



July 22, 2024

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Abby Rives, Division Director, Technology Transfer and Innovation Policy  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Tabak and Ms. Rives,

I am writing on behalf of the Drugs for Neglected Diseases initiative (DNDi) in response to the National Institutes of Health (NIH) Office of Science Policy (OSP) Request for Information on the DRAFT NIH Intramural Research Program (IRP) Policy on Promoting Equity Through Access Planning.

As the largest funder of biomedical research in the world, NIH has the responsibility and leverage, in the form of financial resources, scientific expertise, and public trust, to ensure that the inventions it helps discover and develop actually reach the patients and providers who most need access to them. A new policy to promote equitable access, if well-designed and broadly applied, has the potential to dramatically increase access to urgently needed health tools and technologies in the United States and globally. It can also set an important precedent for other Federal agencies and other public research, science, and technology institutions around the world that are also considering policy options to ensure a greater public return on public investments in health innovation.

We therefore strongly support the NIH proposal to require access planning and base the recommendations herein primarily on our concrete experience as an R&D organization that has negotiated collaborations with public, private, academic, and not-for-profit partners and implemented policies to ensure equitable access to the treatments we and our partners develop.

As such, we recommend that access planning begin at the earliest possible stage and include clear and contractual obligations to affordability; pro-access management of intellectual property (IP) to address potential barriers to R&D, production, and equitable access; registration, supply, and distribution; and transparency and open sharing of knowledge, including research inputs, processes, and outputs.

My colleagues and I stand ready to discuss these recommendations in further detail and look forward to continuing our dialogue with you as the policy is finalized and implemented.

Sincerely,

Rachel M. Cohen  
Senior Advisor

## Drugs for Neglected Diseases initiative Response to Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

July 2024

### I. Executive Summary

The Drugs for Neglected Diseases initiative (DNDi) is an international not-for-profit research and development (R&D) organization that has over the last 20 years discovered, developed, and delivered 13 treatments for six deadly neglected diseases utilizing an alternative, collaborative, not-for-profit R&D model. A key lesson we have learned is that if equitable access to health tools is to be achieved, key provisions related to access must be embedded into the innovation process itself, at the conception phase, and must be as binding as possible in contractual agreements.

We strongly support the National Institutes of Health (NIH) proposal to require access planning and welcome the opportunity to respond to this Request for Information on the DRAFT NIH Intramural Research Program (IRP) Policy on Promoting Equity Through Access Planning. We base our recommendations primarily on our concrete experience as an R&D organization that has negotiated collaborations with public, private, academic, and not-for-profit partners and implemented policies to ensure equitable access to the treatments we and our partners develop. These recommendations include:

- **Policy Scope:** Expand the policy to apply to (a) all NIH funding, in particular extramural research, as the IRP represents only 10% of the NIH budget, and (b) jointly owned, background, and collaboration intellectual property (IP) as long as it is necessary for the full use of NIH IP; this must be clarified from the start.
- **Policy Requirements:**
  - Apply the policy to both underserved communities in the United States and populations living in low- and middle-income countries (LMICs).
  - Ensure a comprehensive and systematic approach to access planning that includes binding, and enforceable terms and conditions *within* licensing agreements, whether early- or late-stage. Agreements should include contractual commitments to affordability; pro-access management of IP; technology transfer; registration, supply, and distribution; and open sharing of research inputs, processes, and outputs.
  - Require supplementary Access Plans if specific information is not available or known at the time the contract is signed.
  - Clarify the circumstances under which a waiver would be granted to a specific licensee and articulate how access would then be guaranteed.
- **Access Planning Tools:** Create specific agreement templates/checklists of key terms and conditions covering early- and late-stage to ensure that all necessary elements are incorporated in agreements, including affordability, availability, acceptability, sustainability, and transparency.
- **Assessing Efforts to Address Access:** Implement a monitoring, compliance, and enforcement framework and ensure rights are retained in the event that a licensee is unable or unwilling to deliver on access obligations.

