

Access Policy

DNDi POLICIES

Access to treatments for the most neglected diseases

I. Preamble

DNDi's vision is to improve the quality of life and the health of people suffering from neglected diseases by using an alternative model to develop drugs for these diseases and by ensuring equitable access to new and field-relevant health tools (Source: Vision Statement of DNDi).

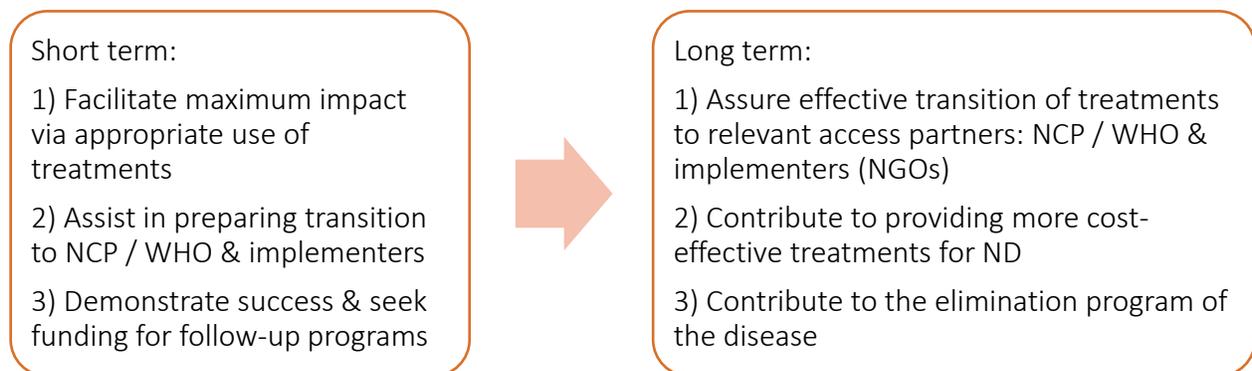
DNDi access strategy and activities are guided by the following principles:

- The need to facilitate equitable access to the new treatments developed by DNDi;
- The desire to transition these treatments, in the long run, to their natural implementers, i.e. National Ministries of Health (MOH) and Control Programs (NCP), WHO and NGOs such as MSF, in order for DNDi to focus on its core activity of Research and Development; and
- A commitment to contribute to the development of approaches for improved access and disseminate knowledge.

The access strategy will ultimately be project specific, pragmatic, and focused on the most pressing “actionable” barriers to access within DNDi's expertise and mandate.

II. Definitions and goals

Access refers to a broad range of activities that ensure treatments developed are translated into interventions which demonstrate public health impact (source PDP Access workshop September 08). DNDi goals with regards to access follow:



Clear objectives will be defined for each access activity, and tools will be built into programs from the beginning to measure progress.

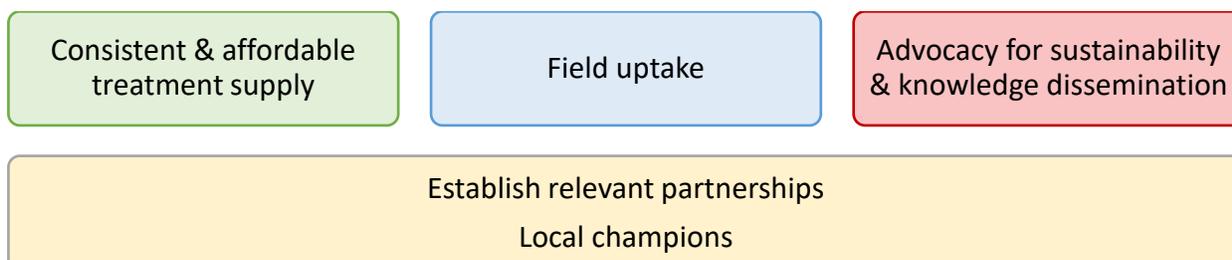
Treatments for the most neglected diseases: many barriers to access

The table below, not exhaustive, summarizes the main barriers to access. These will be addressed on a case by case basis for each project.

Treatment Supply	Field Uptake	Sustainability
<ol style="list-style-type: none"> 1. Drug production not secured in the long run / high price 2. API shortage 3. Lack of accurate demand forecast 4. Short shelf life, inadequate packaging 5. Difficult registration 6. Country or WHO guidelines not optimized 7. Procurement 8. Supply chain poorly functional 	<ol style="list-style-type: none"> 1. Underreporting of cases 2. Insufficient knowledge of patients, providers, buyers, MOH's beliefs about disease-treatments 3. Absence of significant commercial market – patients unable to purchase treatment and with low literacy rates 	<ol style="list-style-type: none"> 1. Disease is not a priority 2. Limited funding in disease endemic country 3. No relevant policies 4. NCP poorly functional, cannot integrate new treatment

III. DNDi access strategy: from developing new drugs to facilitating patients' access to treatment

DNDi access strategy aims to facilitate NCP and other implementers' access work for maximum public health impact. To that aim, DNDi will gather relevant access information during clinical development and introduce new treatments gradually. DNDi's four-pronged access strategy ranges from direct intervention to facilitation, is supported by strong global and in country advocacy for implementation, and aims to facilitate:



DNDi will promote key partnerships with WHO, NCP, NGOs, the manufacturers of those treatments and donors

DNDi will work on access at both the national and international level, i.e. with WHO, and facilitate NCP's work on products recommended by WHO. As specific projects progress towards late clinical development, DNDi will expand clinical platforms and networks to facilitate the transition to NCP/WHO with early cooperation and subsequent optimized program design.

