



Drugs for Neglected Diseases *initiative*

Drugs for Neglected Diseases *initiative* (DNDi)
Briefing Note for 150th Session of the World Health Organization Executive Board
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The Drugs for Neglected Diseases *initiative* ([DNDi](#)) is a not-for-profit research and development (R&D) organisation that discovers, develops, and delivers new treatments for neglected patients. Since its creation in 2003, DNDi has developed nine new and improved treatments for six deadly diseases that have reached millions of people and has dozens of potential new drugs in our pipeline for neglected populations. DNDi, in partnership with the World Health Organization (WHO), jointly established the Global Antibiotic Research and Development Partnership (GARDP), which is essential to enable Member States to deliver on the Global Action Plan on Antimicrobial Resistance.

In response to the COVID-19 pandemic DNDi:

- Established the [COVID-19 Clinical Research Coalition](#) which now includes more than 800 scientific organizations and individual members from nearly 90 countries to accelerate research specific to the needs of people and health systems in low- and middle-income countries.
- Launched [ANTICOV](#), a multi-country, adaptive platform trial conducted in 13 African countries with to identify treatments for mild-to-moderate COVID-19 outpatients, with plans to extend this study in India and Brazil in 2022.
- Collaborated with various research consortia, and now lead a global consortium known as the [COVID Moonshot](#), to identify novel, early-stage discovery projects to contribute to building the pipeline for new treatments for Covid-19, other coronaviruses, and other pathogens of pandemic potential.
- Conducted policy research, analysis, and advocacy, including publishing an [August 2021 Policy Report](#), to increase attention to the need for innovation of and equitable access to therapeutics, in addition to vaccines and other health technologies, for COVID-19 and for future pandemics.

The following are DNDi's comments for consideration by World Health Organization (WHO) Member States on the following agenda items of the 150th session of the Executive Board:

- **Agenda item 8:** The global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections
- **Agenda item 10:** Road map for neglected tropical diseases 2021–2030
- **Agenda item 3 and 15.1**
 - Agenda 3: Outcome of the Second special session of the World Health Assembly, held to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response
 - Agenda 15.1: Strengthening WHO preparedness for and response to health emergencies
- **Agenda item 21.1:** Global strategy and plan of action on public health, innovation and intellectual property

Agenda item 8: The global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections

DNDi congratulates the WHO for the work undertaken to revise the strategies for HIV, viral hepatitis, and sexually transmitted infections (STIs). We request that the Executive Board take note of the following issues and send the strategies for approval to the World Health Assembly.

The Director General's report rightly highlights that while progress has been made on HIV, hepatitis, and STIs over the past several years, most targets for 2020 for these three diseases were missed – likely at least in part due to COVID-19 – and that new tools and technologies are not yet reaching people and translating into reduced morbidity, mortality, and incidence.

HIV: There is enhanced attention to addressing advanced HIV disease (AHD)/AIDS, improving access to new tools, and reducing the major causes of death among people with HIV (PLWHIV) but much more needs to be done. For example, cryptococcal meningitis (CM) is the second largest killer of PLWHIV, and while tools for improving diagnosis, prevention, and treatment exist, access is extremely limited, and survival rates with high-dose fluconazole regimens—still widely used in LMICs—is low at 20-30%. New evidence, new tools, and new targets to end HIV-related deaths from CM are emerging and offer rare opportunities to improve outcomes: earlier diagnosis and use of flucytosine-containing treatments and optimised regimens with liposomal formulations of amphotericin B could more than triple CM survival rates and simplify administration if broadly implemented. Similarly, more progress must be made to close the gap in access to HIV diagnosis, treatment, and care among young children with HIV (all children < 5 years are considered to have AHD given their increased risk of death). Much more progress must be made to rapidly scale up access to existing and soon-to-be-approved paediatric antiretroviral formulations.

Hepatitis C: Most countries are still not close to meeting the treatment and diagnosis targets needed for elimination by 2030, and increased, up-to-date, and detailed information on HCV diagnosis and treatment progress and gaps are vital as a basis for starting the new strategy. In 2020, only 12 countries were on track to achieve HCV elimination by 2030. Not enough patients are diagnosed. When implementing Strategic Area 1 (deliver services) and 3 (use of data) it is critical that Member States explicitly address the urgent need to improve screening and testing. Contrary to what is too often claimed, access to affordable direct acting antiviral treatments is not a reality, particularly in high-burden countries. Actions to remove barriers to scaling up diagnosis and treatments, including using TRIPS flexibilities to allow generic competition, are urgently needed. In addition, despite some progress, insufficient financing will continue to be a challenge for national scale-up and achieving elimination. Innovative approaches such as the Hepatitis C PACT launched by Médecins Sans Frontières (MSF), the Foundation for Innovative New Diagnostics (FIND), Treatment Action Group (TAG), and DNDi are needed that seek to address the -key determinants of HCV access, and support scaling up testing and treatment.

