



43rd Executive Board Meeting
21-22 November 2023
Santiago Dantas room
Itamaraty Place
Brasilia, Brazil

Agenda item 3

Report from the Executive Director

For Information **For Review and Advice** **For Decision**

Introduction

With less than seven years remaining, the world is struggling to achieve the health targets enshrined in the Sustainable Development Goals by 2030. Millions are still not being reached by life-saving healthcare such as HIV treatment or preventive treatment for tuberculosis (TB). We are also still wrestling with the aftermath of the COVID-19 pandemic, which disrupted health programs. Health investment needs are meanwhile outrunning available resources, creating an ever-widening funding gap.

In addition to the devastating death toll due to COVID-19, and other diseases as a consequence, the pandemic further exposed the dramatic inequality in access to health tools and services between high- and low-income countries. Unitaid has mapped such inequities, and their root causes, along each step of the value chain, from research and development to country delivery. We have found opportunities for efficiencies in each step. The lessons learned from COVID-19 now need to inform the next steps in addressing future pandemic and global emergency needs (please see our publication "[Learnings and opportunities for equitable access to lifesaving therapeutics in future pandemics](#)"). Unitaid is working with global, regional, and country stakeholders and supporting ongoing initiatives such as the WHO-led processes for coordination for future pandemics, the 100 Days Mission initiative, as well as those led by the G20, the G7 and other multilateral frameworks.

We are ready to support and lead efforts to ensure access is not an afterthought in the design of the new global health architecture to respond to pandemics (please see our brief "[Access is not an afterthought: Equitable access to therapeutics for pandemic preparedness and response](#)"). However, we remain concerned about the limited attention and leadership in research and development for therapeutics, especially for products that could meet the needs of low- and middle-income countries. In the absence of a dynamic pipeline of promising therapeutics products now, and without early research and development being shaped to account for equitable access down the line, the next pandemic will catch us again without these key tools. However, if therapeutics are strategically deployed together with vaccines and diagnostics, we could mitigate and potentially prevent the effects of a pandemic not only in high income countries but also in low- and middle-countries.

The recent pandemic will not be the last global health emergency we need to contend with. As we look to the future, climate change poses a significant risk to the global health response, potentially compromising Unitaid's vision and the impact we seek to have on people's lives. The change in climate is intensifying, making people more vulnerable to illnesses exacerbated by extreme heat, drought and famine, and increasing the spread of infectious diseases like malaria. Dr. Tedros Adhanom Ghebreyesus, the Director General of the WHO, has underlined that climate is the number one risk in global health.

Global warming affects all aspects of health and influences how and where diseases are transmitted, exposing communities worldwide to new risks. In recent years we have seen how extreme climate events disrupt access to healthcare with increasing frequency and severity, making it harder to achieve greater equity. In this complex and rapidly evolving context Unitaid is planning how we can effectively deliver the healthcare that will be needed in the near future. Our 2023-2027 Strategy establishes climate and health as a priority and we are well-positioned to contribute to building more resilient health systems through our targeted work on products, supply chains and delivery models. Four specific areas inform our future climate and health strategy including Unitaid's contribution to reducing the impact of health products on climate and nature; making products and health interventions more resilient to climate shocks; addressing health needs created or exacerbated by climate change; and mitigating the impact from the Secretariat and our grant portfolio on climate and nature.

In spite of the challenges, there are real grounds for optimism. Opportunities abound for Unitaid to use its expertise to tap into medical science and extend the reach of new health products and solutions and drive equitable access. Impactful innovations, such as long-acting medications and monoclonal antibodies (mAbs), hold out the promise to accelerate progress on HIV and coinfections, TB and malaria, to advance maternal and child health, and enable more effective tools as we work to strengthen pandemic prevention, preparedness and response. Our pivotal role in identifying health innovations and working with scale-up partners to make them affordable and get them to people faster, is widely recognized.

Far from deflating our ambition, the challenges that lie ahead are a spur to action and put a premium on our work to address obstacles and forge a path allowing the best health innovations to flow unimpeded to the communities that most need them. Likewise, global health inequities, accelerating climate change, a growing risk of drug resistance and outbreaks of new disease, are all reasons for Unitaid and our partners to push the boundaries of innovation and alleviate the health burden in low- middle-income countries.

As we look to the future we are determined to remain dynamic and ambitious, and most importantly to push boundaries relentlessly in the years to come in a spirit of hope tempered by realism.

Progress against 2023 Priorities

Delivering impact through Unitaid investments in key health products

Unitaid's portfolio of investments demonstrates a profound capacity and commitment to identifying and introducing game-changing health products in low- and middle-income countries and working towards equitable access.

This year our work on malaria is advancing after two calls for proposals closed in August. In an effort to mitigate antimalarial drug resistance, Unitaid will invest in interventions that rapidly diversify the use of artemisinin-based combination therapy (ACT). This work will support the adoption and increased use of newer ACTs, in particular artesunate-pyronadine (ASPY), and potentially other antimalarials, as part of multiple first-line treatment strategies.

In addition, we will make important investments to accelerate the introduction of new vector control products and strategies to deliver them. Despite progress achieved with affordable vector control interventions, including long-lasting insecticide nets, indoor residual spraying and larvicides, several factors threaten continued success. Insecticide resistance, residual transmission, invasive vector species, and specific challenges in malaria prevention including migrant populations, climate-related crises and conflict settings are some of the obstacles we are up against.

