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## Wellcome Equitable Access Consultation

December 10, 2025

Public Citizen welcomes Wellcome's ongoing efforts to advance equitable access, including through its equitable access consultation and consideration of minimum access standards.<sup>1</sup>

Access obligations, including access plans, should be developed at the earliest opportunity, concurrently with funding agreements. As discussed below, this can be achieved while nonetheless retaining flexibility for Wellcome and its partners.

### 3. Flexible conditions with minimum requirements

#### 3b. Access plans

##### 1. What role does an access plan play and what components should an access plan include?

Public Citizen supports the use of concrete access conditions within funding agreements over more general commitments to develop access plans. In both cases, however, access should be considered at the earliest possible opportunity while remaining flexible based on the specific technology and development stage.

We recommend that Wellcome expand its use of binding conditions to facilitate downstream access. Wellcome can approach this systematically by developing model access conditions grounded in core principles including acceptability, affordability, availability, sustainability, and transparency. We include transparency as a core principle for achieving access as this enables broader stakeholder engagement on equitable access, trust, and broader cooperation within the R&D ecosystem. Additionally, we recommend that, as a key principle, access obligations, including access plans, support not only access to the particular technology being funded but also diffusion of technology and knowledge to the broader benefit of public health. We strongly believe knowledge sharing with LMICs is critical, as knowledge for producing efficacious medical technologies and building on previous innovation should not be concentrated in the hands of firms predominantly situated in high-income nations, wielded to the exclusion of wide swathes of the globe.

In providing for these core principles, Wellcome would clearly communicate how it aims to facilitate equitable access with its partners and provide a baseline to assist in negotiations. We support the development of baseline language that Wellcome may include in funding agreements, including language covering: affordability, adequate and timely supply in LMICs (including arrangements for technology transfer), timely registration, IP and licensing (including step-in rights and humanitarian licensing), transparency, and survival clauses to ensure access obligations follow the technology forward (or to ensure new access plans with specific milestones are created).

Importantly, access conditions can be concrete while balancing concerns about flexibility. Wellcome can include high-level conditions for access that incorporate key access principles, while still accommodating uncertainty in product development and remaining commercially reasonable.

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<sup>1</sup> <https://wellcome.org/our-priorities/strategy/equity/equitable-access-consultation>

Though less desirable, in our view, than access conditions, access plans nonetheless ensure advanced consideration is given to achieving downstream equitable access, affordability, and availability of products. There are several ways access plans should be optimized to ensure they are best suited to support equitable access.

Access plans must include clear milestones, laying out plans and timelines related to pricing, regulatory approvals, supply, technology transfer, and licensing for access in LMICs. Milestones can be tailored based on the particular technology and can be triggered at appropriate points, such as at certain dates or development stages. To assist in the development of appropriate access plans and related milestones, we recommend that Wellcome set out clear definitions for access objectives that should be achieved through access plans. This should include proactively defining affordability for access in LMICs as the sustainable cost of production plus a reasonable profit margin, which is the metric used by the Drugs for Neglected Diseases initiative (DNDi). DNDi defines affordability as the “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; and (c) a reasonable margin to ensure manufacturing and distribution of the Product on a sustainable basis.”<sup>2</sup>

Finally, access plans should be subject to meaningful review and ongoing monitoring by Wellcome. To ensure review remains meaningful over time, we recommend that Wellcome require access plans be subject to review, feedback, and approval.

2. [At what stages of development or at what frequency is it appropriate to develop and update an access plan \(for example, first develop at the start of phase 2 or equivalent, and update at the launch of the product\)?](#)

Access obligations, including access plans, should be developed at the earliest opportunity, concurrently with funding agreements. To account for changes and uncertainty in the development process, Wellcome should meet with partners at regular intervals (at least once per year) to monitor progress on access plans, including to negotiate and finalize any updates that may be needed in response to changing circumstances. Wellcome should also retain the ability to request changes in access plans as needed in response to certain circumstances, such as health emergencies or a partner's failure to comply with their access plan.

