

Drugs for Neglected Diseases initiative (DNDi)

Briefing note for the 154th Session of the WHO Executive Board

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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 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 for consideration by the World Health Organization (WHO) Executive Board on the following agenda items:

- **Agenda item 11:** Road map for neglected tropical diseases 2021–2030
- **Agenda item 12:** Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality
- **Agenda item 22:** Climate change, pollution and health
- **Agenda 23:** Economics and health for all

Agenda item 11: Road map for neglected tropical diseases 2021–2030

DNDi welcomes the Director General’s progress [report](#) on the WHO road map for Neglected Tropical Diseases 2021-2030. The Report notes areas of important progress, such as eight countries eliminating one Neglected Tropical Disease (NTD) in 2022 and six in 2023, and Bangladesh becoming the first country in the world to eliminate visceral leishmaniasis. 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.

Many of the EB154 agenda items provide an opportunity for action on NTDs, including agenda item 12: ‘Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality’ and agenda item 22: ‘Climate change, pollution and Health’, comments for which are included in other sections of this briefing.

When reviewing the report, we ask Member States to note the following issues:

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

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 – an issue currently missing from the DG’s report.

Progress is possible. Recent successful advancement of research and development for new tools includes 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.

Despite progress for some NTDs, however, 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 vulnerable people, including those with NTDs, who are poor or otherwise marginalized.

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 and partnership models and incentives that do not depend on the primarily

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 NTDs¹. More than 500,000 children are infected with leishmaniasis each year, and children account for more than one-third of new cases of Chagas disease. Yet less than half of WHO-recommended medicines for NTDs are approved for children.

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 into addressing 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, these 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 patient 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 report states that the rapid decrease in funding for NTDs since 2020 is currently 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 disease areas such as HIV, TB, and malaria, and noncommunicable diseases such as diabetes, hypertension, and mental health – 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.

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 22 'Climate change, pollution and health' section, below.

¹ 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>

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:**
 - 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 in addressing 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 to ensure that tools developed reach healthcare workers, communities, and patients.

Agenda item 12: Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality

DNDi welcomes the Director General's [progress report](#) 'Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality' and notes the proposed resolution 'Accelerate progress towards reducing maternal, newborn and child mortality in order to achieve SDG targets 3.1 and 3.2'. The resolution and report outline many of the challenges that remain in prioritizing women's and children's health needs and covers many critical areas that require action. DNDi will focus its comments on how a lack of R&D of health tools to address the health requirements of these populations, 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 and ensure they are adequately reflected in the resolution:

1. The need for R&D for children

The report mentions 'treatment of childhood illnesses' as one gap that hinders the achievement of UHC, particularly for lower- 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 ended 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 low-volume markets.^{2,3} 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 formulations lagged 20 years behind that of adults. Children represent 34% of the 20 million DALYs that result from NTDs. For example, leishmaniasis affects more than 500,000 children each year, children represent most of the 400 million annual cases of dengue fever, and over a third of new cases of Chagas disease each year are estimated to be in children.

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.⁴

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

² 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>

³ 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>

⁴ 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>

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 most needed formulations for children across several disease areas via the Paediatric Drug Optimisation (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 into addressing 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 underrepresented in clinical trials. A report to WHA76 from the DG⁵ for 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 the availability of medicines. Together with its partners, DNDi has proposed a safe and ethical clinical trial recruitment [framework](#) for women of childbearing potential. These and other proposals to ensure responsible strategies in 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 reference proposed in the draft resolution of the need for the development of and access to essential medicines for children, 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. These references should be retained.

