



Drugs for Neglected Diseases *initiative*

Drugs for Neglected Diseases *initiative* (DNDi) 74th World Health Assembly

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 eight new and improved treatments for five deadly diseases that have reached millions of people.

In response to the Covid-19 pandemic DNDi

- Participates in Work Stream 1 of the Therapeutics Partnership of the [Access to Covid-19 Tools Accelerator](#) (ACT-A), and supports various research consortia working to identify novel, early-stage discovery projects to contribute to building the pipeline for new treatments .
- Launched [ANTICOV](#), a multi-country, adaptive platform trial conducted in 13 African countries with 26 African and global partners to identify treatments for mild-to-moderate Covid-19 outpatients;
- Co-founded and currently hosts the [Covid-19 Clinical Research Coalition](#), a coalition of nearly 400 individuals and more than 170 institutions from over 60 countries, primarily from low and middle-income countries (LMICs), to facilitate and accelerate research;
- Advocates for R&D to be driven by the public interest and for equitable access to all new Covid-19 health tools.

The following are DNDi's comments for consideration by World Health Organization (WHO) Member States on the following agenda items of 74th annual World Health Assembly:

- **Agenda item 13.4** Global strategy and plan of action on public health, innovation, and intellectual property
- **Agenda item 16** Committing to implementation of the Global Strategy for Women's, Children's, and Adolescents' Health (2016–2030)
- **Agenda item 17.** Public health emergencies: preparedness and response
- **Agenda item 26.3** WHO reform: World health days
- **Agenda item 26.4** The global health sector strategies on, respectively, HIV, viral hepatitis, and sexually transmitted infections, for the period 2016–2021

Agenda item 13.4

Global strategy and plan of action on public health, innovation, and intellectual property

The Global Strategy and Plan of Action (GSPoA) together with the expert review panel recommendations sets out a roadmap of critical actions to secure innovation of and access to essential medicines, diagnostics, vaccines, and other health tools. Despite some progress, it is still not fully implemented. However, the many challenges that gave rise to the GSPoA have yet to be overcome and have in fact become more pronounced during the Covid-19 crisis.

These include management of intellectual property, mechanisms for technology transfer, strengthening of innovative and regulatory capacity, particularly though not only in LMICs, clear policies to enable access, and sustainable financing. Lack of financing both within Member states and for the WHO is identified as a key factor limiting implementation. COVID 19 exemplified the need for transparency throughout the pharmaceutical development chain to inform public investments and strategies (manufacturing, procurement etc). This concern was widely cited at the recent Fair Pricing forum, emphasizing the need to address the recommendation of the expert Panel on transparency.

DNDi urges Member States to accelerate action across the 8 areas of the GSPA.

In particular:

- Provide funding for the WHO to take forward the Expert Panel's priority actions
- 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 & collaborative clinical trial registration processes to ensure timely registration of safe and effective health technologies.
- Implement recommendation 4 from the Expert Review Panel on transparency 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.
- Support the resolution on strengthening local production of medicines and other health technologies to improve access to safe, effective and affordable health technologies. This should be a means to accelerate and focus the GSPoA recommendations on concrete deliverables on technology transfer, innovative and regulatory capacity and sustainable financing. Medicines, vaccines and diagnostics are needed to combat both existing and future health priorities. Member States should seek to mutualize manufacturing needs across disease areas where feasible, pool demand and explore common delivery and access mechanisms.

Agenda item 16**Committing to implementation of the Global Strategy for Women's, Children's and Adolescents' Health (2016–2030)**

DNDi welcomes the progress made by WHO and partners in the implementation of the Global Strategy for Women's, Children's and Adolescents' Health. One element that has not been sufficiently highlighted in the report, however, is the need for research and development (R&D) of health tools to address the needs of children and women, who are disproportionately affected by infectious disease but whose specific medical needs are often neglected in the current biomedical R&D system.

Children are among the most neglected subgroup in drug development and paediatric formulations of drugs are often not developed. The needs of children with HIV illustrate this neglect: despite the multiplicity of antiretrovirals developed to treat HIV over the past 25 years, development of optimal paediatric formulations still lags 20 years behind that of adults. Therefore, designing studies to include paediatric arms and, where needed, accelerating processes for developing, registering, and making available optimal paediatric drug formulations is urgently needed.

We welcome the establishment by the WHO and partners of the Global Accelerator for Paediatric Formulations Network (GAP-f), of which DNDi is a member, as an important step to promote innovation of and access to quality, safe, efficacious, and affordable medicines for children.