3. [Should access plans \(or summary access plans\) be published? Please explain your rationale.](#)

Transparency is a critical enabler of equitable access. Through improved transparency, Wellcome can contribute to normative change in the acceptance and use of access conditions and/or access plans, help build trust among the public, encourage collaboration within the R&D ecosystem, and broaden accountability and stakeholder participation in ensuring equitable access. The COVID-19 pandemic underscored how secrecy can undermine access. Contract secrecy hid unfair terms and encouraged price discrepancies, for example in the case of South Africa, which was charged more for COVID-19 vaccines than rich countries.<sup>3</sup> As pointed out in a recent comment by Medecins Sans Frontieres, secrecy in agreements related to the Oxford-AstraZeneca COVID-19 vaccine hid the fact that, despite public statements promising to sell the vaccine without profit during the course of the pandemic, AstraZeneca was not subject to binding commitments for fair pricing, enabling the company to overcharge countries like South Africa.<sup>4</sup>

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<sup>2</sup> Dominique Moser, Pascale Boulet, Michelle Childs, Mae Shieh & Bernard Pécoul, Striking fair deals for equitable access to medicines, 18 J. INTELL. PROP. L. & PRAC. 323, 331 (2023).

<sup>3</sup><https://www.aljazeera.com/news/2023/9/6/south-africa-held-to-ransom-by-big-pharma-overcharged-for-covid-vaccines>

<sup>4</sup><https://www.citizen.org/wp-content/uploads/MSF.pdf>

Public Citizen advocates for the publication of agreement terms in full. The Medicines Patent Pool has shown that such transparency practices are achievable.<sup>5</sup> We recommend that Wellcome approach transparency similarly by publishing unredacted terms of its agreements online. In the event that such transparency practices are not adopted, Wellcome should, at minimum, require timely publication of any terms related to access, affordability, and accountability (such as step-in rights and termination provisions). In line with this, access plans (as well as any plan modifications, progress reports, and Wellcome's plan feedback) should be made publicly available.

#### 4. Should Wellcome have the right to formally agree an access plan? If so, what should happen if an access plan is not agreed?

Oversight and accountability are needed for any approach seeking to integrate equitable access commitments into Wellcome agreements, regardless of whether Wellcome uses contract conditions or access plans with milestones.

In order to concretely support the achievement of access objectives, Wellcome should establish clearly defined objectives to inform the development and assessment of access plans. Requiring only the submission of access plans without such clear standards and without formal procedures for review, feedback, and approval would be insufficient and would undermine the effectiveness of the proposed policy.

Access plans should be subject to meaningful review and ongoing monitoring by Wellcome. To ensure review remains meaningful over time, we recommend that Wellcome require access plans be subject to review, feedback, and approval. This should include the ability for third parties, such as public health organizations and civil society organizations, to contribute to reviews to ensure appropriate expertise is drawn upon in the development and ongoing review of access plans.

In addition to formal procedures for initial review, feedback, and approval, we urge Wellcome to include affirmative reporting obligations on an annual basis, the right to have third parties present for reviewing reported progress, and audit rights to effectively monitor access planning commitments and milestones.

We recommend that Wellcome require affirmative annual reporting on progress on access obligations (either conditions or access plans with milestones), but integrate flexibility in agreements that allows third parties to be invited to consultations on progress. Civil society and WHO representatives are participants that can assist in these discussions to achieve equitable access. Access plans and related information, including progress reports and feedback, should be made publicly available on Wellcome's website. We also urge Wellcome to adopt provisions for auditing records to verify the accuracy of information received.

To provide accountability, we advocate for the inclusion of accountability terms in agreements, including step-in rights/humanitarian licensing or termination of the agreement. Where a partner breaches an obligation, including an access obligation, Wellcome must reserve the right to respond and must clarify in advance that it intends to use that right if obligations are not met.

### 3c. Reporting

We recommend that Wellcome at minimum require affirmative annual reporting on progress on access obligations (either conditions or access plans with milestones) and that it integrate flexibility by allowing third parties, including public health organizations and civil society experts, to be invited to consultations

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<sup>5</sup> <https://medicinespatentpool.org/progress-achievements/licences>

on progress toward achieving equitable access. As part of this process, Wellcome should retain discretion to formally request changes to access plans.

### 3d. Follow-through mechanisms

1. Where products stall or where the commercialising party does not intend to make a product broadly available, Wellcome does not see the public benefit it intends. Money does not compensate Wellcome for this and therefore Wellcome has historically had a step-in right setting out that in these circumstances, Wellcome can step-in and take over commercialisation of the relevant intellectual property. Are these step-in rights adequate, or should they be strengthened; where could a humanitarian licensing approach be advantageous?