DNDi will identify in-country champions to drive access activities. For all these partnerships and activities, it will be essential to define roles and responsibilities of partners at the conceptual and operational level.

DNDi will ensure consistent and affordable treatment supply from manufacturing partners

1. Enter into agreements with manufacturers to secure long term treatment and/or Active Pharmaceutical Ingredient (API) production. These should be at lowest Cost of Goods Sold (COGS) and price, of acceptable quality, and with IP enabling global access. DNDi recognizes that, for sustainability, the private sector partner needs benefit, visibility on volume, and risk commensurate with potential return. This requires DNDi to understand commercial opportunities for these treatments. In addition, DNDi will define a back up strategy.
2. In early and strong partnerships with WHO, NRA, MOH and other relevant agencies, DNDi will accelerate regulatory approvals and/or WHO and in country guidelines update.
3. With manufacturing and program partners, as well as WHO, DNDi will help to get relevant demand forecasts to facilitate visibility for the manufacturer, key element for production planning and prevention of stock out.

In addition to the above activities, DNDi will also facilitate the following activities led by partners:

4. Extend drugs shelf life and improve the product profile and packaging so it is relevant for targeted health systems, in partnership with manufacturers and main users.
5. Simplify procurement and supply chain in cooperation with partners such as NCP, WHO or/and distributors such as IDA.

DNDi will facilitate field uptake and partners' work on access by collecting relevant information during clinical development

In order to optimally transition treatments to its access partners, NCP/WHO and NGOs, DNDi recognizes these partners' need for epidemiologic, health economics, systems and other data in order to design the most relevant programs, and will:

1. Leverage, with a limited financial contribution, WHO surveillance activities for the most neglected diseases. DNDi has the opportunity to collect epidemiologic data through program implementation, and will do so in a way useful to contribute to WHO global surveillance. In addition, DNDi will advocate for increased resources devoted to WHO surveillance for the most ND.

2. Conduct research with program partners to better understand the populations’ knowledge, attitude and practices on disease and treatment.
3. Conduct pragmatic field Phase IIIb and IV studies and/or demonstration projects in endemic sites with partners and existing relevant platforms.
4. Evaluate synergies and likelihood of integration of new treatments into existing health care systems and explore ways to share resources with other access partners.

DNDi will advocate for implementation and sustainability, and disseminate knowledge

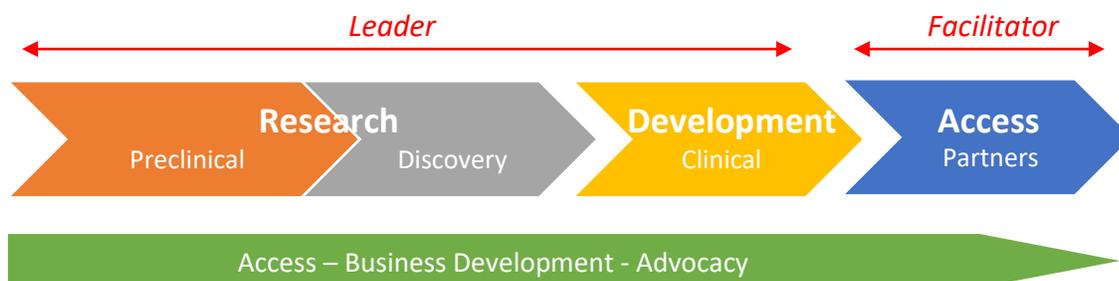
With a strong and clear voice, DNDi, with its partners, advocates to

1. Include the most ND on the global agenda, targeting donors, public health leaders, international organizations, politicians, academia and industry in developed and developing countries.
2. Increase awareness of specific diseases, funding, political will, policies & strengthening of in country NCP and other specific programs.

In addition, knowledge gained will be promptly, proactively and widely disseminated through events and publications. This will also demonstrate DNDi’s achievements and thus contribute to subsequent DNDi projects.

IV. Administration and implementation of the guiding principles

DNDi will begin to work on access from an early phase and continue through all development stages, until Phase IV trials and transition to NCP / WHO. Early phase access activities encompass the following: definition of the initial Target Product Profile (TPP), securing long term access with manufacturers, definition of a regulatory strategy, forecasting demand, and coordination with WHO to define needs for and means to increase surveillance programs. As clinical development progresses, so do access activities, to focus, in later stages, on social science research, updates of TPP and demand forecast, and design of Phase III and IV to collect useful access information. Advocacy for implementation remains a key access component all along. Business development, access and advocacy are integral elements of each project from the beginning, complementing clinical and program expertise and activities. They thus require appropriate human and financial resources. The Executive Director will put in place, subject to Board approval, administrative, financial, technical, and other mechanisms and procedures to ensure its full implementation.



V. Amendments and changes to the guidelines

DNDi retains the right to review, revise and/or amend this policy or any of its terms at its discretion. When warranted, and in agreement with the chair of the Board, the Executive Director will recommend the review, revision or amendment of this policy for further approval by the DNDi Board of Directors.