

DNDi POLICY REPORT
SEPTEMBER 2026

IMPLEMENTING ARTICLE 9.5 OF THE WHO PANDEMIC AGREEMENT



Building on current policy and practice
for publicly funded R&D

DNDi
Best Science
for the Most Neglected

EXECUTIVE SUMMARY

Public R&D funding plays a central role in incentivizing and enabling the development of new health tools, as was made evident during the 2020-2023 COVID-19 pandemic. The use of public funds achieved notable scientific successes in the development of vaccines and other health technologies for COVID-19. Yet at the same time, vast inequities in access to these products highlighted core weaknesses and systemic challenges in global and national access and innovation systems.

The Pandemic Agreement, adopted by Member States during the World Health Assembly in May 2025, seeks to address the lessons of the COVID-19 pandemic by providing a framework for more equitable pandemic prevention, preparedness, and response. As part of this framework, the Agreement includes several provisions aimed at strengthening the R&D ecosystem.

In particular, Article 9.5 requires Member States to develop and implement national and/or regional policies related to the inclusion of access provisions in public R&D funding arrangements for pandemic-related health products. Article 9.5 presents Member States with a landmark opportunity to leverage the power of public funding to drive innovation and access. As one of the few binding ‘shall’ commitments in the Pandemic Agreement, the obligations under Article 9.5 carry both legal weight and ethical urgency.

This publication outlines examples of both well-established and newly emerging policies and practices from which Member States can learn and build as they seek to fulfil these obligations. However, existing approaches do not yet represent an optimal or comprehensive framework of access and innovation conditions for publicly funded R&D, nor is there a one-size-fits-all approach to establishing such frameworks. In practice, policies and practices to secure the successful development of, and equitable access to, the results of publicly funded R&D will need to address multiple considerations across the access and innovation continuum, as appropriate to different national and regional contexts.

What this publication’s examples make clear, though, is that Member States do not need to start from scratch: a growing body of practical experience already exists to draw from, adapt, and build upon as national and regional frameworks take shape.

AS ONE OF THE FEW BINDING ‘SHALL’ COMMITMENTS IN THE PANDEMIC AGREEMENT, THE OBLIGATIONS UNDER ARTICLE 9.5 CARRY BOTH LEGAL WEIGHT AND ETHICAL URGENCY.

MEMBER STATES DO NOT NEED TO START FROM SCRATCH: A GROWING BODY OF PRACTICAL EXPERIENCE ALREADY EXISTS TO DRAW FROM, ADAPT, AND BUILD UPON.

Contents

I. Public R&D funding and the Pandemic Agreement	3
II. Current policies and practices	4
III. Considerations for implementation: from policy to agreement provision	12
IV. Conclusion: achieving greater impact with public R&D funding	14
Recommendations & next steps	15
Annex 1: DNDi’s access policy framework & model agreement provisions	16
Annex 2. Additional resources	18
References	19



I. PUBLIC R&D FUNDING AND THE PANDEMIC AGREEMENT

The COVID-19 pandemic showcased the central role of public R&D funding in incentivizing and enabling the rapid development of new vaccines, diagnostics, and therapeutics. At the same time, the vast inequities in access to the resulting products highlighted critical gaps in national policies and practices, and a lack of global norms, for ensuring equitable access to the results of public R&D funding.

Further, systemic shortcomings in the governance of health R&D were exposed by the barriers to scientific collaboration faced by research organizations, including difficulties in accessing compounds, data, and comparator products for urgently needed clinical trials, as well as limited post-trial access arrangements for resulting products.

The Drugs for Neglected Diseases initiative (DNDi) has 20 years of experience conducting R&D to meet the needs of neglected populations. The barriers that DNDi faced during COVID-19, as well as wider R&D challenges identified during the COVID-19 response – such as a lack of geographically diversified manufacturing capacity, clinical trial and regulatory bottlenecks, and fragmented research efforts – exemplify the chronic failures in medical innovation and access that DNDi and its partners have worked to address over the past two decades.

The Pandemic Agreement, adopted by Member States at the World Health Assembly in May 2025, seeks to address these and other persistent gaps by providing a framework for more equitable pandemic prevention, preparedness, and response. The Agreement contains several provisions aimed at enabling a strengthened R&D ecosystem, including Article 9.5, which relates specifically to public R&D funding.

For the first time in an international health-related legal agreement, Article 9.5 explicitly recognizes the significant role of public funding – and the policies attached to that funding – in shaping innovation and access outcomes. While negotiations on the PABS Annex of the Agreement are ongoing, Member States continue to make investments in R&D, and prompt action to implement the obligations in Article 9.5 is a key opportunity for achieving greater impact with public funding.

What are the requirements of Article 9.5?

Article 9.5 of the WHO Pandemic Agreement*

Each Party shall develop and implement national and/or regional policies, adapted to its domestic circumstances, regarding the inclusion of provisions in publicly funded research and development grants, contracts, and other similar funding arrangements, particularly with private entities and public-private partnerships, for the development of pandemic-related health products, that promote timely and equitable access to such products, particularly for developing countries, during public health emergencies of international concern, including pandemic emergencies, and regarding the publication of such provisions.

Such provisions may include: (i) licensing and/or sublicensing, particularly to manufacturers of developing countries and for the benefit of developing countries, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) provisions enabling access to technology to facilitate research and development and geographically diversified local production (iv) publication of relevant information on clinical trial protocols and relevant research results; and (v) adherence to product allocation frameworks adopted by the World Health Organization.

Article 9.5 is one of the few binding ‘shall’ commitments in the Pandemic Agreement – carrying both legal weight and ethical urgency. It requires Member States to develop and implement national and/or regional policies related to public R&D funding. Importantly, those policies must relate to both: (i) the inclusion of access provisions in public R&D funding arrangements for pandemic-related health products and (ii) the publication of those provisions.

* <https://www.who.int/health-topics/who-pandemic-agreement>

Why does Article 9.5 matter?

The odds of successfully driving healthcare innovation from discovery all the way through to public access to new products can be greatly improved through government policies that ensure the impact of public R&D funding. Embedding access provisions in related contractual and funding mechanisms should be a key component of national and regional R&D ecosystems.

The pathway from early research to the availability of an end product requires multiple 'hand-offs' between product innovators, developers, and manufacturers. Decisions made at each stage of this journey can have a decisive impact – determining both the possibility of follow-on innovation and the likelihood that resulting products will be affordable and accessible where they are needed most, including during health emergencies.

By ensuring that access policies and provisions apply across the innovation and access continuum, especially for publicly funded R&D, governments can ensure that public interest and return remain at the heart of these investments. By publishing these policies and provisions, Member States will provide transparency and clarity over access and knowledge-sharing expectations and commitments, allow for alignment among funding agencies, and enable other stakeholders to hold both funding agencies and funding recipients accountable for the fulfilment of their commitments.