Step-in rights and humanitarian licensing provide necessary accountability and ensure onward access. Where a partner fails to fulfil its obligations or access-related obligations fail to achieve impact, Wellcome must have flexibility to ensure affordability and dissemination of technology for public benefit.

Wellcome should retain its right to step in and take over commercialisation. Wellcome should additionally include standard terms for humanitarian licensing. Including terms for humanitarian licensing establishes a clear expectation of licensing for access, thus providing certainty for business planning across all relevant Wellcome partners. This also helps achieve access objectives by enabling Wellcome to both provide access to health products and encourage further technology development and dissemination of knowledge. To achieve this, Wellcome should affirmatively include provisions for humanitarian licensing and enable the practice of the technology through the inclusion of background IP, know-how, and follow on innovations.

For their humanitarian licenses designed to achieve global access, the Gates Foundation has required that grantees provide the Foundation with “a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license” to use a funded development and essential background IP, defined as “Background Technology that is: (a) owned, controlled, or developed by You, or in-licensed with the right to sublicense; and (b) either incorporated into a Funded Development or reasonably required to exercise the license to a Funded Development.”<sup>6</sup>

DNDi secures a “non-exclusive, worldwide, perpetual, irrevocable, fully paid, royalty-free license, with the right to sublicense to Third Parties under Partner’s rights to and interests in Partner Background Technology and Partner Collaboration Technology” when it is necessary or useful for earlier-stage research and later-stage development purposes, or for non-commercial uses.<sup>7</sup> Importantly, DNDi includes within its definition of background IP “technology developed by such party, after the signature of the agreement outside the scope of the collaboration, and which is necessary or useful to the collaboration or to exercise granted licensing rights.”

CEPI has also included licensing of background IP and enabling rights in its development agreements when exercising a public health license.<sup>8</sup> The public health license is a worldwide, royalty-free license that is triggered upon certain events, such as when an awardee does not wish to continue with CEPI for an

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<sup>6</sup> GHIAA, How Can Agreement Provisions Ensure Sustainable Access to Funded Products?, MAPGUIDE EQUITABLE ACCESS TOOLKIT, <https://ghiaa.org/mapguide-home/mapguide-commentaries/ensuring-sustainability/>.

<sup>7</sup> Dominique Moser, Pascale Boulet, Michelle Childs, Mae Shieh & Bernard Pécoul, Striking fair deals for equitable access to medicines, 18 J. INTELL. PROP. L. & PRAC. 323, 328-29 (2023).

<sup>8</sup> GHIAA, CEPI – Novavax, COVID-19 Vaccine Funding Agreement: Equitable Access | Ensuring continuity, MASTER ALLIANCE PROVISIONS GUIDE (MAPGUIDE), [https://ghiaa.org/provision\\_document/novavax-cepi-outbreak-response-to-novel-coronavirus-covid-19-funding-agreement-5/](https://ghiaa.org/provision_document/novavax-cepi-outbreak-response-to-novel-coronavirus-covid-19-funding-agreement-5/).

additional work package, where the awardee and CEPI agree that the awardee will not be able to accomplish a defined work package, or when the awardee is in breach of the agreement or Equitable Access Plan.<sup>9</sup> CEPI is entitled to sublicense project results, enabling IP and background IP under the agreement's terms, and defines enabling rights as contractual rights, IP or project results that could be asserted by the Awardee against CEPI to prevent the exercise of its public health license.<sup>10</sup> CEPI also defines background IP to include licensed third-party background IP (that is, IP that CEPI's partner is licensing from another entity) and provides for payment to the third party to use their background IP.<sup>11</sup>

We recommend that Wellcome include a clear provision for humanitarian licensing and proactively include provisions for licensing third-party IP. To that end, we prefer the approach used by DNDi of including a provision that affirmatively licenses background IP and improvements in the initial agreement, rather than conditioning a license to background IP on the formal exercise of step-in rights. Any license to background IP, enabling rights, or follow-on technology should be irrevocable, perpetual, transferable, and nonexclusive to ensure certainty for manufacturers supplying LMICs.