We urge Member States to:

- Ensure the retention of references in the draft resolution ‘Accelerate progress towards reducing maternal, newborn and child mortality in order to achieve SDG targets 3.1 and 3.2’ that:
 - **Request Member States to enable access to essential medicines for pregnant and lactating women, newborns, and children** through R&D, manufacturing, registration, and supply; and

⁵ A76/5 [Global Strategy for Women’s, Children’s and Adolescents’ Health \(2016–2030\) \(who.int\)](#)

- **Request the Director General to promote better access to age-appropriate, quality-assured, affordable medicines for women and children** and expand collaborative efforts of the GAP-f network.
- **Support prioritization of and investment in the development of age-appropriate formulations for children with NTDs**, including support for the PADO list of the most needed formulations for children, for several NTDs, 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 22: 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. **While the proposed Climate and Health resolution focuses on many aspects of mitigation, prevention, and adaptation related to climate and health, DNDi focuses these comments on how Member States and the WHO can best reflect the current inadequate level of preparedness to tackle the spread of climate-sensitive infectious diseases, and how R&D for new health tools to prevent and treat them should be considered within 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.^{6,7}

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 1.65 billion people – mostly in the least developed economies and most impoverished communities. They can bring financial devastation to those affected, feeding vicious circles of ill-health and poverty.⁸

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

- **Dengue** is the most prevalent mosquito-borne viral disease worldwide and in 2019 was named by WHO as one of the ten threats to global health, 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, with yearly infection rates now estimated to be as high as 390 million⁹. 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

⁶ 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)

⁷ 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.'

⁸ World Health Organization. Global Report on Neglected Tropical Diseases 2023.

⁹ World Health Organization. Dengue and severe dengue. 2023. Available from: <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>

areas not previously endemic to the disease.¹⁰ According to one study's estimate, the number of people exposed to leishmaniasis may double by 2080.¹¹

- Climate change is also impacting distribution and transmission risk of **Chagas disease**, a potentially fatal parasitic illness. Climate change has facilitated a shift of the vector which causes the disease, thus increasing risk of cases in non-endemic countries.¹²

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 States of America¹³ and Europe¹⁴ and the re-emergence of dengue in Japan¹⁵ – 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 into R&D for health tools to tackle climate-sensitive diseases

As the [DG report](#) highlights, 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 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.¹⁶ 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.**

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

Biopharmaceutical innovation for vaccines, diagnostics, and treatments must be a core component of climate change adaptation strategies and should be included and supported in the proposed resolution. The increased incidence of some climate-sensitive diseases in high-income

¹⁰ World Health Organization. Leishmaniasis, key facts. 2023 Jan 12. Available from: <https://www.who.int/news-room/fact-sheets/detail/leishmaniasis>

¹¹ 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/>

¹² 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_dissertsopen/87/

¹³ 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>

¹⁴ 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>

¹⁵ 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/>

¹⁶ 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.

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 remain a continuing 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 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:

- **Ensure the retention of language in the draft resolution** ‘Climate change and health’ that calls for Member States to support R&D for new health tools to prevent, test, and treat climate-sensitive infectious diseases in order to support affected communities in their efforts to adapt to the impacts of climate change.
- **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.**
- **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 climate sensitive diseases.

Agenda item 23: Economics and health for all

DNDi welcomes the Director General's report on the recommendations of the independent WHO Council on the Economics of Health for All (2021–2023), '[Health for All: Transforming economies to deliver what matters](#)'. When Member States are considering how action can best be advanced on establishing an economy for health for all, we particularly encourage consideration of the Council recommendations on 'Innovating for health for all,' including the following:

Re-orienting the governance of health innovation for the common good

DNDi was established to address a chronic challenge when it comes to meeting the R&D 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 re-orientation of the governance of health innovation for the common good.

We agree that the *directionality* of R&D must be re-oriented 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.

Investing in alternative financing mechanisms and 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.

Conditionalities for public investment to maximize public value, sharing both risk 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 secure rights on 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 or 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 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 Accord (WHO CA+), 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 Accord INB negotiations.**
- Promote and invest in **alternative financing mechanisms, partnership models, and incentives** that do not depend on the profit-seeking model to address key treatment gaps and meet the needs of the most vulnerable populations.
- 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 of the cost of R&D, 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.