Five examples of the types of access provisions that could be included in public R&D funding mechanisms are listed in Article 9.5(i)–(v). However, these examples are neither a prescriptive nor an exhaustive list of all possible approaches. It is up to Member States and their funding agencies to determine the full range of policies and provisions that are most appropriate for securing equitable access to the results of their funding.

II. CURRENT POLICIES AND PRACTICES

National science, technology and innovation frameworks

Many countries have science, technology and innovation (STI) laws or policies that recognize the importance of public funding and governance in R&D in both healthcare and other sectors. Governments seek to mobilize public funding and attract investment to strengthen domestic R&D ecosystems. However, in many countries, these frameworks encompass a range of economic, industrial, and public health objectives that may not always be fully aligned.

The implementation of Article 9.5 provides an opportunity to better align the objectives and impact of national strategies by creating or amending policy frameworks that enable and incentivize innovation while also ensuring that public R&D funding delivers equitable access and public health impact.

Philanthropic and non-profit approaches and resources

This publication focuses on the current – and potential future – approaches of national governments and public agencies, but many philanthropic and non-profit R&D funders and product development partnerships have well-established access policies and practices that have been developed, refined, and proven effective over time. Although these organizations operate with different mandates and leverage than governments and public agencies, examples of non-profit and philanthropic approaches may be a useful reference point for Member States.

One such example is DNDi's access and open innovation framework, details of which are set out in Annex 1. Similarly, non-profit funders such as the Gates Foundation, CEPI, and the Wellcome Trust have published policies, frameworks, and guidelines setting out their respective approaches to the development of and access to healthcare innovations.

There are also a number of published resources providing analysis and examples of approaches to access strategies for R&D, including GHIAA's Equitable Access Toolkit and the UNDP/Uniting Efforts-commissioned survey on Planning for Access During Research and Development. Details on these and other resources are listed in Annex 2.

Existing policies and practices in the context of Article 9.5

This publication aims to provide examples of existing national and regional approaches to access strategies adopted by Member States. The examples outlined below are not exhaustive and are categorized in line with the proposed access provisions for public R&D funding set out in Article 9.5(i)–(v) of the Pandemic Agreement.

Some of these approaches have been in effect for many years. For example, the US Bayh-Dole Act was adopted in 1980 to incentivize the development and commercialization of government-funded inventions with safeguards for public availability. However, a number of new policies and practices have been introduced in recent years, such as the United States NIH Access Planning Policy, Spain's National Pharmaceutical Strategy,⁶ and others discussed below.

These emerging policies and practices potentially indicate a broader shift in national and regional approaches to leveraging public funding to drive access

and innovation for medical products that national implementation of Article 9.5 can solidify and amplify.

The examples below are intended to provide a base from which Member States can learn and build. However, gaps remain to be addressed, including in how access policies and strategies are effectively applied and enforced. These examples of current approaches are not presented as an optimal or comprehensive framework of all access conditions that should or could be applied to publicly funded R&D.

Further, these examples are not mutually exclusive and should not be considered in isolation. In practice, the successful development of, and equitable access to, the products and other outputs resulting from public R&D funding is likely to require policies and provisions addressing multiple considerations across the access and innovation continuum, as appropriate to different national and regional contexts.

Type 1 provisions

Licensing or sublicensing obligations

Article 9.5 text: *(i) licensing and/or sublicensing, particularly to manufacturers of developing countries and for the benefit of developing countries, preferably on a non-exclusive basis.*

How can it impact access to health products?

Requirements for funding recipients to grant licenses to publicly funded patents and other intellectual property (IP) rights to third-party developers or manufacturers, if needed, can provide a mechanism for addressing accessibility, affordability, and availability needs, including, but not limited to, those of developing countries or underserved populations. The use of non-exclusive licenses preserves the opportunity to grant licenses to other entities for R&D of other products, or for manufacturing scale-up and supply of the same licensed product, potentially enabling price competition and increasing supply security while allowing the patent owner to retain the rights to commercialize the product.

Policy and practice examples

Publicly funded R&D often results in the generation of intellectual property rights, which can be in the form of patents or trade secrets. Patent filing is often used as a strategy for protecting the IP owner's commercial interests. Patents and other IP protections can limit, delay, or block downstream innovation, as well as timely and affordable access to an end product, if the rights are not appropriately managed.⁷

The grant of licenses or sublicenses to manufacturers, including those from developing countries, to allow manufacturing of a product to meet national or regional needs, as proposed under Article 9.5(i), is a mechanism for the access-oriented management of IP rights. This approach can be considered as one component of licensing strategies that aim to enable broader access to the products and other results arising from public R&D funding.

Some examples of policies and practices related to the access-oriented management of publicly funded IP include:

Canadian International Research and Development Centre (IDRC) grant terms and licensing guidelines

Mechanisms in the IDRC's General Grant Terms and Conditions⁸ to ensure the management of IP generated with its funding in a way that supports affordability and availability include:

- ▶ Funding recipients must obtain the IDRC's consent before making patent applications and/or licensing or assigning any IP rights arising from the funding. The IDRC has the right to apply certain conditions to its consent.
- ▶ Funding recipients must enter into an Intellectual Property Rights Agreement⁹ with the IDRC when it is deemed likely that a Project Invention (i.e., patents

or patentable IP) will be created. Under the terms of the template Intellectual Property Rights Agreement, when a funding recipient files a patent application, the IDRC will provide a list of countries *‘where rights and licenses to the Project Invention and related Project Intellectual Property Rights must be made available to end users on reasonable terms and conditions which promote affordable and widespread access.’*

Along with its grant terms and related IP rights agreement, the IDRC has published Guidelines for Licensing Project Inventions.¹⁰ These guidelines state that license agreements should be designed to ensure that any resulting products are *‘made available in low and middle-income countries as promptly as possible on terms that target beneficiaries can afford.’* Suggested licensing strategies outlined in the guidelines include:

- ▶ Provisions for tiered, subsidized, at-cost or no-cost pricing models;
- ▶ Non-exclusive licensing or limitation of the scope of exclusive licenses;
- ▶ Detailed and enforceable contractual milestones;
- ▶ Reserving non-commercial and educational use rights for public sector organizations; and
- ▶ Requiring that licensed rights remain available in all countries during a health emergency.

Philippines Technology Transfer Act and IP Guidelines

The Philippines Technology Transfer Act¹¹ requires the State to *‘establish the means to ensure greater public access to technologies and knowledge generated from government-funded R&D while enabling, where appropriate, the management and protection of related intellectual property.’* Actions that government funding agencies must take include monitoring the effectiveness of a funding recipient in protecting and commercializing publicly funded IP, as well as ensuring sufficient freedom to use the IP for further research *‘to expand the knowledge frontier’* and to meet publication obligations.