2. To what extent would Wellcome becoming a party to onward licensing agreements encourage adherence to access objectives and access plans or are there other approaches that could be considered?

As discussed above, Wellcome should retain rights in IP as both an accountability tool and to provide flexibility to carry innovations forward should the partner fail to achieve access obligations.

3. How could/should access plans be connected to follow-through mechanisms? For example, if access plans are formally accepted by Wellcome, should this mean that if the access plans are adhered to, this would guarantee that follow-through mechanisms will not be utilised.

Wellcome must include clear and predictable accountability mechanisms to ensure compliance with access obligations and flexibility for Wellcome to enable onward innovation and access. Accountability mechanisms and Wellcome's right to act for access should not be traded in exchange for access plans which may or may not ultimately deliver on necessary public health objectives.

## 4. Transparency

1. What information that Wellcome holds do you think would deliver the most impact if it were to be made transparent; what would be the benefit of such transparency (and to whom)? How should Wellcome disclose information to avoid discouraging innovators from wishing to work with us?

Public Citizen advocates for the publication of agreement terms in full. The Medicines Patent Pool has shown that such transparency practices are feasible.<sup>12</sup> We recommend that Wellcome approach transparency similarly by publishing unredacted terms of its agreements online. In the event that such transparency practices are not adopted, Wellcome should, at minimum, require timely publication of any terms related to access, affordability, and accountability (such as step-in rights and termination provisions). In line with this, access plans (as well as any plan modifications, progress reports, and Wellcome's plan feedback) should be made publicly available. Transparency expectations should be laid out clearly to give predictability for Wellcome and its partners. Delivering on clear transparency principles encourages accountability, including on the achievement and measurement of access obligations, public trust and understanding, and provides ancillary benefit by helping establish equitable

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<sup>9</sup> Id.

<sup>10</sup> Id.

<sup>11</sup> Id.

<sup>12</sup> <https://medicinespatentpool.org/progress-achievements/licences>

access norms across the research and development landscape and aiding other funders' and governments' negotiations with potential partners.

2. Are there key considerations/concerns around transparency (in general or in particular) from innovators that you think we should be considering in the exploration of this topic?

As stated above, transparency is a key enabler for equitable access. It should be treated as such. We recommend that Wellcome expressly provide that it will publish, at minimum, any terms related to access, affordability, and accountability (such as step-in rights and termination provisions). In line with this, access plans (as well as any plan modifications, progress reports, and Wellcome's plan feedback) should be made publicly available.

Regarding improving transparency in agreement terms, including access-related provisions and access plans, we urge Wellcome not to accede to *carte blanche* assertions of trade secret protections on information, particularly with respect to pricing and supply in LMICs. That is, information as basic as the pricing should not be withheld. It is flawed to claim that the pricing of any medical product is proprietary and commercially sensitive; price competition is a normal function of markets and arguments that concealing prices fosters innovation are dubious.<sup>13</sup> Disclosure of supply and pricing terms in access plans would also be consistent with the resolution approved by the World Health Assembly on "Improving the transparency of markets for medicines, vaccines, and other health products."<sup>14</sup>

## 5. Final thoughts

In addition to suggested terms and considerations included in this comment, Public Citizen includes additional detailed language suggestions for key access-related terms in its comment to the U.S. National Institutes of Health (NIH) regarding its recently-adopted licensing policy to support equitable access to NIH-owned inventions. While this policy was limited only to NIH's intramural research program, many of the access conditions and considerations are appropriate for both licensing agreements and R&D funding agreements. Public Citizen's comments are available here: <https://www.citizen.org/wp-content/uploads/Public-Citizen.pdf>. We also note that DNDi provides key insights into balancing access and sustainability in funding agreements in the following publications: <https://dndi.org/wp-content/uploads/2025/11/DNDi-OpenScience-PolicyReport-2025.pdf> and <https://academic.oup.com/jiplp/article/18/4/323/7115852?login=false>.

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<sup>13</sup> Robin C. Feldman & Charles Tait Graves, Naked Price and Pharmaceutical Trade Overreach, 22 YALE J.L. & TECH. 61, 97 (2020).

<sup>14</sup> World Health Assembly, Res. 72.8, Improving the Transparency of Markets for Medicines, Vaccines, and Other Health Products, W.H.O. Doc. A72-R8 (May 28, 2019).