## I. Introduction

The Drugs for Neglected Diseases initiative (DNDi) is an international not-for-profit research and development (R&D) organization that discovers, develops, and delivers new treatments for neglected patients. Since our creation in 2003 by Doctors Without Borders/Médecins Sans Frontières (MSF) as well as public health and research institutions in Brazil, France, India, Kenya, and Malaysia 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.

Equitable access has always been at the heart of DNDi's approach to innovation for neglected communities and our commitment to access influences all aspects of the organization's work – from how we define target product profiles<sup>1</sup> and manage intellectual property and licensing<sup>2</sup> to how we determine regulatory strategies and support adoption, introduction, and 'last mile' delivery of our treatments.

A key lesson we have learned over the course of the last 20 years is that if the goal is to ensure equitable access to health tools, we must embed access provisions into the innovation process itself, at the conception phase – not just once a product is in late-stage clinical development or has received regulatory approval – and ensure such provisions are as binding as possible.

As the largest funder of biomedical research in the world, the National Institutes of Health (NIH) has the responsibility and leverage, in the form of financial resources, scientific expertise, and public trust, to ensure that the inventions it helps discover and develop actually reach the patients and providers who most need access to them. A new policy to promote equitable access, if well-designed and broadly applied, has the potential to dramatically increase access to urgently needed health tools and technologies in the United States and globally. It can also set an important precedent for other Federal agencies and other public research, science, and technology institutions around the world that are also considering policy options to ensure a greater public return on public investments in health innovation.

**We are pleased to have the opportunity to respond to this Request for Information on the DRAFT NIH Intramural Research Program Policy on Promoting Equity Through Access Planning (89 FR 45003) and base these comments and recommendations primarily on our concrete experience as an R&D organization that has firsthand experience negotiating collaborations and implementing policies to ensure equitable access to the treatments we and our partners develop.**

## II. Summary of DNDi's Approach and Experience: Collaboration and Licensing Agreements

For each R&D collaboration, DNDi negotiates pro-access terms and conditions in contractual agreements with our many partners, which include public, private, academic, philanthropic, and not-for-profit entities. Private entities include large and small pharmaceutical and biotechnology companies. DNDi's public IP policy<sup>3</sup> has been fundamental to creating a common vision with public and private partners and to our ability to deliver 13 affordable and accessible treatments for six deadly diseases.

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<sup>1</sup> DNDi, [Selecting for success in the field: the target product profile](#).

<sup>2</sup> DNDi, [Intellectual Property Policy](#), updated December 2024.

<sup>3</sup> [DNDi's Intellectual Property Policy](#) includes two guiding principles: (1) the need to ensure that drugs are affordable and access is equitable for patients who need them; and (2) the desire to develop drugs as public goods when possible.

We have made our ‘model agreements’ (or templates) public<sup>4</sup> to show how we ensure equitable access to knowledge, data, and, ultimately, end products once they are approved – from the laboratory bench to the patient’s bedside.<sup>5</sup> We apply conditions at all stages of the R&D process – from early drug discovery and preclinical research to clinical trials and large-scale implementation studies.

DNDi has negotiated two types of collaboration and licensing agreements:

- **Research Collaboration and License Agreements (RCLA),<sup>6</sup>** which address early research activities ranging from early-stage discovery (hit-to-lead and lead optimization) to preclinical studies, including pharmaceutical development and manufacturing activities related to candidate compounds, until one or several candidates are selected for human clinical trials.
- **Development Collaboration and License Agreements (DCLA),<sup>7</sup>** which typically cover clinical development activities from Phase I clinical trials in healthy volunteers to Phase II/proof-of-concept and Phase III studies, as well as pharmaceutical development and manufacturing, registration and distribution/delivery activities.

Access planning at DNDi begins at the earliest possible stage and includes clear and contractual commitments to affordability; pro-access management of intellectual property (IP) to address potential barriers to R&D, production, and equitable access; and technology transfer to ensure all necessary knowledge, data, and know-how is ‘pulled through’ to the next stage of R&D and to third parties whenever necessary; registration, supply, and distribution; and transparency and open sharing of knowledge, including research inputs, processes, and outputs.