The Guidelines on Intellectual Property Valuation, Commercialization & Information Sharing¹² subsequently issued by the Department of Science and Technology (DOST), Department of Trade and Industry, and Intellectual Property Office of the Philippines require the public funding agency and the funding recipient to *‘use their sound discretion in determining whether IP protection should be sought and enforced’* as the most effective means of achieving public benefit. The guidelines additionally remind funding recipients that the primary objective of IP commercialization agreements must align with the requirements of the Philippine Technology Transfer Act to enable greater public access to the technologies and knowledge generated from public R&D funding. The guidelines further require licenses of publicly funded IP to be guided by the principle of public interest over income generation, including *‘the assurance of greater accessibility and affordability to all persons*

or entities who may need the technologies.’ Some of the suggested approaches for achieving affordability and accessibility objectives outlined in the guidelines include limiting the territory and field of any exclusive license, and reserving rights to grant licenses to third parties that can address unmet market or public health needs.

South Africa IPR Act and SAMRC policies

South Africa’s Intellectual Property Rights from Publicly Financed Research and Development Act (‘IPR Act’) requires that any transactions for the licensing or assignment of publicly funded IP take into account a list of considerations including preferring the use of non-exclusive licensing and granting preference to parties that seek to use the IP in ways that provide optimal benefits to the economy and quality of life of the people of South Africa.

Under the South African Medical Research Council (SAMRC)’s general funding terms and conditions,¹³ funding recipients must protect, manage, and commercialize publicly funded IP in accordance with the IPR Act. This includes a requirement for funding recipients to include affordability and accessibility provisions in any future commercialization agreements.

The SAMRC’s Management and Commercialization of Intellectual Property Policy¹⁴ also sets out similar conditions for the licensing of SAMRC-owned IP, requiring that all licenses granted by SAMRC that *‘relate to new health solutions that may benefit developing country or poorer populations shall incorporate socially responsible licensing provisions to ensure affordable access.’*

India DBT IP Guidelines and BIRAC Global Access Terms

The Indian Department of Biotechnology’s (DBT) IP Guidelines¹⁵ recognize that *‘IP arising out of public-funded research is a huge asset and must be appropriately harnessed for maximizing socio-economic impact and achieving public good.’* The Guidelines include principles for the use of both exclusive and non-exclusive licensing as potential means of IP commercialization, and funding recipients are required to report details of licensing mechanisms to DBT. Among the licensing principles in the Guidelines are requirements for exclusive license agreements for technologies intended for large-scale public deployment to include an affordability provision for Indian markets.

The Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit enterprise established by DBT to strengthen biotechnology innovation capabilities in India to increase global competitiveness and develop affordable products.¹⁶ BIRAC’s template Grant-in-aid Letter Agreement¹⁷ sets out an IP Governing Framework with global access requirements, including that *‘Project Developments and/or New IP are made available and accessible at an affordable price to people most in need within developing countries.’*

Reserved rights for the State

In addition to establishing requirements for funding recipients to manage publicly funded IP in a manner intended to achieve public benefit, some countries have established laws or regulations that allow the State to use publicly funded IP if it is needed to respond to an emergency or support the public interest.

This approach is included in the Philippines Technology Transfer Act and South Africa's IPR Act referenced above. In the case of the Philippines Technology Transfer Act, a government funding agency has the right to assume ownership of potential IP rights in the event of an emergency *'or where the public interest requires, and in particular concerns for national security, nutrition, health, or the development of other vital sectors of the national economy.'* In such cases, the funding agency must share any profits that it generates with the funding recipient, and the IP rights will revert to the funding recipient once the emergency or public interest requirement has ended. The South African IPR Act requires that all licenses or assignments of publicly funded IP include a royalty-free license to the State *'to use or have the intellectual property used throughout the world for the health, security and emergency needs of the Republic.'*

A further example is the national law establishing **Colombia's National Development Plan 2022 – 2026**,¹⁸ which allows the State to reserve the right to obtain a non-exclusive license to any IP derived from publicly funded projects, if required in the public interest. The State may also require that the owners of publicly funded IP transfer ownership to the State for national defence or security purposes. The relevant article of the national law is also incorporated into the terms of reference for health R&D grants from the Ministry of Science, Technology and Innovation.¹⁹

Government licensing during COVID-19

The Spanish National Research Council (CSIC) and the US National Institutes of Health (NIH) contributed to the WHO COVID-19 Technology Access Pool (C-TAP, now the Health Technology Access Programme – HTAP) in the form of non-exclusive licenses to the Medicines Patent Pool (MPP).²⁰ These licenses aimed to facilitate equitable access to government-developed technologies by allowing manufacturers sublicensed by MPP to use the licensed IP to develop and manufacture products to be made available on an affordable basis.

Type 2 provisions

Affordable pricing

Article 9.5 text: *(iii) affordable pricing policies*

How can it impact access to health products?

Affordability is widely acknowledged as a key component of equitable access. Assessment of an 'affordable price' is likely to depend on the context of a particular product and the patients that it needs to reach, taking into account both sustainability for the manufacturer and affordability for local and regional needs. The development and implementation of affordable pricing policies or provisions for public R&D funding agreements provides an opportunity to set clear definitions and enforceable obligations for the affordability of publicly funded products. Policy and practice examples

Affordability requirements for Horizon Europe programmes

The EU Council Regulation²¹ establishing the rules and objectives for the Global Health European & Developing Countries Clinical Trials Partnership 3 (EDCTP3) and the Innovative Health Initiative (IHI) includes a requirement for funding recipients to ensure that products arising from EDCTP3 or IHI-funded projects are made *'affordable, available and accessible to the public at fair and reasonable conditions.'*

This requirement is reflected in the 2026 programme of work for EDCTP3,²² which states that particular attention will be paid to ensuring that funding recipients understand their legal obligation to ensure affordable access.

The IHI 2026 Work Programme²³ similarly outlines a specific provision for relevant projects that will require funding recipients to use their best efforts to make products based on the results of clinical studies under an IHI project *'broadly available and accessible, at fair and reasonable conditions.'*

For projects funded under both EDCTP3 and IHI, affordability obligations will continue to apply for four years after the project ends.

Indian Council of Medical Research (ICMR) reasonable pricing requirements

The ICMR's Guidelines for Technology Development Collaboration,²⁴ which apply to products developed with ICMR support, include a requirement for ICMR's grantees, licensees, and collaboration partners to *'make every effort to commercialize the technology at a reasonable price,'* as well as to make the product available at a discounted price to the Government of India, or as otherwise required in the national interest.

Access to technology

Article 9.5 text: (iii) *provisions enabling access to technology to facilitate research and development and geographically diversified local production*

How can it impact access to health products?

Sharing data, materials, processes, know-how, and other information – including through disclosure, licensing, and technology transfer agreements – can provide the technical knowledge and training needed for researchers and geographically diversified developers and manufacturers to develop and supply quality-assured products that meet national and regional accessibility, availability, and affordability needs.