There is a persistent knowledge gap when it comes to understanding whether and how medicines act differently in males and females. The knowledge gap is even wider when it comes to pregnant and lactating women, and women of childbearing age, who are often excluded from clinical trials due to concerns about effects on the foetus. One mitigating precaution for this group is to require the use of contraception. Long acting or not; however, contraceptives are not always widely available, culturally acceptable, adhered to, or effective in preventing pregnancy. This exclusion results in delays in the availability of medicines, and health care providers often must make decisions on treatments with little or no data on teratogenicity and effective benefits for women. Based on its experience, DNDi's has developed a [proposal](#) for a safe, ethical framework for the recruitment of women susceptible to and becoming pregnant in clinical trials of new drugs for NTDs, which is based on a benefit and/or risk assessment of participation versus non-participation. This and other proposals to ensure responsible clinical research strategies to model and contribute to best practices in gender-responsive drug development should be integrated into the strategy.

DNDi urges Member States to ensure that innovation of –and access to– safe, efficient and affordable medicines for children and women is integrated into the strategy, including a requirement to report on progress in addressing their needs.

Agenda item 17

Public health emergencies: preparedness and response

The global response to Covid-19 is enabling major scientific advances and the development of new health technologies, particularly vaccines and diagnostics, at unprecedented speed. But it has also thrown into sharp relief the limited commitment to prioritizing and financing research needs in resource-limited settings, power imbalances when it comes to who has a seat at the priority-setting and decision-making table, and the lack of coordination and globally agreed rules to ensure equitable access to any new health tools developed. Without exception, WHO Members States have faced challenges to access health tools and technologies for Covid-19. Today, the situation is critical in the Indian sub-continent and Latin America.

Global vaccine equity for Covid-19 is the defining challenge of 2021. But the need for treatments at all stages of the disease must not be ignored. Much more needs to be done to address all severe complications of the disease, including post-Covid-19 syndrome, and to prevent more patients from progressing to the point that they require hospitalization and intensive care.

Urgent steps must be taken to ‘course-correct’ to ensure equitable access to Covid-19 vaccines, therapeutics, diagnostics, and other essential health tools. In the longer term, enabling frameworks and specific policies must be put into place to ensure that for ongoing and future pandemics, the benefits of scientific progress will be equitably shared and considered global public goods, available to all.

As highlighted in the final report of the Independent Panel for Pandemic Preparedness and Response (IPPR), there is an urgent need to transform the current international architecture that has emerged to promote innovation of and access to Covid-19 tools, such as the Access to Covid-19 Tools Accelerator (ACT-A), into a “truly global end-to-end platform for vaccines, diagnostics, therapeutics, and essential supplies, shifting from a model where innovation is left to the market to a model aimed at delivering global public goods.”

DNDi urges Member States to accelerate and prioritize the following critical steps:

In the short-term, for Covid-19:

- **Share** supply of vaccines and ensure equitable allocation to countries in need, with a priority focus on frontline health workers, those with underlying conditions, and other populations at highest risk of severe disease and death.
- **Support** the proposal of South Africa and India to waive all intellectual property related to all Covid-19 technologies as a first step toward enabling transfer of technology and know-how and expansion of manufacturing capacity in and for LMICs.
- **Support** the Covid-19 Technology Access Pool (C-TAP), Medicines Patent Pool, or other IP pooling and/or technology transfer mechanisms/hubs and use their leverage to ensure companies come to the table to share relevant know-how and technology.
- **Make** investments to expand, build, and sustain manufacturing capacity in hubs in Africa, Asia, and Latin America for Covid-19 vaccines and therapeutics. Ensure investments in ACT-A are equally distributed across the pillars of therapeutics, diagnostics, vaccines and health systems.
- **Support the setting up** a dynamic, open, and collaborative platform under WHO’s leadership to improve therapeutic R&D coordination and collaboration, reduce duplication, and accelerate the availability of clinical trial results to inform clinical practice.

In the longer term, and in new pandemic preparedness and response initiatives, financing mechanisms, and legal instruments being discussed and debated:

- **Ensure** researchers, public health experts, civil society, and political leaders from LMICs are equal partners when it comes to R&D priority-setting, decision-making, and resource-allocation and integrate solutions and innovations originating in LMICs into international pandemic preparedness and response mechanisms.
- **Commit** to transparency and open sharing of research knowledge, data, and costs and require that R&D funding, including from international and multilateral organizations, be made *conditional* on results and data, promising

compounds, clinical trial protocols, and contract terms being put in the public domain – particularly when public resources are involved in funding research and/or in advanced purchase commitments.

