Treatment Action Group

Submission to the Office of the High Commissioner for Human Rights

Date: 20 January 2025

Re: Call for inputs for the comprehensive report, incl. new developments, in ensuring access to medicines, vaccines and other health products

Introduction

1. Treatment Action Group (TAG) is an independent, activist, and community-based research and policy think tank committed to racial, gender, and LGBTQ+ equity; social justice; and liberation, fighting to end HIV, tuberculosis (TB), and hepatitis C virus (HCV). We are science-based activists working to expand and accelerate vital research and effective community engagement with research and policy institutions for an end to the HIV, TB, and HCV pandemics.

2. This submission is based on TAG's ongoing analyses of the right to enjoy the benefits of scientific progress and its application (right to science), supported by interrelated obligations under the right to the highest attainable standard of physical and mental health.

3. Our overarching recommendation to OHCHR is to **include a substantive discussion of state obligations under the right to science as they relate to access to medicines** in the forthcoming comprehensive report to be presented to the Human Rights Council at its fifty-ninth session in June 2025.

Strengthening International Normative Standards

4. Under the right to health, access to essential medicines, as defined by WHO, is a core obligation, one that states must take immediate steps to fulfill regardless of resource constraints. Outside of "essential medicines," CESCR General Comment 14 specifies other core obligations encompassing access to medicines more generally, including that health facilities, goods, and services must be equitably distributed and made accessible in a nondiscriminatory manner. Immunization against infectious diseases is considered an "*obligation of comparable priority*" as are "*measures to prevent, treat, and control epidemic and endemic diseases*."[1]

5. Despite this clear and longstanding normative standard, states continue to fall short of the duty to ensure access to medicines, vaccines, and other health products as a core obligation. At best, states have taken some steps that would satisfy the progressive realization of this right; however, progress has been uneven, and TAG is concerned that recent developments at the international level threaten to further degrade access to medicines under the right to health as well as the right to science.

6. Grave inequalities in access to vaccines, antivirals, and other medical countermeasures during the COVID-19 pandemic cost millions of lives and demonstrated the urgency of reforming

[1] OHCRH (2000) CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) <https://www.ohchr.org/sites/default/files/Documents/Issues/Women/WRGS/Health/GC14.pdf> accessed 20 January 2025

legal, policy, and regulatory frameworks to approach medicines access from a human rights perspective. Yet, instead of reaching for human rights solutions to the medicines access crisis, states continue to approach the issue narrowly as one of trade and economic policy divorced from human rights law.

7. In 2016, four years before the COVID-19 pandemic, the report of the UN Secretary-General's High-level Panel on Access to Medicines pointed out the "*policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies*."[2] Today, four years from the start of the pandemic, this "policy incoherence" now threatens to become a clear policy preference for approaching access to medicines and health technologies as a matter of trade alone.

8. This trend can be observed in stymied negotiations at the WHO International Negotiating Body (INB) to create a Pandemic Accord.[3] It has also borne out in negotiations behind political declarations of recent UNGA special sessions on health, including High-Level Meetings (HLM) on Tuberculosis (2023), Universal Health Coverage (2023), Pandemic Prevention, Preparedness, and Response (2023), and Antimicrobial Resistance (2024).

9. These documents acknowledge human rights and even recognize access to medicines as lacking, but proposed actions and solutions — such as sharing technology and know-how, publishing contract terms between funders and product developers, expanding regional manufacturing, attaching access conditionalities to public research funding, or de-linking the costs of research and development from the price and sales volumes of final products — over-rely on "*voluntary measures*" or are subject to "*mutually-agreed terms*."