The development of R&D and manufacturing expertise through disclosure and technology transfer arrangements for the results of public funding can also contribute more broadly to the regional capacity strengthening objectives of Article 11 of the Pandemic Agreement.

Policy and practice examples

Collaboration and technology transfer under EDCTP3

EDCTP3's 2026 work programme encourages funding applicants and recipients to collaborate with the Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) hub* or other African partnerships, including through technology transfer agreements. It also requires institutions and researchers from sub-Saharan Africa to be strongly represented in funded research consortia.

UK National Institute of Health Research (NIHR) global health research contracts

The NIHR uses a standard research contract for global health research funded using Official Development Assistance.²⁵ The contract terms require that any proposed commercial use of IP, know-how, or data generated with the NIHR funding includes 'a clear plan to build new businesses and/or achieve business growth in the relevant LMIC(s).'

The NIHR has also published core guidance for its global health research programme which supports applied health research for the direct and primary benefit of LMIC populations. This guidance includes requirements for building sustainable and equitable partnerships, as well as training and capacity strengthening at both individual and institutional levels.

Inclusion of technology transfer in license agreements

Technology transfer commitments can be included as part of licenses of publicly funded IP to enable the licensee to make effective use of the licensed rights and successfully manufacture a licensed product. The license agreement between CSIC and WHO C-TAP/ MPP referenced under Type 1 provisions, above, is one example of technology transfer for IP developed with public funding. CSIC's technology transfer commitments[†] include:

- ▶ Provision of materials at manufacturing cost;
- ▶ Facilitating the transfer of materials and know-how from CSIC's manufacturing partner; and
- ▶ Technical support including training for engineers, direct advice on the use of know-how for product manufacturing, and consultation on questions including quality and regulatory matters.

* MAV+ is an EU –AU partnership aimed at tackling barriers to manufacturing and access to health products and technologies in Africa. https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives/team-europe-initiative-manufacturing-and-access-vaccines-medicines-and-health-technologies-africa_en

[†] An extract of technology transfer provisions from the agreement is available from: https://ghiaa.org/provision_document/csic-mpp-c-tap-covid-19-vaccine-patent-and-material-license-agreement-7/

Publication of clinical trial protocols and research results

Article 9.5 text: (iv) publication of relevant information on clinical trial protocols and relevant research results

How can it impact access to health products?

Timely and open publication of clinical trial protocols and research results enables the global research community to access and build upon existing research, thereby reducing duplication and supporting the efficient use of resources. The broad dissemination of research results can also help to build public trust in healthcare interventions.

Policy and practice examples

WHO Joint Statement on Public Disclosure of Results from Clinical Trials

A number of public funding and research agencies are signatories of the Joint Statement on Public Disclosure of Results from Clinical Trials²⁷, which recognizes that ‘prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance.’ Signatories of the joint statement commit to developing and implementing a policy specifying timeframes for the prospective registration of clinical trials and disclosure of trial results. Examples of such policies from joint statement signatories include:

- ▶ UK NIHR Policy On Clinical Trial Registration & Disclosure Of Results;²⁸
- ▶ French Institut national de la santé et de la recherche médicale (INSERM) Good Ethical Practices and Open Science Charter;²⁹ and
- ▶ Research Council of Norway (RCN) Requirements and Guidelines for Registration and Disclosure of Medical and Health-Related Studies Involving Human Participants.³⁰

Open access and open science

Open science approaches include the publication of research results, as proposed under Article 9.5(iv), but they can also extend more broadly to the sharing of research practices, data, and methods in a collaborative and transparent approach to scientific research.³¹ Building on multilateral initiatives such as the UNESCO Recommendation on Open Science,³² a number of countries and national research agencies have moved towards establishing open science policies and practices.³³ Some examples of these approaches are outlined below; further examples are available from the EC-OECD STIP Compass Open Science Policy Portal.*

- ▶ **Malaysia – Open Science Guidelines and Platform:** The Malaysia Open Science Platform (MOSP) initiative was launched by the Malaysian Ministry of Science,

Technology and Innovation (MOSTI) and the Academy of Sciences Malaysia (ASM) in 2019. MOSP was subsequently identified in Malaysia’s National Policy on Science, Technology and Innovation 2021–2030 as part of an open data-sharing strategy to promote research, development, commercialization, and innovation. In 2023, MOSP was officially launched as a publicly accessible research data-sharing platform.

MOSP developed the National Guidelines on Open Science in Publicly Funded Research in response to the national policy. These guidelines, which were developed to align with the OECD’s Principles and Guidelines for Access to Research Data from Public Funding,³⁴ apply to all research activities conducted in universities, research institutes, and government entities that have received funding from the Malaysian government.

Specific research data management requirements for publicly funded research in the national guidelines include developing data management plans, depositing research data in an institutional repository, and making data available for sharing via MOSP.

- ▶ **South Africa – Open Science Policy:** The South African Open Science Policy applies to publicly funded research processes and outputs, and to data acquired or generated utilizing public funds. It was established following a 2019 White Paper on Science, Technology, and Innovation, which mandated the development of a national open science framework.

The policy defines open access in the publicly funded context as ‘enabling appropriate access, utilization and sharing of publicly funded research outputs and data to all levels of society.’ It establishes six guiding principles: (i) FAIR[†] data and outputs; (ii) use of CARE[‡] principles for indigenous data governance; (iii) TRUST[§] principles for data repositories; (iv) flexible, context-driven approaches to open science; (v) a sustainable implementation model; and (vi) an ‘as open as possible, as closed as necessary’ approach to the sharing of research outputs.

The policy recognizes the need for alignment with existing laws, including those related to intellectual property. It also acknowledges that open science must be supported by an appropriate infrastructure, and proposes the establishment of an Open Science Observatory for monitoring and evaluating open science outcomes.

* <https://stip.oecd.org/stip/open-science-portal>

[†] Findable, accessible (discoverable), inter-operable, and re-usable.

[‡] Collective benefit, authority to control, responsibility, and ethics

[§] Transparency, responsibility, user community, sustainability, and technology

- ▶ **Brazil – institutional policies and repositories:** Some public health research and research funding institutions in Brazil have adopted institutional policies promoting open science, open access, and research data sharing. For example:
 - The São Paulo Research Foundation's (FAPESP) approach to open science centres on making the results of research funded by FAPESP publicly available as quickly as possible while safeguarding the principles of scientific ethics, privacy, and security, and the protection of intellectual property.³⁵ FAPESP's open science initiatives include:
 - ▶ The Scientific Electronic Library Online (SciELO) programme to support research communication infrastructure (created, funded, and governed in collaboration with other public agencies);
 - ▶ A code of good research practices that highlights the need for transparency of FAPESP-funded research processes and results;
 - ▶ An open access policy that requires all articles arising in whole or in part from FAPESP funding to be made publicly available;
 - ▶ A requirement for data management plans describing the data that will be generated by funded research, how it will be made public, and how it will be preserved; and
 - ▶ COVID-19 Data Sharing/BR, an open data repository for COVID-19 testing in Brazil.
 - **Fiocruz**, a public health research and development institution affiliated with the Brazilian Ministry of Health, launched a policy on Open Access to Knowledge in 2014,³⁶ along with a paper on the development and implementation of the policy.³⁷ The objectives of the policy include supporting free public access to, and greater visibility of, the institution's intellectual output. The main vehicle for operationalizing the policy is Arca Dados, Fiocruz's official institutional repository.
- **Spain – open science strategy and institutional repository:** Spain's STI law³⁸ requires open access to any results of publicly funded research that are published in scientific journals. The National Open Science Strategy (2023–2027)³⁹ builds on the STI law by making compliance with open access publication obligations an assessment criterion for public funding calls and requiring strengthened interministerial coordination for compliance monitoring. The strategy further requires the development of data management plans for results of publicly funded research and incorporates consideration of open science approaches into the scoring criteria for public funding proposals.