- **Guarantee** that health tools are free of intellectual property restrictions, which can obstruct research and large-scale production of affordable health technologies, and ensure robust mechanisms and rules are in place for technology transfer, equitable allocation (within and between countries), and affordable pricing of health tools. No new legal rights should be sought, and technology owners should either not enforce their existing IP or share it via non-exclusive licensing globally; countries must use all legal mechanisms, including TRIPS flexibilities and more permanent solutions to persistent IP obstacles should be developed.
- **Mobilise** substantial additional resources to make significant and sustained investments in ‘pathogen-agnostic’ R&D for a wide range of technologies as well as cross-cutting strategies and programmes that can benefit all R&D efforts, across disease areas, particularly in LMICs, and ensure such funding comes with conditions that will ensure collaboration over competition and equitable allocation of and access to new health tools.

Agenda item 26.3

WHO reform: World health days

DNDi welcomes and supports the decision EB148(10) to adopt 30 January as World Neglected Tropical Diseases (NTD) Day. The general lack of awareness and clinical experience in recognizing and managing NTDs highlights the need to raise awareness for all NTDs. However, in order to reach the targets, set by the WHO 2021-2030 Roadmap on NTDs, much more needs to be done and we ask Member States to build on the momentum from this decision to take concrete actions to meet these targets.

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 between NTD programmatic approaches and other priorities, which Member States will discuss at the WHA, such as the management of Covid-19, malnutrition, maternal and child health, and other infectious diseases such as HIV, TB and malaria, and with noncommunicable diseases such as diabetes, hypertension, or mental health issues.

There is a need to accelerate and support R&D of health tools to close diagnostic and treatment gaps. 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. Improving health and saving lives requires bold new commitments to accelerating innovation and advancing robust test-and-treat strategies to ensure that no one is left behind.

The past year should have been a landmark year for collective action on NTDs with the launch of the WHO Roadmap and the Kigali Summit on Malaria and NTDs. However, the Roadmap launch was delayed, and the Kigali Summit has been postponed. The current focus on pandemics, and 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. We cannot protect the past decade’s gains against NTDs, and achieve the Sustainable Development Goals, without renewed and expanded public leadership, sustained funding, cooperation and resolve – including in R&D to discover, develop, and deliver the necessary health tools and technologies that will enable the achievement of elimination goals.

We call on Member States to approve decision EB148(10) and commit to support the critical building-blocks of long-term sustainable elimination of NTDs, including sustained investment in innovation and access to new health tools to prevent, diagnose and treat neglected diseases.

Agenda item 26.4

The global health sector strategies on, respectively, HIV, viral hepatitis, and sexually transmitted infections, for the period 2016–2021

The Director General's report highlights welcome progress in relation to the existing strategies for HIV, viral hepatitis and sexually transmitted infections. However, significant challenges in reaching the SDG 2030 elimination goals for these diseases must be addressed as part of the new strategies. These include:

For 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 the new strategy. In 2020, only 12 countries were on track to achieve HCV elimination by 2030. Not enough patients are diagnosed and, 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.

For HIV: In relation to HIV, additional attention needs to be given to neglected populations, particularly infants and young children who are at the highest risk of dying without access to treatment, and the leading killers of people with HIV, particularly those with advanced HIV.

- Only 53% of the 1.8 million children living with HIV globally were diagnosed and on treatment, and much more must be done to rapidly scale up access to optimized paediatric antiretroviral formulations as soon as they are approved and explore new delivery systems for adolescents and others who face unique adherence challenges.
- A more ambitious research agenda for advanced HIV is also critically important to reduce HIV-related mortality. For example, cryptococcal meningitis (CM) is a leading cause of death of people living with HIV, but while tests and medicines for prevention and treatment exist, access is extremely limited, and survival rates with the treatments commonly used in LMICs is a mere 20%. New evidence, new tools, and new targets to end HIV-related deaths, including those from CM, are emerging. Earlier diagnosis and optimized treatment could more than triple survival rates if implemented widely.

For STIs: The growing threat of drug-resistant infections is emphasized in the report on STIs and worryingly highlights, for example, that 32 of the 64 countries monitoring gonorrhoea antimicrobial resistance reported decreased susceptibility or resistance to last line treatments. The new health sector strategy should include increased investments in surveillance, development of new tests and treatments to address current and future needs, and the appropriate introduction, optimal use, and stewardship of novel and existing therapies.

DNDi welcomes and supports decision EB 148(13) which calls for a broad consultation process for the development of global health sector strategies on these three matters for the period 2022–2030.

DNDi calls for Member States to approve decision EB148(13) and actively engage in the development and implementation of new HCV, HIV, and STI strategies. Progress can only happen with sustained political will, appropriate health tools, and sustainable financing.