These commitments correspond with the four factors influencing access identified in the RFI, namely affordability, availability, acceptability, and sustainability – with the addition of transparency as a fifth dimension. In addition to enabling accountability, DNDi believes in the intrinsic advantages of transparency, knowledge-sharing, and open collaborations, which can attract additional researchers to a neglected field, enable more and different results, and potentially accelerate the R&D process by reducing duplication and making R&D activities more efficient and less expensive.

These five aspects form the basis for more detailed access planning downstream, whether in the form of more detailed contractual obligations or specific access plans.

### **Pro-Access Management of IP: ‘Gold Standard’ Licensing Terms and Conditions**

DNDi considers the following to be the ‘gold standard’ for licensing terms and conditions it seeks with partners:

- i. Non-exclusive, perpetual, irrevocable, royalty-free, fully paid up, sub-licensable licensing rights granted to each other:
  - a. In the field of a specific disease or diseases;
  - b. Worldwide for research, development, and manufacturing;
  - c. For endemic countries for distribution.

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<sup>4</sup> ‘Model agreements’ available at DNDi website: [Pro-access policies](#).

<sup>5</sup> Dominique Junod Moser, Pascale Boulet, Michelle Childs, Mae Shieh, Bernard Pécol, Striking fair deals for equitable access to medicines, *Journal of Intellectual Property Law & Practice*, Volume 18, Issue 4, April 2023, Pages 323–335, <https://doi.org/10.1093/jiplp/jpad025>

<sup>6</sup> RCLA template available [here](#).

<sup>7</sup> DCLA template available [here](#).

- ii. Distribution under the license is constrained to compliance with the principle of Affordable Basis, which means pricing of the final product set at the lowest sustainable level covering manufacturing and distribution costs and including a reasonable margin.
- iii. Licensing terms apply to Background IP and Collaboration IP (generated during the collaboration).<sup>8</sup>

### **Affordability**

The notion of ‘affordability’ is defined in general terms in the RCLA template and provides a framework for the negotiation of subsequent development collaboration agreements. DNDi defines “affordable pricing at the lowest sustainable level” as including: (1) the full production costs, as optimized without compromising quality; (2) direct distribution costs; and (3) a reasonable margin to ensure manufacturing and distribution on a sustainable basis. It also binds the partner in the exercise of its (perpetual) licensing rights after the contract has expired.

The definition of ‘affordable basis’ is intended to facilitate equitable access to the product in all countries where patients need the product, irrespective of a country’s economic classification. This definition also aims to ensure that the industrial partner does not incur a loss and allows a reasonable and sustainable margin in the production and distribution of the final product.

In the DCLA, the negotiating parties may go into greater detail in defining affordability by inserting a price ceiling, by setting the profit margin that would be considered reasonable, and/or by describing the cost items that may be included in production/distribution costs. The DCLA template also considers additional investments that the partner may make to improve the manufacturing process, after which the resulting cost reductions would need to be passed through to further reduce the price.

### **Sustainable Production and Supply**

DNDi works with different partners at all stages of the R&D process. There can be benefits in securing one industrial partner that will assume responsibility for pharmaceutical development, registration, and ‘last mile’ access. However, from the start of discussions about a possible collaboration a common understanding is reached with the potential partner(s) on the need to ensure equitable access for neglected populations.

While RCLAs conclude once a clinical candidate is nominated, it includes an option for the partner to maintain their involvement by becoming DNDi’s development and distribution partner. DNDi and the partner will engage in good faith negotiations to establish the terms for collaborating on the clinical development of the drug and distributing the product affordably within the designated territories.

Additionally, DNDi may grant the development partner a non-exclusive, worldwide license to utilize DNDi technology for the commercialization of the product in markets outside the territory. This license will be contingent upon the partner setting a price that enables purchasers in specific sectors to acquire the product in sufficient quantities to meet public health or individual needs, thereby preventing excessive pricing.

