

DNDi POLICIES

ACCESS POLICY

April 2020

I. Preamble

DNDi's commitment to the health and wellbeing of neglected patients guides everything we do as an organisation, including our work to ensure equitable and affordable access to the treatments we develop. We have established a series of foundational principles that govern our approach to access – from the design of target product profiles and our stance on intellectual property and licensing, to our selection of partners and our approach to in-country implementation activities.

Since our inception, DNDi's direct involvement in in-country implementation has been relatively limited in scope compared to our core research and development (R&D) mandate – for two main reasons. First, some of our pharmaceutical partners have directly taken on this responsibility. This was the case with DNDi's artesunate-amodiaquine (ASAQ) project, for which Sanofi led on manufacturing and regulatory approval, committed at the outset to a 'no-profit, no-loss' pricing structure, and distributed drugs to Ministries of Health. Secondly, there have been instances where other organizations were better equipped to implement in-country implementation activities, either because they had the organizational expertise and/or the funding to do so.

However, given that DNDi now has several products progressing from clinical development to the implementation phase, there is a more important need for DNDi intervention to ensure access by playing a more active downstream role in implementation. This access policy revision reflects this new organizational shift – one where DNDi moves from a 'hand-off' to a more 'hands-on' approach to addressing in-country implementation issues.

This revised access policy builds on previous policies and is intended to provide high-level, directional guidance. It does not prescribe detailed requirements or guidelines for specific activities, nor does it capture our position on intellectual property, regulatory affairs, or open access to data.¹

II. Approach to access

Our approach to access is end-to-end, extending from drug discovery to product launch/introduction and scale-up.

From the very beginning of every R&D project, DNDi engages with a diverse range of stakeholders to establish access plans tailored to the specific disease, epidemiological context, and prevailing market conditions. The process focuses on identifying 1) critical potential access barriers along the product value chain, 2) potential upstream and downstream interventions to

¹DNDi policies for these and other subjects can be found at <https://dndi.org/about/dndi-policies>.

address barriers and improve patient access, and 3) the most appropriate stakeholders to take on these interventions.

To help guide this process, DNDi employs an access framework (Fig. 1) that captures a range of critical access dimensions that must be considered along the product value chain. This framework is a blend of several existing methodologies that are used by other global health organizations, including the 5A methodology, USAID Idea to Impact framework, and Global Fund/Unitaid health market framework.

Figure 1: DNDi Access Framework



* To be interpreted in accordance with DNDi's regulatory policy

Going forward, DNDi will apply four core principles to guide our access interventions:

- **Equitable and affordable access:** We have a responsibility to ensure treatments are affordable and accessible for everyone who needs them, irrespective of location, gender, socioeconomic status, or other factors.
- **Catalytic impact:** Our interventions should create the right enabling environment, respond to critical gaps, contribute to the broader knowledge base, and facilitate a paradigm shift in the way partners deliver services in order to amplify benefits for patients.

- **SMART² partnerships:** To ensure maximum impact, we proactively forge partnerships with both industry and non-industry actors and seek out partners whose expertise and reach are complementary to our own.
- **Country ownership:** For the impact of our work to be sustained, governments need to be in the driver's seat and the intervention we introduce must be integrated into national health systems.

III. Strategic priorities

DNDi's unique blend of scientific and technical expertise, combined with our strong convening power and network, puts us in a unique position to take on catalytic projects in the regions where we operate. To ensure we stay true to these core strengths, we have identified three strategic priorities where we believe DNDi can have transformational impact.

Poor health and inequitable access to healthcare are determined by a range of factors including biology, socioeconomic status, sex, gender, age, ethnicity, and race. These factors will be integrated in our strategic priorities, including through the application of social, economic, and gender considerations in programme design, as well as the incorporation of gender-disaggregated data in our reporting.

Priority 1: Securing affordable and sustainable production and supply

In line with our intellectual property and regulatory policies, DNDi is committed to working with industry and non-industry partners (e.g. Ministries of Health, the World Health Organization, non-governmental organizations, and civil society groups) to secure products of the highest quality standard at the lowest sustainable price, and to secure long-term supply agreements based on the principles of transparency, equity, and fairness. To achieve this, we will:

- **Negotiate agreements with manufacturers** for the sustainable production of drugs at the lowest sustainable price, of acceptable quality, and with intellectual property rights enabling sufficient access globally.
- **Provide the necessary support to global and national regulators** to accelerate registration of products through existing and emerging regulatory mechanisms. We will also continue to support efforts to strengthen and harmonize national and regional regulatory bodies where relevant.
- **Support interventions to reduce procurement and supply chain bottlenecks** that result in inefficiencies and disruptions in supply. This includes, but is not limited to pooled

² Specific, measurable, achievable, realistic, and timebound

procurement mechanisms, particularly in cases where supply is at risk because the market is small or fragmented.

- **Support technology transfer to local manufacturing partners**, where feasible, as a tool to build local capacity and improve security of supply and sustainable production.

Priority 2: Introduction and adoption of registered products and innovative solutions nationally and regionally

Supporting critical interventions to facilitate product introduction and adoption at national and regional levels will be a key focus of our work moving forward – carried out in accordance with the four core principles described above. Interventions will include but not be limited to:

- **Working with industrial partners to develop go-to-market strategies** that are sustainable and lead to long-term impact for patients.
- **Conducting Phase IIIb and Phase IV studies and in-country demonstration projects** to assess acceptability, feasibility, and knowledge, attitudes, and practices on diseases and treatments.
- **Supporting guideline and policy changes.**
- **Providing technical support to Ministries of Health** on a range of implementation activities, including operational planning, training and mentoring, tool-kit development, patient awareness, and data management.
- **Developing investment cases** and other health economic tools as an advocacy tool for unlocking long-term funding.
- **Engaging public leaders and patient advocates** to share lessons learned and improve access to treatment for neglected patients. Both in the design of its interventions and its advocacy, DNDi will work closely with patient networks and advocates and contribute to strengthening patient advocacy for access.

Priority 3: Improving market dynamics

Improving market dynamics refers to how we influence the practices of manufacturers, buyers, suppliers, governments, donors, healthcare providers, and consumers to improve how treatment is produced, procured, distributed, and delivered. DNDi is committed to playing a more central role in this area by helping to evaluate market shortcomings, coordinate global actors, and advocate for solutions to maximize value for money and health impact.

Because DNDi has limited buying power, we are restricted in what we can do to directly move or influence specific market levers (e.g. pricing) using traditional procurement and financing

instruments. However, our convening role with industry and non-industry partners allows us to contribute.

DNDi will focus on **strengthening market transparency** by systematically collecting and compiling market intelligence at several points during product development and launch to promote transparency and improve the rigor of the decision-making process among partners. This will include sharing timely and accurate market forecasts and evaluations of current and future market trends, including R&D cost and other pricing-related data.

DNDi will also **directly contribute to the knowledge base and formulation of global market-shaping efforts** by:

- **Identifying market barriers and solutions** to improve market dynamics and working with partners to deploy solutions.
- **Leveraging the reach and capacity of organizations** with relatively higher buying power to achieve market-shaping objectives.
- **Identifying further strategies to incentivize sustainable pricing and production**, which may entail blended finance with the support of national or regional finance institutions.
- **Supporting advocacy efforts** related to market-shaping.

IV. Amendments and changes to the policy

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 Executive Team.