10. Where language acknowledges access to medicines as an important issue, it is usually contained to describing the problem without committing states to take specific actions to address it. In the most concerning cases, member states have put forward reservations undermining consensus text related to access to medicines. One illustrative example comes from the 2024 political declaration on Antimicrobial Resistance (AMR):

    a. Following precedent set in 2023 TB political declaration,[4] the 2024 AMR political declaration explicitly recognizes the right to science in relation to medicines access: "*Reaffirm the right of every human being to the enjoyment of the highest attainable standard of physical and mental health, and to enjoy the benefits of scientific progress and its application in order to advance towards universal access to quality, affordable, inclusive, equitable and timely prevention, diagnosis, treatment, care and awareness-raising related to antimicrobial resistance, and address its economic and social determinants*" (para. 54).[5]

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[2] Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines (2016) <http://www.unsgaccessmeds.org/final-report> accessed 20 January 2025

[3] Frick, Mike and Gisa Dang (2023) Right to science principles should guide global governance on health. https://www.frontiersin.org/journals/sociology/articles/10.3389/fsoc.2023.1271063/full accessed 20 January 2025.

[4] Para. 39 of the 2023 TB political declaration connects the right to science to access to TB medicines: "*Commit to protect and promote the right to the enjoyment of the highest attainable standard of physical and mental health, and the right to enjoy the benefits of scientific progress and its application in order to advance towards universal access to quality, affordable, inclusive, equitable and timely prevention, diagnosis, treatment, care and awareness-raising related to tuberculosis, and address its economic and social determinants.*" https://digitallibrary.un.org/record/4022582?v=pdf&ln=en

[5] Political Declaration of the High-level Meeting on Antimicrobial Resistance (2024) <https://www.un.org/pga/wp-content/uploads/sites/108/2024/09/FINAL-Text-AMR-to-PGA.pdf> accessed 20 January 2025

b. However, amendments put forward by several states undermine the application of right to science principles to address medicines access where they appear later in the text. After inclusion in the final draft of the political declaration, paragraphs 82 and 87 were nullified by objection during the adoption procedure, effectively striking any mention of certain access initiatives for AMR medical countermeasures:

   i. The United States led withdrawal from paragraph 82 of the political declaration and its acknowledgement of the need to remove trade barriers to facilitate the movement of medical goods across states;[6]

   ii. The European Union dissociated from the reference in paragraph 87 to technology transfer, linked to the objective of "*equitable and effective access to vaccines, therapeutics, diagnostics and essential supplies, as well as for clinical trials*," with support from the United States and other high-income member states.[7]

c. This was not the first time that high-income countries blocked global action that could improve medicines access among under-resourced populations. TAG has repeatedly observed similar behavior in the WHO International Negotiating Body process to arrive at a new global Pandemic Accord.[8]

11. Not only does such state behavior run counter to obligations of availability and accessibility under the right to health and the right to science, the latter of which also requires international cooperation on global threats, of which AMR is one. The human rights implications of such a dynamic go well beyond and threaten the core human right that underlies all others: the human right to life.

12. In TAG's view, the trend to frame medicines access as a technical problem of trade law, the preference for voluntary measures, and the lack of specificity in naming solutions is a consequence of states ignoring available and tested human rights standards and tools for increasing access to health technologies. As a starting point for correcting this, states should recognize that ensuring access to medicines is a core obligation under international human rights law, one anchored not only in the right to health, but also in the right to science.

13. Accordingly, **TAG encourages OHCHR to use the forthcoming comprehensive report to call attention to the inter-related dimensions of the right to science and the right to health in the context of medicines access**. In particular, the report should 1) articulate state obligations on science and access to medicines and 2) propose specific areas of state action. The following two sections provide our recommendations in each of these areas:

[6] United States Mission to the United Nations (2024) Written Explanation of Position at the Political Declaration of the UNGA High-level Meeting on Antimicrobial Resistance. <https://usun.usmission.gov/written-explanation-of-position-at-the-political-declaration-of-the-unga-high-level-meeting-on-antimicrobial-resistance/> accessed 20 January 2025

[7] TAG observational notes (2024) on file with TAG.

[8] Frick, Mike and Gisa Dang (2024) A New Pandemic Agreement Cannot Succeed If It Ignores Human Rights. In: TAGLine November 2024 < https://www.treatmentactiongroup.org/resources/tagline/tagline-november-2024/a-new-pandemic-agreement-cannot-succeed-if-it-ignores-human-rights/> accessed 20 January 2025.

