

Fight AIDS + TB

Open Letter to the Unitaid Executive Board

RE: Prioritising AHD/AIDS and TB treatment in Unitaid's 2022-2026 investment and strategic plans

8 December 2021

Dear Representatives,

We are writing as concerned advocates to seek your leadership and the voice of Unitaid's Board in ensuring that more attention is paid to the drivers of readily preventable AIDS and tuberculosis (TB) deaths in Unitaid's current Investment Plan and Strategic Framework for 2022-2026.

The need for this support could not be more pressing. Having already missed the 2020 target to reduce AIDS deaths to 500,000 annually, UNAIDS estimates there is a risk of 7.7 million AIDS-related deaths over the next decade unless there is a course-correction in HIV service coverage.ⁱ And, for the first time in a decade, TB deaths, including deaths from TB among people living with HIV, are rising.ⁱⁱ This reversal of progress can be stopped but not without focused leadership and intervention from Unitaid.

Advanced HIV disease (AHD)/AIDS

We welcome Unitaid's financial support to date for advanced HIV disease (AHD) and AIDS. But we urge that this area continues to be a priority intervention in the current Investment Plan as well as the next strategy as we are far from introducing and scaling up access to the medical tools needed to better detect, prevent, and treat AHD/AIDS in national programmes.

Unfortunately, we still face reluctance from governments and global health actors to invest in diagnosing and treating life-threatening opportunistic infections (most notably, TB and cryptococcal meningitis) and providing hospitalisation and care to people critically ill with AHD/AIDS.

Just as we cannot allow AHD/AIDS deaths to be invisible, we cannot silently tolerate suffering from opportunistic infections like cryptococcal meningitis that are responsible for hundreds of thousands of deaths each year. Many of these investments are urgently required and delay to a later date during the next Strategic Period would translate into years of avoidable mortality from AHD/AIDS.

There are significant areas for which Unitaid has a unique role and added value to ensure that the global community responds to AHD/AIDS.

Unitaid's leadership in this area can help realise critical goals, including:

- Encouraging governments to set goals and report on progress for the rollout of the AHD/AIDS package of care,ⁱⁱⁱ and incidence, treatment coverage, and mortality of AHD/AIDS and cryptococcal meningitis.
- Supporting the accelerated adoption of the AHD/AIDS package of care,^{iv,v} including innovations in cryptococcal meningitis treatment which can drastically improve the otherwise abysmal survival rates (around 20%) from fluconazole monotherapy that is the standard of care in many countries.^{vi vii}
- Catalyzing scale-up of critical AHD/AIDS diagnostics, including cryptococcal meningitis antigen (CrAg) screening tests for TB, and also supporting the introduction of more effective tests with greatly improved sensitivity for TB screening.
- Increasing availability and affordability of flucytosine and liposomal amphotericin B (LAmB), including generic versions, and access to fluconazole for prevention.

Shorter TB treatment regimens

In addition to ongoing and planned investments in TB preventive treatment and TB diagnostics, **Unitaid's support to catalyze access and address market barriers to shorter regimens for treating drug-sensitive and drug-resistant TB is critically important.**

For the first time in more than 40 years, we are beginning to realize real advances in shortening treatment for both drug-resistant and drug-sensitive TB. In the last two years, studies have demonstrated that four-month regimens can safely and effectively cure drug-sensitive TB and that six-month regimens can do the same for drug-resistant TB.^{viii, ix, x, xi} In 2022, results from several phase III trials (SimpliciTB, RIFASHORT, and TRUNCATE-TB) may lead to further changes to the treatment landscape for TB.^{xii, xiii, xiv, xv} These shorter regimens, which shift several second-line medicines to first-line and require administration at different doses and in new combinations, are advancing against the backdrop of an increasingly decentralized and fragmented market for TB medicines more and more reliant on domestic financing. This is especially true for drug-sensitive TB.^{xvi}

The need for Unitaid's investment to support market interventions and catalytic activities is increasingly urgent to move programs to take up these new, shorter regimens—several of which will require new formulations of existing medicines—while ensuring affordability, quality, and supply security for global TB medicines. Anticipated barriers, including the cost, supply, and in-country registration of medicines, threaten access to these long sought-after shorter regimens. Unitaid has a long legacy of success in addressing similar issues through its strategic investments and it is currently well positioned to overcome these new barriers.

Unitaid's catalytic role

Unitaid's comparative strength means it can add value and is needed for AHD/AIDS and TB where there are important medical innovations to be introduced and scaled-up through greater affordability and accessibility.

In summary, we ask that the Board prioritise measures needed most for preventing deaths from AHD/AIDS and for anticipating and addressing access barriers to long sought after shorter, safer treatment regimens for TB and that this be reflected in the Investment Plan through 2023 and the Strategic Framework for 2022-2026.

Thank you for considering these requests.