At an institutional level, CSIC's open access mandate⁴⁰ encourages the deposit of peer-reviewed publications, metadata, and supporting datasets in the 'Digital. CSIC' repository. Supporting datasets must be FAIR and accompanied by a standard licence that indicates the conditions of use and favours scientific reproducibility. The mandate also indicates that commitments to open science will be considered favourably in evaluation processes. To support compliance, CSIC provides training and support on open science-related issues.
- **Mexico – open access laws:** Mexico's STI law⁴¹ requires open access to results and other information derived from publicly funded research. In accordance with the requirements under the STI law, a national repository⁴² has been established for the publication of research results.

The terms of reference for scientific research funding from the Department of Science, Humanities, Technology, and Innovation (SECIHTI)⁴³ include a corresponding obligation for open access publication of research results, enabling their integration into the national repository to contribute to the transparency, reproducibility, and social impact of publicly funded research.

Type 5 provisions

Product allocation frameworks

Article 9.5 text: *(v) adherence to product allocation frameworks adopted by the World Health Organization.*

How can it impact access to health products?

Requirements for adherence to allocation frameworks are a potential mechanism for ensuring that health products are made available in a timely manner where they are most needed. This can be particularly important when supplies of vaccines, diagnostics, treatments, and/or other health tools are limited. Including these

requirements in policies and provisions for public R&D funding connects directly to achieving the objective of Article 13 of the Pandemic Agreement to ensure 'the equitable and timely allocation of pandemic-related health products, based on public health risk and need' through a Global Supply Chain and Logistics Network.

The inclusion of provisions related to product allocation frameworks in the Pandemic Agreement is an acknowledgement of lessons learned from the COVAX Facility. This voluntary mechanism aimed to

enable global access to COVID-19 vaccines through pooled procurement and equitable allocation, but faced implementation challenges by underestimating the degree to which higher-income countries would act in service to national interests and companies would prioritize commercial interests.⁴⁴ This combination of vaccine nationalism and prioritization of profitability over public interest left the COVAX Facility unable to secure sufficient and timely supplies of COVID-19 vaccines for equitable distribution to low- and middle-income countries.⁴⁵

Agreement publication

In addition to creating access-related policies and provisions, Article 9.5 of the Pandemic Agreement requires Member States to establish policies for publishing those provisions. This publication requirement also aligns with Articles 11.1(c) and 14.1 of the Agreement, which establish commitments to publish the terms of license agreements for government-owned technologies and purchase agreements for pandemic-related health products.

Policy and practice examples

Many countries have freedom of information laws to enable the public to access information held by government authorities, which could include access provisions in R&D funding agreements. However, these laws often only require the release of information, which may be redacted, in response to a freedom of information request, rather than mandating proactive publication.⁴⁶

Some government agencies have also taken steps towards transparency over agreement provisions through the publication of template or model terms. However, these may not capture additional or modified commitments that are negotiated on a case-by-case

Policy and practice examples

Some of the examples of Type 1 and Type 2 provisions outlined above include high-level requirements for the availability and accessibility of publicly funded products. However, to date, these requirements do not generally appear to extend to more detailed obligations to adhere to specific product allocation frameworks. This is an area for Member States to explore further alongside the implementation of Article 13 and Article 9.5.

basis. Beyond the publication of agreement provisions, some funding agencies support transparency by publishing data, information, and analysis related to the use and outcomes of public R&D funding.

Example approaches to the publication of funding terms and related information include:

- ▶ The **NIHR** includes a provision in its standard contracts for global health research⁴⁷ stating 'Notwithstanding any other term of the Contract, the Contractor hereby gives consent for the Authority to publish the Contract in its entirety, including from time to time any agreed changes to the Contract, to the general public.'

The NIHR also publishes summaries of all awards granted,⁴⁸ management information datasets related to its funding,⁴⁹ and research stories illustrating the impact of public funding.⁵⁰

- ▶ The **FAPESP** publishes copies of its research collaboration agreements and funding agreements for international research collaboration⁵¹ in addition to grant agreement templates.⁵² FAPESP also publishes a virtual library with details of its research funding,⁵³ and annual and thematic activity reports.⁵⁴

Access plans

A number of R&D funders, including public funding agencies, require grantees – whether funding or IP license recipients – to develop an access plan. Access plans set out the actions the grantee plans to take to make a medical product promptly and sustainably available, affordable, and accessible.

Access plans alone do not address all of the considerations needed to secure the successful development of, and access to, the results of publicly funded R&D. However, access planning requirements, supported by appropriate implementation, monitoring, and update mechanisms by both funders and grantees, can be one component of a broader innovation and access policy framework for public R&D funding.

Access plans can be developed early in the R&D process and updated over time as more information becomes available about product characteristics, patient populations, and regulatory and procurement arrangements. This approach encourages the early consideration of potential barriers to access – for example, when public funding is granted for early-stage research – and can provide a structure for establishing more detailed access commitments as later R&D milestones are reached.

Some examples of public agency policies and practices for access plans include:

- ▶ The **US NIH Access Planning Policy**⁵⁵ requires applicants for licenses to NIH-developed health technologies to submit an access plan including strategies to address product affordability, availability, acceptability, and sustainability. Licensees must submit a non-confidential version of their access plan within three months of a licensed product receiving FDA approval.

The development of the NIH Access Planning Policy was informed through a stakeholder consultation process that included a public workshop,⁵⁶ an opportunity for public comment on a request for information on the draft policy,⁵⁷ with all responses published in full, and transparency over how the stakeholder input received had been used to inform the final policy. The policy was originally published in January 2025 with a 'phase-in' period, meaning that it would only begin to apply to license applications made from October 2025.