State Obligations on Science and Access to Medicines

14. ICESCR Article 15.2 charges states three core obligations under the right to science. To fully realize the right, states must take steps to "*develop, diffuse, and conserve*" science. Resonating with prior right to health analysis, CESCR General Comment 25 reiterates that the AAAQ standard — availability, accessibility, acceptability, and quality — used to define access under the right to health, also applies to the right to science. In the context of access to medicines, vaccines, and other health products – all tangible products of scientific discovery and thus explicitly covered under the right to science – the right to science obligates states to:[9]

    a. *Develop* the tangible and intangible benefits of science, i.e., to secure public resources for research and development of the scientific process with the goal to provide a life of dignity to all of humanity; also, to

    b. *Diffuse* the tangible and intangible benefits of science, i.e., to understand that public investments in science must be linked to the availability, accessibility, acceptability, and quality (AAAQ) of the derived goods for public enjoyment without discrimination; and to

    c. *Conserve* the tangible and intangible benefits of science, i.e., to take into account the ability of future generations to benefit from science. This duty to "*conserve*" science and its benefits calls on states to ensure access not only for people alive to today, but also for future generations.

15. Several core obligations under the right to science identified in CESCR General Comment 25 apply to access to medicines:[10]
    a. "*Ensure access to those applications of scientific progress that are critical to the enjoyment of the right to health and other economic, social, and cultural rights*;"
    b. "*Ensure that in the allocation of public resources, priority is given to research in areas where there is the greatest need for scientific progress in health, food and other basic needs related to economic, social and cultural rights and the well-being of the population, especially with regard to vulnerable and marginalized groups*;"
    c. "*Ensure that health professionals are properly trained in using and applying modern technologies and medicines resulting from scientific progress*;"
    d. "*Foster the development of international contacts and cooperation in the scientific field, without imposing restrictions on the movements of persons, goods, and knowledge beyond those that are justifiable in accordance with article 4 of the Covenant*."

16. Indeed, CESCR General Comment 25 directly addresses the "*complex relationship*" between the right to science and intellectual property rights, stating that "intellectual property can negatively affect the advancement of science and access to its benefits, in at least in three ways".[11] Paragraph 62 concludes that "*ultimately, intellectual property is a social product and*

[9] United Nations (2020) General comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights). <https://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmlBEDzFEovLCuW1a0Szab0oXTdImnsJZZVQdxONLLLJiul8wRmVtR5Kxx73i0Uz0k13FeZiqChAWHKFuBqp%2B4RaxfUzqSAfyZYAR%2Fq7sqC7AHRa48PPRRALHB> accessed 20 January 2025
[10] Ibid. Para 52.
[11] Ibid. Para 60.

has a social function and consequently, States parties have a duty to prevent unreasonably high costs for access to essential medicines" and tasks states with the following measures:

a. *"to counter distortions of funding associated with intellectual property, States should provide adequate financial support for research that is important for the enjoyment of economic, social and cultural rights, either through national efforts or, if necessary, by resorting to international and technical cooperation. States could also resort to other incentives, such as so-called market entry rewards, which delink remuneration of successful research from future sales, thus fostering research by private actors in these otherwise neglected fields."*

b. *"to guarantee the social dimensions of intellectual property, in accordance with the international human rights obligations they have undertaken (E/C.12/2001/15, para. 18). A balance must be reached between intellectual property and the open access and sharing of scientific knowledge and its applications, especially those linked to the realization of other economic, social and cultural rights, such as the rights to health, education and food."*

17. TAG **encourages OHCHR to use the forthcoming comprehensive report to remind states of these existing human rights obligations and to recognize the right to science as "a significant mediator"[12] between human rights and property rights.**

Areas of Action on Science and Access to Medicines

18. Recognizing the right to science adds several important dimensions to the access to medicines conversation that would strengthen OHCHR's forthcoming report. Below we call out four "areas of action." The analysis behind each area is based on TAG's own research, research by other civil society organizations, and the experiences of communities affected by TB. For each area, we have provided an example of the current problem and proposed a rights-based solution grounded in the right to science.