Sincerely,

The Fight AIDS Coalition
Grupo de Ativistas em Tratamentos (GAT), Portugal
Alliance Burundaise pour la lutte contre la Tuberculose, la Lepre et les autres Maladies (ABTL), Burundi
American Thoracic Society, United States
Americas TB Coalition, United States
Among Karsa Indonesia, Indonesia
Asia Pacific Council of AIDS Service Organizations (APCASO), Thailand
ARK Foundation, India
Ashar Alo Society, Bangladesh
Asia Pacific Network of People Living with HIV (APN+), Thailand
Association of people living with HIV/AIDS (APL+), Laos
Cambodia People living with HIV Network (CPN+), Cambodia
Club des Amis Damien (CAD), Democratic Republic of the Congo
CommonSpirit Health, U.S.
Community and Family Aid Foundation, Ghana
Community Network for Empowerment (CoNE), India
Council of people Living with HIV AIDS of Kerala (CPK), India
Delft CAB Cape town, South Africa
Delft Task applied science CAB, South Africa
Drugs for Neglected Diseases initiative (DNDi), Global
EMPOWER INDIA, India
European Respiratory Society, Belgium
Fenway Health, U.S.
Fight AIDS Coalition (FAC) India, India
FIND, the global alliance for diagnostics, Switzerland, India, Kenya, South Africa
Global Alliance for Human Rights, India
Global Alliance for TB Drug Development, Inc., U.S.
Global Network of People Living with HIV (GNP+), Netherlands
Global TB Community Advisory Board (TB CAB), Global
Grupo De Prevenção As DST/HIV/Aids E Drogas, Brasil
Health GAP, Global
Human Touch Foundation, India
Human Touch Foundation Goa, India
International AIDS Vaccine Initiative (IAVI), U.S.
International Community of Women living with HIV Eastern Africa (ICWEA)
International Treatment Preparedness Coalition (ITPC Global), South Africa
ITPC LATCA - Peru, Perú
ITPC-MENA, Morocco

Maryknoll Sisters, U.S.
 Matahari Global Solutions
 Medical Mycology Society of Nigeria, Nigeria
 Médecins Sans Frontières (MSF) Access Campaign, Global
 MPact: Global Action for Gay Health & Rights, U.S.
 Mumbai TB collective, India
 National Association of PLHA in Nepal, Nepal
 NIMR-Muhimbili Centre, Tanzania
 Observatório Tuberculose Brasil, Brasil
 Partners In Health (PIH), U.S.
 Perinatal HIV Research Unit (PHRU) Matlosana, South Africa
 Positive Malaysian Treatment Access & Advocacy Group (MTAAG+), Malaysia
 Rede Paulista de Controle Social da Tuberculose, Brasil
 REDE-TB Brazilian TB Research Network, Brasil
 Results Canada, Canada
 Sahara CFRCAR, India
 Sikkim Drug Users' Forum, India
 Sisters of St. Francis of Philadelphia, U.S.
 Stop TB Partnership, Switzerland
 Stop TB Canada, Canada
 Stop TB communities delegation, Kenya
 Stop TB RDC, Democratic Republic of the Congo
 STOP TB USA, U.S.
 Success Capital Organisation, Botswana
 TB Europe Coalition (TBEC), Netherlands
 TB Proof, South Africa
 The Global Coalition of TB Activists (GCTA),
 The New Liberation Education Economic Development, India
 THINK, South Africa
 Thomas Wuoto, Kenya
 Treatment Action Group (TAG), United States
 Tuberculosis Vaccine Initiative (TBVI),
 Vietnam Network of People living with HIV (VNP+), Vietnam
 Centre for Civil Society (University of KwaZulu-Natal), South Africa
 Western Harm Reduction Network, India
 Wote Youth Development Projects, Kenya
 Yayasan Menara Agung Pengharapan Internasional (MAP Internasional), Indonesia
 Zimbabwe National Network of People Living with HIV (ZNNP+), Zimbabwe

Dorothy Christine Adongo, Founder and Convener of the Integrity Social Justice Centre,
 Kenya
 Alexandre Alanio, France
 Ketho Angami, India
 Ms Prathna Bagrath, Rhodes University, South Africa
 David Barr, U.S.
 Susan Blank, MD, MPH, U.S.
 Brian Citro, Human Rights Lawyer, U.S.
 Gisa Dang, You&Me LLC, U.S.
 Stuart Flavell, past International Coordinator, GNP+, U.S.

Rebecca Gathercole, St George's University of London, United Kingdom
Nelesh Govender, National Institute for Communicable Diseases, South Africa
Prof Shabbar Jaffar, United Kingdom
Francis Joseph, India
Omar Juma, Tanzania
Kezhosano Kikhi, Advocate ,India
Sharonann Lynch, O'Neill Institute at Georgetown University, U.S.
Robert Makombe, South Africa
Juliette McHardy, Fellow, O'Neill Institute, New Zealand
Assoc. Prof. David Meya, College of Health Sciences, Makerere University, Uganda
Luciana Nemeth, Global TB Caucus, Spain
Joseph Osmundson, Clinical Assistant Professor, NYU, U.S.
Miriam Rabkin, Associate Professor of Medicine and Epidemiology, Columbia University
Mailman School of Public Health, U.S.
Bobby Ramakant, CNS, India/Thailand
Audrey Rodrigues(Chairperson) CAB, UCTLI, Cape Town, South Africa
Michael D. Sangster, Canada
Prashant Sharma, Health Activist, Sikkim, India
Jose Roberto Lapa e Silva, Brasil
Nestani Tukvadze, MD, Georgia
Thomas Wuoto, Mambokaaje CBO, Kenya
Wendy Zodinpuui, India
Rokozi, India

CC: Unitaid Secretariat

ⁱ UNAIDS. Unequal, unprepared, under threat: why bold action against inequalities is need end AIDS, stop COVID-190 and Prepare for Future Pandemics. Geneva: Joint United Nations Programme on HIV/AIDS; 2021. Available from: https://www.unaids.org/sites/default/files/media_asset/2021_WAD_report_en.pdf.