STIs: We note the importance of providing integrated services, the critical role of surveillance, and the challenge of antimicrobial resistance, especially as it relates to gonorrhoea. Equitable and reliable access to high-quality and affordable diagnostics, treatments, and other health products must be prioritized by Member States and should be accompanied by additional funding and the combined efforts of the public, private, and not-for-profit sectors to improve access to novel health products and appropriate services.

DNDi supports the recommendation to adopt a resolution supporting the global health sector strategies on these three matters for the period 2022–2030 and calls for Member States to actively engage in its implementation. Progress can only happen with sustained political will, appropriate health tools, and sustainable financing.

Agenda item 10: Road map for neglected tropical diseases 2021–2030

DNDi welcomes the Director General's two-year review report of the Roadmap for Neglected Tropical Diseases 2021-2030 and targets for the eradication, elimination, and control of NTDs. The Report notes areas of important progress, however, much more needs to be done and we ask Member States to take concrete actions to help meet these targets. When reviewing the report, we ask Member States to note the following issues:

Address the impact of COVID-19. The COVID-19 pandemic and related restrictions have significantly disrupted essential services and activities for NTDs. While more comprehensive data is needed, there are already examples of negative impacts. A recent [paper](#) notes that COVID-19-related restrictions were the main cause for the halving of active screening people for human African trypanosomiasis (HAT) from 2.8 million people in 2019 to 1.6 million in 2020. The current focus on pandemics, and resulting shifts in funding, should not be at the expense of programmes that address the needs of some of the most neglected populations. NTDs are a litmus test of quality universal health coverage, the basis of health security. Concerted action is needed now to implement the Roadmap while responding to COVID-19 and preparing for future pandemics, as well as coping with the impacts of climate change, such as the spread of mosquito-borne neglected tropical diseases like Dengue, to prevent the unravelling of years of progress.

Integration and cross-cutting approaches across disease areas. Many people with NTDs can simultaneously be co-infected with more than one NTD or suffer from other untreated and underdiagnosed medical conditions. There are synergies and opportunities for shared services and integration between NTD programmatic approaches and other priorities which Member States will discuss at the Executive Board, and which should be systematically identified. This includes COVID-19, other infectious diseases such as HIV, TB and malaria, and noncommunicable diseases such as diabetes, hypertension, or mental health issues. Mutualizing manufacturing needs across disease areas where feasible, pooling the demand, and exploring common delivery and access mechanisms for health tools should also be prioritized.

Build on positive examples identified, such as the remarkable progress made in the South East Asia Region where 98% of implementation units achieved the threshold for the elimination of visceral leishmaniasis as a public health problem. Greater efforts are needed to progress disease control and build future elimination programmes in the East Africa region, which is now the region with the highest burden and the region where donor funding cuts have also threatened national control programmes. Challenges remain in ensuring sustainable access to diagnostics and treatment.

Invest in R&D for missing health tools. Current tests and treatments for most NTDs have serious limitations that hamper the provision of lifesaving medical care and impede disease control and elimination efforts. New and better diagnostic tests – particularly rapid point of care tests – are needed as well as safer, effective affordable and more patient-friendly treatments that can be used in health centres, close to the communities affected. This is for example the case for mycetoma, leishmaniasis, Chagas disease, and onchocerciasis (river blindness). Furthermore, treatments should be suitable for children and pregnant and breastfeeding women. Out of the 1.7 billion people affected by NTDs, almost half are children, yet there are few treatments available for them. There has been reluctance to include pregnant women as well as women susceptible to becoming pregnant in clinical trials because of the potential risk of exposing the foetus to investigational drugs. The resulting knowledge gap leaves many women without timely or appropriate treatment options. More gender-responsive approaches should be explored. In response DNDi with its partners has proposed a safe and ethical clinical trial recruitment [framework](#) for women susceptible to becoming pregnant.

We urge Member states to:

- **Invest in research and innovation in new drugs and diagnostics**
 - a. Sustain and expand investments in innovation to accelerate research and development of health tools to close diagnostic and treatment gaps.

- b. Ensure that key treatment gaps are addressed: such as treatments designed for children, pregnant and breastfeeding women, as well as shorter, simplified regimens that can avoid the need for hospitalisation and support UHC.
 - c. Address knowledge gaps in disease biology, such as for Chagas disease, which limit the development of accurate treatments and diagnostics , by investing in fundamental research activities.
 - d. Leverage and expand the scientific, technical, programmatic and human capacity within the countries and communities most directly affected by NTDs, and in support of cross-cutting strategies across diseases areas.
- **Mobilise substantial additional resources to make significant and sustained investments.** It will also be important to facilitate sustainable financing through alignment of domestic funding strategies and expanded NTD donor resources
 - **Make concrete commitments to address the burden of NTDs, including by signing the [The Kigali Declaration](#).**

Agenda item 3 and 15.1

- Agenda 3: Outcome of the Second special session of the World Health Assembly, held to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response
- Agenda 15.1: Strengthening WHO preparedness for and response to health emergencies

DNDi notes that the Executive Board will be discussing the decision to establish an intergovernmental negotiating body (INB) to strengthen pandemic prevention, preparedness and response and the interim report of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR).