    a. **First, the right to science links access to medicines to state policies toward research and innovation.** Some necessary health technologies are inaccessible because they have not yet been created by research, often owing to an innovation system that pursues priorities based on profit potential rather than public health needs. In other cases, access barriers to existing technologies could have been lessened or avoided altogether if they had been addressed at earlier stages of research and development. The right to science redirects attention to planning for access at upstream stages of research and development as an important determinant of access to health technologies downstream.

        i. Example of current problems: Uniting Efforts for Innovation, Access and Delivery — a partnership between the Government of Japan, the United Nations Development Programme (UNDP)-led Access and Delivery

[12] United Nations (2020) General comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights). Paragraph 69 <https://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmlBEDzFEovLCuW1a0Szab0oXTdImnsJZZVQdxONLLLJiul8wRmVtR5Kxx73i0Uz0k13FeZiqChAWHKFuBqp%2B4RaxfUzqSAfyZYAR%2Fq7sqC7AHRa48PPRRALHB> accessed 20 January 2025

Partnership, and the Global Health Innovative Technology Fund (GHIT Fund) — commissioned a report on how funders in the global health R&D space plan for access and delivery of health technologies during the R&D process.[13] The report found that funders and innovators lack a shared definition of what "access" means. Overall, the report found that: 1) Many funders and developers have not published access plans/policies, even where they require them; 2) Most access policies and practices focus on availability and affordability over other dimensions of the AAAQ; 3) Approaches drift over time (swinging between prescriptive to principles-based approaches); and 4) there are ample opportunities for improvement, particularly with respect to addressing access at early stages of R&D.

ii. Proposed rights-based solutions: TAG calls for a renewed effort by states to fulfill their human rights obligations by ensuring that medicines developers and product sponsors respect and protect human rights. At a minimum, public funders should require product developers to publish access plans that address key determinants of medicines access. Such access plans should be a requirement at all stages of R&D but can grow in specificity and detail as research progresses from early discovery to regulatory approval. For therapeutics, such access plans should entail the domains of a) pre-approval access (i.e., access to patients, including those who are not clinical trial participants, in urgent need of new therapies before full regulatory approval), b) pricing, c) regulatory plans including seeking World Health Organization recommendation / prequalification as well as registration with national regulatory authorities, d) transparency, e) community engagement, f) intellectual property strategy including secondary patents, licensing plans, and tech transfer plans, g) manufacturing plans including anticipated volumes to ensure adequate supply, h) plans for research and formulations / product alterations to maximize access for key populations, such as pediatric formulations or adaptations of devices for children, or inclusion of pregnant and lactating participants in research studies. For vaccines and diagnostics, the same domains should be included in access plans, except for pre-approval access. States should also direct resources toward a *purposive development* of science and technology to uphold the right to health, in particular to address the unmet health needs of vulnerable and marginalized groups.[14]

b. **Second, the right to science illuminates the interdependence of participation in science and the ability to access to benefits and applications of scientific progress.** The 2024 report of the Special Rapporteur in the field of cultural rights – Right to

[13] Uniting Efforts for Innovation, Access, and Delivery (2024) **New Uniting Efforts report:** Planning for access during research and development: Policies, practices and opportunities to ensure health technologies are available to those that need them most. <https://www.unitingeffortsforhealth.org/new-uniting-efforts-report-planning-for-access-during-research-and-development> accessed 20 January 2025

[14] GC 25 (para 67): "States should promote scientific research, through financial support or other incentives, to create new medical applications and make them accessible and affordable to everyone, especially the most vulnerable [. . .] In particular, in accordance with the Covenant, States parties should prioritize the promotion of scientific progress to facilitate better and more accessible means for the prevention, control and treatment of epidemic, endemic, occupational and other diseases (art. 12 (2) (c))."