If the partner chooses not to exercise this option or if a development and licensing agreement cannot be successfully negotiated, DNDi is free to pursue negotiations with any other third party for clinical development and downstream access activities. In these cases, the RCLA stipulates that the licenses granted to DNDi will extend beyond the original territory, thereby incentivizing potential future partners.

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<sup>8</sup> *Idem.*

## **Termination of Rights and Survival of Access Obligations**

In cases of early termination of the collaboration – because of a partner withdrawing or defaulting in delivering its contractual obligations – DNDi agreements require that the partner extends any limited licensing rights to worldwide full exploitation rights for DNDi to continue the project in the field with a different partner.

Furthermore, to ensure DNDi rights can be efficiently exercised, DNDi agreement templates also include clauses to secure the transfer of all necessary data, material processes, know-how and other knowledge (‘technology transfer’) so that DNDi may proceed with another partner. Such ‘march-in rights’-type provisions are critical to ensure that necessary information or material is not lost and DNDi activities are minimally affected by a partner’s withdrawal.

### **III. Response to Proposed Aspects of the DRAFT NIH Policy**

#### **I. Policy Scope**

DNDi welcomes and strongly supports the NIH proposal to require access planning, including specific contractual terms and conditions, to inventions developed through its IRP. This is an important first step and if designed and implemented correctly, will make an important contribution to improving access to critically important knowledge and health tools.

However, at present, NIH’s proposed policy has several important limitations in terms of scope. First, it would only apply to “inventions made by investigators in the NIH Intramural Research Program” and second, it would only apply to inventions solely owned by the agency.<sup>9</sup> NIH’s IRP represents only about 10% of NIH’s research expenditures; an estimated 80-85% of NIH funding goes to extramural research through grants, contracts, and other awards.<sup>10</sup> While applying conditions to inventions developed through its IRP is an important first step, DNDi strongly recommends expanding this policy to apply to all NIH funding, and in particular extramural research.

Moreover, while the policy contemplates that it could be applied to jointly owned intellectual property (IP) “at a later date,” this policy could and should apply immediately to jointly owned IP to clarify this from the start. It should also apply to background and collaboration IP owned by third parties, as long as it is necessary for the full use of NIH IP.

#### **II. Policy Requirements**

First, and foremost, based on DNDi’s experience, we recommend that NIH include specific terms and conditions within licensing agreements to achieve equitable access so that these obligations are binding and enforceable, whether a technology is in early- or late-stage development. It is possible – and necessary – to build flexibility into licensing terms and conditions and to have tiers of specificity depending upon the development stage.

There may also be a need to have supplementary Access Plans if specific information is not available or known at the time the contract is signed. For example, it may be that more knowledge needs to be generated as part of the project, for example in relation to the specific disease epidemiology, supply and distribution channels, and health system and service delivery capacities in different countries.

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<sup>9</sup> Federal Register, [National Institutes of Health \(NIH\) Office of Science Policy \(OSP\): Request for Information on Draft Intramural Research Program Policy: Promoting Equity Through Access Planning](#), May 22, 2024.

<sup>10</sup> NIH, [What We Do: Budget](#).

DNDi recommends that a comprehensive and systematic approach to access planning be developed – including through specific agreement templates that cover early- and late-stage to ensure that all necessary elements are included in agreements and/or checklists of key terms and conditions. Even if not all terms will apply to all agreements, the use of standard templates and/or checklists can serve as a prompt to ensure that each of the key terms is positively considered when drafting an agreement (see section III below for further details).