- ▶ Applicants for funding under the **EDCTP3** programme are required to submit an *'appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions.'*

Access plans must be submitted with proposals, and an explanation of any updates to, or deviations from, an access plan must be provided as part of a funding recipient's periodic reporting.⁵⁸ Final access plans submitted as project deliverables are published on the EU Funding and Tenders Portal.⁵⁹ The published plan for the malaria treatment Pyramax is one example.⁶⁰

- ▶ The **Global Coalition for Local and Regional Production, Innovation and Equitable Access** was initially established under Brazil's G20 presidency and only open to G20 countries but is now also open to participation by other governments, regional entities, and international organizations. The first call for proposals issued by the Coalition⁶¹ requires applicants to submit an access plan *'to ensure that equity and access, particularly for populations in developing countries and persons in vulnerable situations, are at the core of the projects supported under the initiative.'* Guiding commitments are required as part of the call application process, and selected applicants must then develop detailed access plans.

Each of the access plan requirements outlined above is accompanied by implementation guidance or templates setting out required access plan components and potential access strategies.*

III. CONSIDERATIONS FOR IMPLEMENTATION: FROM POLICY TO AGREEMENT PROVISION

Article 9.5 of the Pandemic Agreement requires Member States not only to develop policies related to access conditions for publicly funded R&D, but also to implement those policies. Such implementation may be in the form of the development, monitoring, and enforcement of access provisions in grant terms, agreements, and other relevant funding mechanisms.

There is no one-size-fits-all approach to developing these provisions;⁶² they will need to be appropriate to the funding contexts of different public agencies and R&D

programmes and supported by the necessary resources and expertise for implementation. There are, however, some general considerations for the development of agreement provisions including:

- ▶ **Pass-through provisions:** Academic and research institutions receive a substantial proportion of overall public R&D funding in some countries,⁶³ and in some cases funding eligibility is limited to these types of organizations.[†] The results of this early-stage funding often take the form of intangible research outputs,

* NIH Implementation Guidance: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-137.html>; EDCTP3 Access Plan Template: https://www.global-health-edctp3.europa.eu/funding/legal-and-financial-guidance_en#dissemination-and-exploitation; Global Coalition for Local and Regional Production, Innovation and Equitable Access Call Annex: <https://globalcoalitionforlocalproduction.org/wp-content/uploads/2026/05/ANNEX-F-D6.-ACCESS-PLAN-FOR-PROPOSALS-OF-PROJECTS-UNDER-THE-GLOBAL-COALITION-FOR-LOCAL-AND-REGIONAL-PRODUCTION-INNOVATION-AND-EQUITABLE-ACCESS.pdf>

[†] See, for example, the eligibility conditions for grants from the SAMRC: <https://www.samrc.ac.za/sites/default/files/attachments/2024-09/SAMRC%20Terms%20and%20Conditions%20of%20Funding.pdf>

such as IP and data, which academic institutions themselves sometimes do not have the capacity to translate into tangible medical products. The achievement of public benefit in the form of access to affordable medical products is therefore dependent on the academic institution entering into licenses or similar agreements with downstream development and commercialization partners.⁶⁴

In this context, the institution in direct receipt of the public funding does not have direct control over some of the factors that can impact access to an end product, such as product pricing, registration, and supply. Some public funding agreements address this scenario by requiring the pass-through of access obligations to the developers and manufacturers that have an influence over the downstream factors impacting access to an end product.

For example:

- The IP provisions of the **SAMRC's General Terms and Conditions of Funding**⁶⁵ state: 'The SAMRC is committed to ensuring that any Foreground IP resulting from research conducted with public funds (through the SAMRC) is commercialized to the benefit of the people of South Africa. Recipients of SAMRC funding are therefore required to ensure that any agreement concluded for the commercialization of Foreground IP provides that any resulting products shall be made *available and accessible at an affordable price to people most in need within developing countries, including the Republic of South Africa.*'

- The global access terms of **BIRAC's template Grant-in-aid Letter Agreement**⁶ require funding recipients to '*ensure Global Access in all present and future research and development agreements in a suitable form.*'

- ▶ **Monitoring mechanisms:** Public R&D funding agreements often include reporting provisions requiring funding recipients to provide periodic updates on R&D progress, as well as audit rights to enable validation of the funding recipient's reports and compliance with the terms and conditions of funding. To support the effective implementation of access provisions, these requirements can also extend to updates on progress against, and compliance with, access obligations. For example:

- The **Canadian IDRC's standard grant terms** require prompt notification of '*any and all Project Inventions,*' as well as the submission of technical reports in accordance with a milestone schedule with '*sufficient information for Centre staff to determine the progress of the Project as well as its technical success.*' Guidelines for the preparation of these reports are provided on the IDRC's website.⁶⁷

- The reporting requirements for funded projects under **EDCTP3**⁶⁸ include a summary of achievements (such as WHO pre-qualification, marketing approvals, or integration of a product into health programmes), a list of exploitable results arising from the project, the current development or exploitation status of results including '*qualitative and quantitative efforts on accessibility and affordability,*' confirmation of compliance with specific obligations (including access conditions), and an explanation of any updates to or deviations from an access plan.

When funding agreements include requirements for access commitments to be passed through to future developers and manufacturers (as explained above), reporting obligations may also need to extend to those future partners. To facilitate continued monitoring, public funding agencies may also require funding recipients to provide details of their licensing and commercialization agreements for publicly funded IP. For example, the FAPESP's IP Policy⁶⁹ requires annual reporting on IP exploitation agreements, and the DBT's IP Guidelines⁷⁰ require funding recipients to report details of their license agreements.

- ▶ **Enforcement mechanisms:** Alongside the reporting requirements that enable funding agencies to monitor progress and compliance with access conditions, effective implementation requires funding agencies to have the right to enforce access provisions in the event of non-compliance.

One consequence of non-compliance may be a right for the funding agency to suspend or terminate funding. However, while this approach can safeguard public funds from misuse, it does not provide funding agencies with access or rights to the IP or other results already generated with the public funding to enable continued development and realization of the intended public health impact. To address this issue, a number of countries and funding agencies have established laws, policies and/or agreement provisions giving them the right to access and use publicly funded IP and research outputs in certain circumstances. These are sometimes referred to as 'step-in' or 'march-in' rights. For example:

- The **US Bayh-Dole Act**⁷¹ establishes 'march-in rights' which require recipients of public R&D funding to grant a licence to a Subject Invention (i.e., an invention created under a funding agreement) to a third party on reasonable terms and in any field of use, under certain circumstances. If the funding recipient refuses to grant a licence, then the funding agency can grant the licence itself.

Circumstances under which the march-in rights can be exercised include if: (i) the funding recipient has not or will not achieve Practical Application of the Subject Invention (meaning that the invention has not been used in a way that makes the benefits ‘*available to the public on reasonable terms*’); (ii) it is required to alleviate health or safety needs; or (iii) it is required to meet public use requirements.

- Under the **EDCTP3 2026 Work Programme**,⁷² funding recipients will have one year after the end of a project to make resulting health technologies broadly accessible and available. If they are unable to meet this requirement after one year, funding recipients must use the Horizon Results Platform to find other parties that are able to do so.