participate in Science (A/HRC/55/44) – posits that "*Participation [in science] also enables access. It is a prerequisite for access to the benefits of scientific progress, ensuring that it is applicable and relevant to specific groups of people*." As an example, the report cites "*the participation of pregnant women, children, and people with disabilities or living with HIV in research, guaranteeing their access to specific medical treatment.*" States cannot guarantee nondiscrimination in the ability of people to enjoy the benefits of science if certain groups are excluded from research, under-represented in health innovation, or prevented from shaping the overall direction of the scientific agenda.

i. Example of current problems: The systematic exclusion of certain groups from medical research reinforces disparities in which some populations shoulder a greater burden of disease than others. In the context of TB, this manifests in the tendency of clinical trials to favor enrollment of "typical" TB patients with easier-to-treat forms of disease. As a result, people with complicating comorbidities (e.g., HIV, diabetes) or severe disease manifestations (e.g., TB meningitis) are left out of trials; they are not allowed to participate in research, even if they would choose to do so after providing informed consent, because they have been labelled as 'ineligible' per the protocols governing clinical trials. Other groups deemed vulnerable to harm as a class — e.g., children, adolescents, and pregnant women — are excluded out of a misplaced desire to protect these populations from potential risks. In reality, research protection interpreted as exclusion amplifies TB-related harms. Evidence-based guidelines cannot be made in the absence of evidence that an intervention works in a particular population. Some of the populations most vulnerable to TB are either not represented in treatment guidance produced by the World Health Organization or must wait years for well-established medicines and interventions to be recommended for their use.[15]

ii. Proposed rights-based solutions: States should create avenues for the meaningful participation of communities at all stages of research and development. Supporting this, General Comment 25 clarifies that the right to science "*cannot be interpreted as establishing a rigid distinction between the scientist who produces science and the general population, entitled only to enjoy the benefits derived from research conducted by scientists*." Ethical guidelines governing medical research, such as the Declaration of Helsinki, also see participation as essential for promoting the health and rights of potential research participants.[16] In fostering participation in science, states can draw on many effective models, including the rich tradition of community

[15] For a fuller exploration of how participation in science shapes access to the benefits of science, see: https://www.treatmentactiongroup.org/letter/submission-on-the-right-to-access-and-take-part-in-scientific-progress/

[16] Declaration of Helsinki (2024) para. 6: "*Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights. Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed. Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results*." <https://www.wma.net/policies-post/wma-declaration-of-helsinki/> accessed 20 January 2025

participation in global health research, which dates back to the start of the AIDS movement. Today, this history has evolved into a widely recognized norm that communities affected by a particular disease or condition have a right to participate in research as more than just clinical trial participants or passive beneficiaries of medical advancement. Best practices for operationalizing this norm exist in the form of guidelines, such as the Good Participatory Practice (GPP) guidelines, and there are specific models for operationalizing this norm, including Community Advisory Boards (CABs). Composed of people living with and affected by TB, HIV, or other diseases, CABs act in an advisory capacity to scientists, funders, and pharmaceutical companies conducting clinical trials or public health studies. In addition, states should ensure that vulnerable and marginalized groups are represented in research studies. Here again, the Declaration of Helsinki recognizes that "[certain] *individuals, groups, and communities have distinctive health needs" and that "their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion*."[17]

c. **Third, the right to science lends credence to the idea that access to medicines would be strengthened by embedding conditionalities across the research and development process and in any agreements between public research funders and product developers.** The inclusion of pro-access conditionalities is necessary to ensure that the public does not pay twice for innovation: first through taxes that are used to fund said research and then again when governments purchase the tangible benefits of said research at prices set by private developers who benefitted from public research investments but control access to the resulting products through intellectual property, marketing plans and product formulations (which can lead to lack of availability in geographic areas or for populations not deemed lucrative).

   i. Example of current problems: The public sector accounts for 70% of annual spending on TB research and development but the resulting products are often priced out of reach for many by the pharmaceutical companies that benefited from public funding of the R&D.[18] A case in point is the drug bedaquiline, the backbone of WHO-recommended regimens to treat drug-resistant TB. Commercialized and owned by the pharmaceutical company by Johnson and Johnson, bedaquiline was developed through substantial public resources. Peer-reviewed research shows that total public investments in the development of bedaquiline exceeded the originator's funding by a factor of 1.6 – 5.1. Public contributions took the form of clinical trials funding (US$109–252 million), tax credits to the innovator company (US$22–36 million), tax deductions (US$8–27 million), administration of a drug donation program for early market access (US$5 million), and innovation rewards including a priority review voucher (revenues at US$300–400 million). Despite the public sector