At present, NIH’s proposed policy has several important limitations in terms of requirements, including that it:

- **Unnecessarily limits the populations that could benefit from it.** The new policy rightly focuses on both underserved communities in the United States and populations living in low- and middle-income countries (LMICs), but the proposed language that would incorporate a requirement for an “Access Plan” in already existing IRP model license agreements is unnecessarily limited by the “and/or” clause. **DNDi recommends removing “and/or” and replacing with “and” to ensure the broadest possible interpretation.**
- **Is too vague.** The paragraph in the draft policy of what an Access Plan (or licensing conditions) should include states that such Plans “shall include, but not be limited to, a brief description of the Licensed Product(s); the anticipated patient population(s); other products, tools, facilities, or unique resources that would be necessary for use of the Licensed Product; and *one or more strategies* to mitigate access challenges across criteria including affordability, availability, acceptability, and sustainability...”<sup>11</sup> (emphasis added). This could be interpreted to mean that, for example, just convening a meeting with local clinicians and communities to “tick the box” for acceptability would satisfy the requirement for an Access Plan. **DNDi recommends a more comprehensive and specific approach.**
- **Is triggered too late.** The current draft language states that “Within 3 months of a Licensed Product entering a first pivotal clinical trial (a Phase III trial or the equivalent), Licensee will provide NIH with an Access Plan (as defined)...”<sup>12</sup> Providing an Access Plan only three months after the beginning of a Phase III trial (or equivalent) will exclude (a) critically important provisions that can and should be in place in contractual agreements and at an earlier stage – especially to ensure knowledge transfer across the innovation lifecycle – and (b) clearly articulated (even if high-level) commitments to availability, affordability, acceptability, sustainability, and transparency, which may require that decisions be made well before Phase III (e.g. about formulation, which can be a major determinant of acceptability and affordability, or regulatory strategy, which can determine which studies are required and what ethics approval processes and timelines need to be met). **DNDi recommends that access conditions be incorporated into licensing agreements as early as possible; these early-stage contractual obligations can be complemented by more specific access planning later if specific information is not available or known at the time the contract is signed. If the licensing agreement is later-stage, these specific details can be incorporated into the contract itself.**
- **Leaves open the option for licensees to obtain a waiver.** It is not clear why a waiver would be needed. Licensees should be in a position to articulate how access will be assured, even if this plan involves working in partnership with third parties (including manufacturers, nonprofit product development partnerships, patent or technology pools, etc.) to achieve access objectives. **DNDi recommends that NIH clarify the circumstances under which a waiver would be granted to a specific licensee and articulate how access would then be guaranteed.**

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<sup>11</sup> Federal Register, [National Institutes of Health \(NIH\) Office of Science Policy \(OSP\): Request for Information on Draft Intramural Research Program Policy: Promoting Equity Through Access Planning](#), May 22, 2024.

<sup>12</sup> *Idem*.

### III. Access Planning Tools

As stated above, DNDi recommends that concrete pro-access terms and conditions be incorporated into NIH licensing agreements whenever possible to ensure that commitments to access are binding and enforceable. This can be complemented where necessary by supplementary Access Plans. Together, these can provide the basis for comprehensive access planning. This implies that there would be some sort of oversight and accountability mechanism in place to monitor progress toward successful execution of access-related activities and provide a forum for both parties to address any unforeseen issues and course-correct.

The new NIH policy should do more than “mitigate access challenges”: it should enable equity and access to be built into the innovation process itself as a key design feature, whether upstream or downstream. Access planning tools – such as specific templates and/or checklists – should be developed to incorporate the potential strategies listed in the RFI as well as other critical elements. To the extent possible, these strategies should not be considered optional; rather they should be considered minimum standards, contractual obligations, and requirements without which the plan would not be deemed acceptable. In nnex is a chart (Figure 1) with potential requirements for access planning that could be used and adapted to develop such templates or checklists.

### IV. Assessing Efforts to Address Access

As described above, even at a very early stage, it is possible to have specific (even if high-level) contractual obligations that will ensure availability, affordability, acceptability, sustainability, and transparency, complemented when needed by well-designed and more detailed Access Plans.