ⁱⁱ WHO. Global tuberculosis report 2021. Geneva; October 2021. Available from: <https://www.who.int/publications/i/item/9789240037021>.

ⁱⁱⁱ MSF. 20-tool checklist for diagnosing, treating and preventing AIDS: Diagnostic and treatment checklist for the management of HIV and advanced HIV disease in outpatient settings. January 2021. Available from: <https://msfaccess.org/20-tool-checklist-diagnosing-treating-and-preventing-aids>.

^{iv} WHO. Package Of Care for Children and Adolescents with Advanced HIV Disease: STOP AIDS. July 2020. Available from: <https://www.who.int/publications/i/item/9789240008045>.

^v WHO Advanced HIV disease (AHD) Guidelines. July 2017. Available from: <https://www.who.int/publications/i/item/9789241550062>.

^{vi} Lawrence DS et al. Single high-dose liposomal amphotericin based regimen for treatment of HIV-associated Cryptococcal Meningitis: results of the phase-3 Ambition-cm Randomised Trial. 11th IAS Conference on HIV Science, abstract OALB01LB03, 2021.

^{vii} Ending Cryptococcal Meningitis Deaths by 2030 – Strategic Framework. South Africa; 2021. Available from: https://msfaccess.org/sites/default/files/2021-05/Cryptococcal%20Meningitis_Briefing_Doc-END_CM%20DEATHS_2030-strategic%20framework_ENG_14.5.2021.pdf.

^{viii} Dorman SE, Nahid P, Kurbatova EV, et al. Four-month rifapentine regimens with or without moxifloxacin for tuberculosis. N Engl J Med 2021; 384:1705–18. doi: [10.1056/NEJMoa2033400](https://doi.org/10.1056/NEJMoa2033400).

^{ix} McKenna, Lindsay. The 2020 TB Treatment Pipeline Report. Treatment Action Group, New York: 2020. Available from: https://www.treatmentactiongroup.org/wp-content/uploads/2020/11/pipeline_tb_treatment_2020_final.pdf.

^x Conradie F, Everitt D, Olugbosi M, et al. High rate of successful outcomes treating highly resistant TB in the ZeNix study of pretomanid, bedaquiline and alternative doses and durations of linezolid. Oral abstract presented at: 11th IAS Conference on HIV Science, 21 July 2021. Available from: <https://theprogramme.ias2021.org/Abstract/Abstract/2405>.

^{xi} Nyang'wa, Bern Thomas. TB-PRACTECAL stage 2 efficacy results. Presented at: SP-34 TB-PRACTECAL: trial results and next steps, 52nd Union World Conference on Lung Health, 22 October 2021.

^{xii} McKenna, Lindsay. The 2021 TB Treatment Pipeline Report. Treatment Action Group, New York: 2021. Available from: https://www.treatmentactiongroup.org/wp-content/uploads/2021/11/pipeline_TB_Treatment_2021_final.pdf.

^{xiii} Global Alliance for TB Drug Development. Trial to Evaluate the Efficacy, Safety and Tolerability of BPamZ in Drug-Sensitive (DS-TB) Adult Patients and Drug-Resistant (DR-TB) Adult Patients. July 2018 start date. Available from: <https://clinicaltrials.gov/ct2/show/NCT03338621>.

^{xiv} St George's, University of London. A Randomised Trial to Evaluate Toxicity and Efficacy of 1200mg and 1800mg Rifampicin for Pulmonary Tuberculosis (RIFASHORT). October 2015 start date. Available from: <https://clinicaltrials.gov/ct2/show/NCT02581527>.

^{xv} University College, London. Two-month Regimens Using Novel Combinations to Augment Treatment Effectiveness for Drug-sensitive Tuberculosis (TRUNCATE-TB). March 2018 start date. Available from: <https://clinicaltrials.gov/ct2/show/NCT03474198>.

^{xvi} Waning, Brenda. GDF: Connecting People, Programs, and Policies to TB Innovations. Presentation to the 34th Meeting of the Stop TB Partnership Coordinating Board. 29 September 2021. Available from: <https://stoptb.org/assets/documents/about/cb/meetings/34/34-06%20Accelerating%20New%20TB%20Tools%20and%20Approaches/34-6.16%20GDF%20Connecting%20People,%20Programs,%20and%20Policies%20to%20TB%20Innovations.pdf>.