[17] Declaration of Helsinki (2024) <https://www.wma.net/policies-post/wma-declaration-of-helsinki/> accessed 20 January 2025
[18] Frick, Mike; Henry Ian and Erica Lessem (2016) Falling Short of the Rights to Health and Scientific Progress. <https://pmc.ncbi.nlm.nih.gov/articles/PMC5070677/> accessed 20 January 2025

underwriting the development of bedaquiline, Johnson and Johnson maintained a monopoly on the drug until activist pressure and a series of domestic patent oppositions forced the company to commit to not enforce secondary patients on bedaquiline in 134 low- and middle-income countries.[19] Bedaquiline is an example of the need to find a fair balance between the R&D investments of the private sector, the R&D investments of the public sector, and the prices paid by health systems and patients.

ii. Proposed rights-based solution: Attaching stronger conditionalities to public funding agreements would help to ensure the accessibility, affordability, and availability of products developed through publicly funded science. Conditionalities are a common feature of industrial policy and their application to health research would not be unique.[20] Conditionalities on medicines research could address factors such as intellectual property management, data sharing, technology out-licensing, product pricing, supply availability, requirements for national regulatory registration, requirements for studying the product and developing formulations/assays for key populations such as children and other contractual terms that shape access to medicines. The GHIAA database provides examples of research agreements that have employed such access-oriented sponsorship in the past, e.g., licensing agreements where a global health license will revert back to the financing foundation if agreement terms for access are not met.

d. **Fourth, the right to science emphasizes the importance of the human rights principle of transparency for ensuring access to medicines.** Transparency is important for improving the availability, affordability, and efficiency of TB health products. States, in particular, require access to data on pricing, intellectual property, manufacturing and research costs to make informed decisions in the manufacturing, purchasing, and procurement of health technologies.[21] Transparency should apply to information of sales volumes, licensing terms, access plans, public investments into research and development.

i. Example of current problems: The current lack of transparency has limited access to new TB drugs, drug regimens, and diagnostics – and threatens to curtail the affordability of future vaccines against TB – in several ways for both high-income and low- and middle-income countries.

1. Licensing deals for candidate TB vaccines in late-stage development made between funders, research product sponsors, and manufacturers are not published. This has made it difficult for governments to plan for the introduction of new TB vaccines because the terms of the

[19] Johnson and Johnson (2023) Press Release. <https://www.jnj.com/media-center/press-releases/johnson-johnson-confirms-intent-not-to-enforce-patents-for-sirturo-bedaquiline-for-the-treatment-of-multidrug-resistant-tuberculosis-in-134-low-and-middle-income-countries> accessed 20 January 2025.
[20] Mazzucato and Rodrik (2023) Industrial Policy with Conditionalities: A Taxonomy and Sample Cases <https://drodrik.scholar.harvard.edu/sites/scholar.harvard.edu/files/dani-rodrik/files/conditionality_mazzucato_rodrik_0927202.pdf> accessed 20 January 2025.
[21] Gotham et al. (2020) Public investments in the clinical development of bedaquiline. PLoS One https://pmc.ncbi.nlm.nih.gov/articles/PMC7500616/ accessed 20 January 2025

licenses including geographic scope, price, eligibility for concessional pricing, registration requirements, and other access conditionalities are not available to decision-makers in countries where new TB vaccines are needed most.[22]