In our view, it is unfortunate that NIH does not “expect licensees to address each issue but instead address elements of patient access that are relevant to the specific product in question to expand access.”<sup>13</sup> We recommend that a ‘dashboard’ approach based on agreement templates or checklists be considered when NIH assesses licensing terms and conditions and Access Plans. This could help form the basis for a monitoring, compliance, and enforcement framework, which would both require developers to consider and articulate plans for all five dimensions, including in contractual agreements where possible, *and* give NIH greater leverage in ensuring weak plans are strengthened and rights are retained in the event that a licensee is unable or unwilling to deliver on access commitments.

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<sup>13</sup> Federal Register, [National Institutes of Health \(NIH\) Office of Science Policy \(OSP\): Request for Information on Draft Intramural Research Program Policy: Promoting Equity Through Access Planning](#), May 22, 2024.



**Figure 1: Potential Requirements for Access Planning**

	<b>Upstream (early discovery, preclinical research)</b>	<b>Downstream (Phase I, II, III clinical trials, registration, distribution)</b>
<b>Affordability</b>	<p>Define target price in TPPs, whenever possible</p> <p>Commit to ‘affordability’ of the final product (with a clear definition of affordability)<sup>14</sup></p>	<p>Determine ‘lowest sustainable price’ for specific product<sup>15</sup> and define ‘price ceiling,’ where appropriate, as a condition of licensing</p> <p>Optimize dose, formulation, and manufacturing processes to reduce cost of goods (COGs)</p>
<b>Availability</b>	<p>Define high-level regulatory strategy and include commitment to preparation and submission of all filings and applications for regulatory approval</p> <p>Include ‘technology transfer’ provisions to ensure all necessary rights will be made available, if needed, to at least one third party to continue clinical development</p>	<p>Provide more detailed regulatory strategy, including list of endemic countries (and/or target communities), and sequence and estimated timelines for registration</p> <p>Submit additional commercialization plans targeted to other markets where needs exist</p> <p>Include ‘technology transfer’ provisions to ensure all necessary rights will be made available, if needed, to at least one third party to continue to make/distribute the product and provide such third parties with the full registration dossier and any additional relevant IP, data, material processes, or know-how necessary to manufacture the product</p> <p>Commit to engage with international and national clinical guideline development processes, as appropriate, to ensure incorporation of latest evidence related to product and support adoption and uptake</p>
<b>Acceptability</b>	<p>Conduct early needs assessments to help determine key elements of TPP, e.g. safety, route of administration, stability</p> <p>Ensure input into TPP definition from local clinicians, researchers, regulators, patient/community groups</p>	<p>Implement community advisory mechanism(s)</p> <p>Commit to partner with ministries of health/clinicians and patient/community-based organizations for service delivery, where appropriate</p>
<b>Sustainability</b>	<p>Include technology transfer provisions (as above) to ensure further development and ultimately (if successful) access to final product</p> <p>Describe plans to work with relevant public health-oriented partners</p>	<p>Define mechanism(s) by which geographically diverse production will be enabled to ensure supply autonomy and stability, where appropriate</p> <p>Define financing plan (e.g. via commercial and/or public funding, insurance coverage decisions, global health actors, e.g. Global Fund, Gavi, etc.)</p> <p>Define plans to meet high or low demand (including via demand aggregation/pooled procurement mechanisms, e.g. Global TB Drug Facility, PAHO revolving funds)</p> <p>Define plans to work with relevant public health-oriented partners such as not-for-profit product development partnerships, patent and technology pools, etc., if appropriate</p>
<b>Transparency</b>	<p>Disclose COGs</p> <p>Ensure open sharing of research inputs, processes, and outputs</p> <p>Publish research results (negative and positive and in open access journals whenever possible)</p>	<p>Include audit right on the final price as a contractual commitment</p> <p>Require regular reports on sales (to assess whether access is achieved or not)</p> <p>Document and publish R&amp;D costs</p>

<sup>14</sup> Again, DNDi defines ‘affordable pricing at the lowest sustainable level’ as including: (1) the full production costs, as optimized without compromising quality; (2) direct distribution costs; and (3) a reasonable margin to ensure manufacturing and distribution on a sustainable basis.

<sup>15</sup> *Idem.*