If the accessibility and availability obligation remains unmet, the funding agency can request that the funding recipient ‘*grant non-exclusive licences – under fair and reasonable conditions – to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible.*’

These obligations must also be passed on as part of any transfer of ownership or licensing of project results.

- The mandatory agreement provisions set out in the **ICMR Guidelines for Technology Development Collaboration**⁷³ include a ‘march-in rights’ provision which states that ICMR will retain a non-exclusive license to a product developed with ICMR support and may require a licensee or grantee to transfer and provide training on technical know-how to a third party. March-in rights specifically apply if supply needs are not being met at a reasonable price, or the technology has not been commercialized within two years of a license grant from ICMR. ICMR also retains the right to commercialize the product in the public interest, as determined by the Government of India.
- Under **South Africa’s IPR Act**⁷⁴, if a licensee or assignee of publicly funded IP fails to commercialise the IP to the benefit of the people of South Africa, the National Intellectual Property Management Office may require the grant of a license in ‘*any field of use to any person on reasonable terms.*’ Additionally, the National Intellectual Property Management Office (NIPMO) may request the conversion of an exclusive license of publicly funded IP to a non-exclusive license if the licensee is unable to continue commercialization of the IP within South Africa.

IV. CONCLUSION: ACHIEVING GREATER IMPACT WITH PUBLIC R&D FUNDING

Article 9.5 of the Pandemic Agreement provides a landmark opportunity for Member States to leverage the power of public R&D funding as a key driver for the innovation of, and access to, pandemic-related health products. Some countries have existing frameworks for achieving public benefit with the results of public funding, and there are examples of good practices that Member States can draw upon. However, there is more to be done to ensure that national and regional policies encompass the full range of approaches needed to realize commitments to equitable access in pandemic prevention, preparedness, and response.

As Member States continue their role as major investors in medical R&D, prompt action to implement the commitments under Article 9.5 is critical for ensuring more equitable health emergency preparedness and response through broad, timely, and affordable access to publicly funded innovations.

ARTICLE 9.5 OF THE PANDEMIC AGREEMENT PROVIDES A LANDMARK OPPORTUNITY FOR MEMBER STATES TO LEVERAGE THE POWER OF PUBLIC R&D FUNDING AS A KEY DRIVER FOR THE INNOVATION OF, AND ACCESS TO, PANDEMIC-RELATED HEALTH PRODUCTS.

Recommendations and next steps

Policy development

Article 9.5 creates an obligation for Member States to develop policies regarding the inclusion of equitable access provisions in publicly funded R&D arrangements for pandemic-related health products, and regarding the publication of those provisions. As they seek to fulfil these obligations, Member States may wish to consider:

- ▶ **Conducting a detailed review of existing national policies and practices** related to public R&D funding (including non-healthcare sectors where applicable) to:
 - Identify where new policies are needed and/or where current policies can be strengthened or updated;
 - Identify current access-related practices that should be documented in formal policies;
 - Ensure the alignment of policies across relevant R&D funding agencies at national level; and
 - Assess the interactions between national policies and any relevant regional policies for public R&D funding.
- ▶ **Engaging in public consultation processes** to obtain community, civil society, and other expert input from relevant stakeholders across the R&D and access ecosystem, and to enable early engagement with parties that new or updated policies will directly impact
- ▶ **Conducting an assessment of the current scope of public R&D funding**, and ambitions for future funding in line with national science, technology and innovation strategies to ensure that funding policies account for access conditions encompassing the full scope of potential outputs from research data to medical products.

Policy implementation

As they seek to fulfil the policy implementation obligations under Article 9.5, Member States may wish to consider:

- ▶ **Making policies and model agreement provisions easily accessible** to funding recipients and the general public, for example through publication across relevant funding agency websites.
- ▶ **Drawing on examples of existing access provisions** including those from non-profit and philanthropic organizations to support the development of template and model access provisions that are appropriate for the national and/or regional context.
- ▶ **Publishing guidelines to support funding recipients' compliance with the access requirements** in new or updated policies and agreement provisions.
- ▶ **Establishing a phase-in period** to allow funding recipients sufficient time to understand and prepare for compliance with new access conditions.
- ▶ **Establishing the national or regional infrastructure that will be required to enable the fulfilment of policy requirements**, for example platforms for the dissemination of research results and deposit of research data, and a repository for the publication of funding agreement provisions.
- ▶ **Examining whether existing policy requirements and agreement provisions are sufficient** to enable funding agencies to monitor, and if necessary enforce, compliance with access conditions.
- ▶ **Support the establishment of a multilateral process** under the WHO Pandemic Agreement through which Member States can voluntarily share progress, experiences, challenges, and good practices related to the implementation of Article 9.5, with a view to promoting policy coherence and mutual learning.

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ANNEX 1

DNDi'S ACCESS POLICY FRAMEWORK & MODEL AGREEMENT PROVISIONS

DNDi's approach to enabling equitable access to the results of its R&D projects is articulated through a framework of access, IP and open innovation policies, and through contractual commitments in collaboration agreements. All of DNDi's access-related policies, as well as its model agreement provisions, are publicly available on DNDi's website.⁵

Policy framework

- ▶ **Access Policy:** This policy sets out DNDi's role in supporting equitable access, and high-level principles for its access interventions, including the negotiation of agreements to secure the sustainable supply of quality-assured products at the lowest sustainable price.
- ▶ **IP Policy:** This policy is based on the core principles of: (i) the need to ensure that drugs are affordable and accessible in an equitable manner to patients who need them; and (ii) the desire to develop drugs as global public goods* whenever possible. The policy outlines key considerations for DNDi's approach to IP, including:
 - Placing the results of its work in the public domain where the acquisition of IP rights is not necessary to promote DNDi's mission and goals;
 - Negotiating terms with DNDi's partners to ensure that they will not use IP in a manner that impedes equitable access or follow-on research;
 - Ensuring that any IP transfer or licensing agreements allow the continuing availability of technology to support further research; and
 - Ensuring that technologies developed under DNDi sponsorship are made affordable and accessible to the public.
- ▶ **Scientific Communications Policy:** The purpose of this policy is to ensure timely and accurate dissemination of research findings. DNDi commits to publishing all study results, regardless of their outcome, in open-access, peer-reviewed journals, promoting greater availability and accessibility of research findings.
- ▶ **Policy On Sharing And Secondary Use Of Human Subject Research Data:** The purpose of this policy is to enable other researchers to validate findings from DNDi-sponsored research (including negative outcomes) and contribute to broader knowledge generation, while ensuring patient confidentiality. This policy, along with DNDi's Scientific Communications Policy, also reflects DNDi's commitments as a signatory to the WHO Joint Statement on Public Disclosure of Results From Clinical Trials.