The report rightly identifies equity (or the lack thereof) as being at the core of the breakdown of the current response to COVID-19, in particular as it relates to incentivizing innovation and ensuring equitable access to essential health tools and technologies. Member States can take a stepwise approach to addressing these issues by first taking all necessary steps to ‘course-correct’ to ensure equitable access to COVID-19 vaccines, diagnostics, and treatments.

Looking ahead, DNDi would be pleased to offer our own concrete experience as an R&D organization and support a dedicated meeting, ‘deep dive,’ or continuing dialogue on:

“c) Equity in pandemic prevention preparedness and response, with particular attention to timely sharing of data and equitable access to medical countermeasures and incentivizing innovation and technology transfer to scale up local and regional production of medical countermeasures, as well as addressing access barriers;”¹

In the meantime, DNDi recommends that Member States consider the following recommendations on innovation and equitable access to inform negotiations of a pandemic instrument:

- Ensure researchers, public health experts, civil society, and political leaders from LMICs are equal partners when it comes to the conduct of R&D as well as R&D priority-setting, decision-making, and resource-allocation.
- Commit to globally agreed norms to ensure the development of essential health tools and technologies as global public goods, including open sharing of research knowledge (both inputs and outputs); transparency; management of intellectual property, including more systemic solutions to overcome persistent IP obstacles; and technology transfer.
- Agree to robust rules and mechanisms to facilitate R&D coordination and collaboration and support clinical trial networks, especially in LMICs; national, regional, and collaborative regulatory mechanisms; pooled procurement; distributed (e.g. local and regional) manufacturing capacity; affordability; and equitable allocation of essential health tools and technologies within and between countries.
- Mobilise substantial, additional, and rapid public investments to ensure at-risk financing of end-to-end ‘pathogen-agnostic’ R&D for a wide range of technologies that correspond to public health priorities and foreground the public interest.

Agenda item 21.1: Global strategy and plan of action on public health, innovation and intellectual property

DNDi supports the resolution to extend the Global Strategy and Plan of Action (GSPoA), which continues to play a critical role in strengthening innovation of and access to essential medicines, diagnostics, vaccines, and other health tools. The many challenges to equitable access to COVID-19 technologies are a stark reminder of the continued importance of the GSPoA, and the critical role WHO and Member States must play to overcome barriers to innovation and access to medical technologies.

COVID-19 has illustrated many of the challenges that must be overcome to ensure that other health crises, including future pandemics, do not result in gross inequity of access to medical technologies. The two broad lessons of the pandemic are:

First, market-based approaches alone will not be enough to discover, develop, and ensure access to necessary health tools. Traditional market incentives alone fail to respond to, prioritize, and ensure R&D investments where the need is uncertain, or 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, whether other pandemic threats, AMR, NTDs, or diseases that predominantly affect children. Even where innovations have been developed, companies engage in a limited 'contract manufacturing model' of technology transfer, in which they retain control over IP, production, supply, and pricing.

Second, major public and philanthropic funding for research – whether through direct R&D subsidies or pre-purchase commitments – de-risks the R&D enterprise and funders should therefore secure a public return on their public, or public interest-driven, investments. This means requiring clear and transparent terms and conditions that ensure open collaboration, affordability, availability, and equitable allocation of essential health tools and embracing and financing alternative, needs-driven R&D models.

These lessons, amongst others related to the management of IP, the lack of technology transfer, the need for regulatory capacity, and the lack of sustainable financing, must all inspire Member States and WHO itself to ensure the GSPoA not only looks to fully implement the mandate provided, but also learns from and overcomes the inequitable access to medical technologies that continues to undermine the global response.

DNDi urges Member States to support the report and accelerate action across the following areas of the GSPoA:

- Provide sustained and adequate financing for WHO to fully implement the GSPoA.
- Promote and develop sustainable financing mechanisms to support research and development, which should separate the price of final products from R&D costs.
- Ensure TRIPS flexibilities are implemented in national legislation, with technical support from the WHO where needed. Support the WHO and partners' work on patent databases and patent pooling and enact other policies for the pro-access management of intellectual property to ensure that all people are guaranteed timely and equitable access to the fruits of scientific progress.
- Support WHO, as well as regional and national regulatory authorities and agencies, to strengthen national and regional regulatory functions and systems, including collaborative regulatory reviews and collaborative clinical trial registration processes to ensure timely registration of safe and effective health technologies.
- Improve transparency, 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.
- Integrate key elements of the GSPoA into the deliberations of a pandemic preparedness framework to improve access to safe, effective, and affordable health technologies for both existing and future health priorities. This should be a means to accelerate and focus the GSPA recommendations on concrete deliverables related to technology transfer, strengthening regulatory capacity and sustainable financing. Member States should seek to mutualize manufacturing needs across disease areas where feasible, pool demand, and explore common delivery and access mechanisms.