Increased attention is also needed to meet the needs of people at greatest risk of hepatitis C infection, such as people who inject drugs, who are already marginalized and face barriers to accessing national healthcare systems and services. Despite some progress, insufficient financing will continue to be a challenge for national scale-up and elimination efforts; the public health response to viral hepatitis has been severely underfunded to date. Investment case studies conducted for several countries show that there is a USD 2-3 return on investment for every dollar invested for hepatitis B and C interventions.²⁸

We urge Member States to:

- **Address the urgent need to support broader access to testing**, including community-based screening approaches;
- Support **better linkages between diagnosis and provision of treatment** and care;
- Include new, affordable direct-acting antivirals in national essential medicines lists, such as ravidasvir, which was added to the WHO Essential Medicines List in 2023;
- Implement a **combination of social and medical interventions** to promote uptake of testing and treatment and improve patient engagement and retention in care;
- Support **actions to remove barriers to scaling up diagnosis and treatment**, including patent and other barriers to lowering the cost of generic competition; and
- Maintain **sustained financing and political will** to reach hepatitis C elimination targets.

²⁷ World Health Organization. Global Hepatitis Report 2024.

²⁸ World Health Organization. Global Hepatitis Report 2024.