Actionable agreement provisions

DNDi negotiates two main types of collaboration and licensing agreements: (i) research collaboration and license agreements (RCLA) for early research activities from discovery through to pre-clinical studies; and (ii) development collaboration and license agreements (DCLA) for later stage R&D and commercialization activities including Phase I to Phase III clinical trials, as well as product manufacturing, registration, and distribution.

Some of the key access conditions included in DNDi's agreements to implement its policy framework are outlined below. Further details are available in DNDi's paper *Striking Fair Deals for Equitable Access to Medicines*.⁷⁶

* 'Public goods are those that are available to all ('nonexcludable') and that can be enjoyed over and over again by anyone without diminishing the benefits they deliver to others ('nonrival')...Global public goods are those whose benefits affect all citizens of the world.' <https://www.imf.org/en/publications/fandd/issues/2021/12/global-public-goods-chin-basics>

- ▶ **Public domain provisions:** For projects based on technology that is publicly available and unencumbered by IP rights, DNDi aims to negotiate provisions allowing new data generated through the project to be placed in the public domain, free of IP rights. These public domain provisions are included in most of DNDi's collaboration agreements with academic institutions.
- ▶ **Regulatory exclusivity waivers:** When the activities under a development collaboration extend to regulatory approvals, DNDi's DCLA provisions include a commitment on the part of DNDi and its partner '(a) to not seek or (b) to waive, regulatory exclusivity in relation to any data relating to the Product and arising directly or indirectly from the Marketing Authorization of the Product.' The goal of this provision is to ensure alignment with DNDi's IP policy by preventing the grant of any exclusive rights on the data package submitted for regulatory approval.
- ▶ **License grants:** A key requirement of DNDi's RCLAs and DCLAs is that DNDi and its partner grant each other licenses to use all of the IP rights necessary for the development and distribution of the product. Guiding principles for the license grants between DNDi and its partners include:
 - Non-exclusivity - to enable sharing with the larger research community, and to allow licensing to additional manufacturers to support local production and sustainable supply;
 - Sub-license rights - to enable DNDi to engage other partners;
 - Royalty-free - to support achievement of the lowest sustainable price for the product. This also aligns with DNDi's IP policy, which states that DNDi will not finance its activities through IP revenues;
 - Worldwide R&D and manufacturing rights - so that the parties can make the most efficient use of resources wherever they are located; and
 - Broad sales and distribution territory - to enable access to a product for all of the patients that need it, regardless of whether they are in low-, middle- or high-income countries.
- ▶ **Product affordability:** DNDi sets out principles for making products available on an Affordable Basis in its early-stage RCLAs to provide a framework for negotiation of future development agreements. Affordable Basis is defined as:

'pricing of a Product at the lowest sustainable level which may include only: (a) the full production costs, as optimized without compromising the quality of the Product; (b) direct distribution costs; (c) a reasonable margin to ensure manufacturing and distribution of the Product on a sustainable basis.'

This definition aims to minimize the likelihood of product pricing becoming a barrier to access while also allowing DNDi's partner to make a reasonable return to support supply security and sustainability.

The affordable pricing principles established in an RCLA can be developed further in a DCLA, for example by setting a maximum price and/or defining a partner's reasonable margin. Other pricing-related considerations added to DCLAs include a technology transfer to an alternative manufacturer if such a transfer will result in a reduced product price without delaying access or compromising quality. The DCLA template also includes rights for DNDi to review and audit its partners' calculation of product price in compliance with the Affordable Basis.

- ▶ **Rights upon termination:** DNDi's agreement templates include provisions intended to enable the continued development of a product in the case of early agreement termination, for example because a partner's priorities have changed, or the partner does not meet its obligations (including those related to product affordability and accessibility).
- In addition to securing licenses to necessary IP rights, the agreement termination provisions also require the partner to complete a technology transfer. This requirement aims to ensure that DNDi can effectively exercise the IP rights to continue product development and distribution with another partner with minimum disruption.
- ▶ **Disclosable information:** To support transparency, DNDi's agreement templates include a definition of Disclosable Information which may be published on the parties' websites and/or in annual reports. The definition includes information related to product access and affordability.

ANNEX 2

ADDITIONAL RESOURCES

Access policies and frameworks published by non-profit and philanthropic organizations

- ▶ CARB-X Stewardship & Access Plan Development Guide: <https://carb-x.org/about/stewardship-and-access/>
- ▶ CEPI Equitable Access Policy, Equitable Access Framework and related materials: <https://cepi.net/equitable-access>
- ▶ DNDi Access Policy and Pro-Access IP Policies: https://dndi.org/wp-content/uploads/2020/08/DNDi_Access_Policy.pdf and <https://dndi.org/advocacy/pro-access-policies-intellectual-property-licensing/>
- ▶ FIND Global Access Policy: https://www.finddx.org/wp-content/uploads/2021/07/FIND-Global-Access-Policy_PL-02-08-07_V1.1_JUL2021.pdf
- ▶ Gates Foundation Global Access Statement and related materials: <https://www.gatesfoundation.org/about/policies-and-resources/global-access-statement>
- ▶ GHIT Fund Access Policy: <https://www.ghitfund.org/applyforfunding/accesspolicy/en>
- ▶ MMV Management of IP: https://www.mmv.org/sites/default/files/content/document/MMV%20IP%20Management%20-%20Guiding%20principles_%202023.pdf
- ▶ MPP published license agreements: <https://medicinespatentpool.org/progress-achievements/licences>
- ▶ RIGHT Foundation Global Access Policy: <https://rightfoundation.kr/en/access-policy/>
- ▶ Wellcome Trust Statement on Equitable Access to Healthcare Interventions: <https://wellcome.org/what-we-do/our-work/access-healthcare-interventions/wellcomes-approach-equitable-access-healthcare-interventions>

Access and innovation policy resources

- ▶ Geneva Graduate Institute Database of Alternative R&D Initiatives - results of a project analysing alternative business models for innovation and global access to medicines: <https://www.graduateinstitute.ch/research-clusters/global-health/alternative-innovation-models-medicines-public-interest>
- ▶ GHIAA Equitable Access Toolkit – practical guidance, analysis and examples of access-oriented policies, partnerships and agreement provisions: <https://ghiaa.org/mapguide-home/equitable-access-toolkit/>
- ▶ UNDP/Uniting Efforts-commissioned survey on Planning for Access During Research and Development - analysis of funder and innovator policies and practices in planning for access during R&D: https://adphealth.org/upload/resource/Planning_for_access_during_research_and_development_260824.pdf
- ▶ WIPO-commissioned Discussion Paper on IP and Access to Publicly Funded Research Results in Health Emergencies – examining government policies, regulation, and practical management of publicly funded research results: https://www.wipo.int/meetings/en/details.jsp?meeting_id=81448

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Established in 2003, the Drugs for Neglected Diseases initiative, DNDi, is an international not-for-profit organization that discovers, develops, and delivers safe, effective, and affordable treatments for the most neglected patients.

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