2. New drugs have dramatically improved and shortened TB treatment but comprehensive research on the price of new medicines by MSF indicates that these regimens "*continue to remain inaccessible to many people, in part due to their high prices and licensing arrangements by pharmaceutical corporations and other drug developers.*" This research indicates that opaque and restrictive licensing arrangements drive the high prices and lack of availability of TB medicines.[23] The prices of new TB drugs that are at the heart of shorter treatment regimens including bedaquiline, delamanid, and pretomanid are confidential in high-income countries. Based on research conducted by MSF, the price of the 6-month regimen the WHO recommends for drug-resistant TB – BPaL, using drugs bedaquiline, pretomanid, and linezolid – can cost anywhere from EUR20,000 per treatment course in France and Germany to EUR25,0000 In Poland and Italy.[24] When purchased through the Global Drug Facility — a UN-hosted mechanism which pools TB drug procurement and bargains with suppliers collectively on behalf of multiple country governments, publishing its prices transparently — the cost of the BPaL regimen is USD $345.[25]

ii. Proposed rights-based solution: Transparency requirements must become standard in the research in development of health products, especially treatment, diagnostic, and preventative measures, funded with public resources. Licensing deals including public funding must be made public and posted in an accessible format. Transparency requirements should include the pricing of e.g., drug components and calculations for the pricing of therapeutic, diagnostic, and preventive health products.

[22] Treatment Action Group. 2022 TB Vaccine Pipeline Report. https://www.treatmentactiongroup.org/resources/pipeline-report/2022-pipeline-report/ accessed 20 January 2025
[23] MSF. (2022) DR-TB Drugs Under the Microscope. < https://www.msfaccess.org/dr-tb-drugs-under-microscope-8th-edition > accessed 20 January 2025.
[24] Ibid.
[25] Stop TB Partnership. https://www.stoptb.org/what-we-do/facilitate-access-tb-drugs-diagnostics/global-drug-facility-gdf/buyers/plan-order accessed 20 January 2025.

Summary of Recommendations:

19. Based on the underlying human rights-based analysis and the provided examples, TAG strongly encourages OHCHR to use the forthcoming comprehensive report to:

    a. **Include a substantive discussion of state obligations under the right to science as they relate to access to medicines** in the forthcoming comprehensive report to be presented to the Human Rights Council at its fifty-ninth session in June 2025.

    b. **Call attention to the inter-related dimensions of the right to science and the right to health** in the context of medicines access.

    c. Remind states of these existing human rights obligations and to **recognize the right to science as "a significant mediator" between human rights and property rights**.

    d. Continue to **issue human rights-based submissions to the WHO INB Pandemic Accord process**, thereby supporting states to not remove any additional human rights-based language from the text and reinstate human rights references deleted in the negotiations. Without this, the Pandemic Accord will not change the status quo for access to medicines as needed for a life with dignity for all of humanity.

    e. **Counsel states towards recognizing that voluntary actions remain non-actions on access to medicines**.

    f. Encourage states **to include the right to science in their CESCR state party reviews.**

20. TAG calls on states to:

    a. **Commit to a renewed effort to fulfill their human rights obligations by ensuring that medicines developers and product sponsors respect and protect human rights:**

        i. At a minimum, public funders should require product developers to publish access plans that address key determinants of medicines access.

        ii. Such access plans should be a requirement at all stages of R&D but can grow in specificity and detail as research progresses from early discovery to regulatory approval

    b. **Create avenues for the meaningful participation of communities at all stages of scientific research and development**:

        i. Best practices for operationalizing this norm exist in the form of guidelines, such as the Good Participatory Practice (GPP) guidelines, and there are specific models for operationalizing this norm, including Community Advisory Boards (CABs).

        ii. States should ensure that vulnerable and marginalized groups are represented in research studies.

c. **Attach stronger conditionalities to public funding agreements would help to ensure the accessibility, affordability, and availability of products developed through publicly funded science**:

   i. Conditionalities on medicines research could address factors such as intellectual property management, data sharing, technology out-licensing, product pricing, supply availability, requirements for national regulatory registration, requirements for studying the product and developing formulations/assays for key populations such as children and other contractual terms that shape access to medicines

   ii. Licensing deals including public funding must be made public and posted in an accessible format. Transparency requirements should include the pricing of e.g., drug components and calculations for the pricing of therapeutic, diagnostic, and preventive health products.