Our work will help to gather the epidemiological and operational evidence needed to inform the introduction of new vector control tools, considering cost and deployment strategies in specific settings. Through our investment we also help to establish healthy market conditions for new tools, including supply security and sustainable pricing.

At the United Nations High-Level Meeting on Tuberculosis in September, world leaders committed to ambitious new targets to end TB. Unitaid's Executive Board Chair set the scene underlining that the world is not sufficiently aware that tuberculosis is the deadliest infectious disease after Covid-19. She spoke to the leading role Unitaid has been playing, notably our contribution to the first pediatric formulations for children, advances in pediatric diagnosis, expansion of access to shorter, more effective preventive treatments as well as technologies that can rapidly identify multidrug-resistant tuberculosis.

As the largest multilateral funder of TB research and development globally, Unitaid remains deeply committed to this fight. With support from the Board, we are making important investments. The pandemic had a significant impact on efforts to address TB, limiting case detection and reducing the number of people on treatment. To overcome these setbacks, we must improve detection tools, accelerate the adoption of new drugs, and address drug-resistant tuberculosis (DR-TB), which poses a particularly difficult challenge. Therefore, in September Unitaid launched a call for proposals to increase the number of people cured from drug-resistant TB by supporting the introduction and scale-up of new DR-TB drugs and regimens. The call for proposals focuses on the breadth of DR-TB care needed to enable accelerated detection, prevention and treatment, and considers people-centered approaches, community-driven demand creation and innovative case-finding.

Leadership by civil society and communities is central to this work and will be critical to understanding not only the needs of affected communities but also the obstacles they face in accessing treatment. To address gaps in the TB response, these partners will play a key role in engaging policymakers and at-risk populations. They will also help to improve understanding of drug-resistant TB treatment, increase demand for new regimens and diagnostics, and strengthen links between health services.

At the same time, we are seeing significant results from our previous TB investments. At this year's Union World Conference on Lung Health taking place in Paris mid-November, programs and research studies supported by Unitaid will be in the spotlight. The results of significant clinical trials evaluating multidrug-resistant tuberculosis (MDR-TB) treatment and prevention will be presented.

Unitaid has invested more than \$80 million in the endTB clinical trial which set out to identify shorter, more tolerable and injection-free treatments for MDR-TB. Over six years, the trial followed more than 700 volunteers with MDR-TB or rifampicin-resistant TB (RR-TB) in seven countries: Georgia, India, Kazakhstan, Lesotho, Pakistan, Peru and South Africa. These long-awaited results include details on the efficacy of five main combinations of treatment and the hope is that they will result in promising changes to WHO recommendations. In addition, results from the TB-CHAMP trial, which led to the first evaluation of MDR-TB prevention for children will also be presented. This will provide the first-ever high-quality evidence into MDR-TB preventive therapies for children - a much-needed intervention to protect those at highest risk. Treatment for MDR-TB is very burdensome and expensive, so preventive treatment is critical.

This work is a part of a broader piece of Unitaid's efforts to improve child friendly treatments for MDR-TB. In collaboration with Stellenbosch University through the BENEFIT Kids project we are working to not only prevent MDR-TB, but to advance MDR-TB treatment for children. Unitaid's investments are producing critical evidence on dosing, safety, and efficacy — evidence that is shaping WHO policy recommendations and facilitating the production of new TB medications tailored for children.

In relation to our long-standing work on TB, I am pleased to report that following extensive advocacy efforts from the TB community, partners and Unitaid, Johnson & Johnson announced in late September that they would not enforce their secondary patents related to Bedaquiline – a crucial medication for combating DR-TB. This development represents a significant step forward in enhancing access to essential TB treatment, not only in low- and middle-income countries but also in upper-middle income countries. This builds on over a decade of our work and more than US\$ 100 million of Unitaid investments to generate the evidence needed to introduce and scale the use of Bedaquiline in regimens appropriate for most patients suffering from drug resistant TB.

As we move forward, Unitaid is focused on closing the TB diagnostic gap, introducing new treatments, reducing the cost of vital medicines, and ensuring everyone at risk of TB can access high quality preventive care and avoid illness. The experience of affected communities will continue to guide our efforts. At the same time, we also need industry to invest more in TB treatment and diagnostics.

As a member of the newly established TB Vaccine Accelerator Council, we will work alongside partners to support the development and availability of TB vaccines that are effective in halting the epidemic. The Council is a WHO initiative that will work to boost the TB vaccine pipeline and facilitate the licensing and use of safe TB vaccines that are impactful in ending the TB epidemic. To do this the Council will foster innovative and sustainable financial solutions as well as partnerships. It will also work to identify market solutions to incentivize TB vaccine development, manufacturing and access as well as strengthen advocacy with decision makers, including through political platforms such as the African Union, G20, G7, and others.

Creating systemic conditions for sustainable, equitable access & fostering inclusive and demand driven partnerships for innovation

As we implement our portfolio and kick start new investments, we continuously scan the horizon to identify promising opportunities to enable equitable access in a way that is sustainable. At the Board meeting in November, Unitaid will consider a new Area for Intervention which puts forward a ground breaking opportunity to advance equitable access to monoclonal antibodies (mAbs) that can treat and prevent infectious diseases in low- and middle-income countries. In exploring opportunities related to mAbs we are preparing for the future.

Monoclonal antibodies have enormous potential to address unmet needs in infectious diseases in low- and middle-income countries by providing a highly effective response. However, severe barriers currently limit access in low- and middle-income countries to existing monoclonal antibodies and further restrict investment in developing new mAbs solutions that target priority diseases in these countries. Very high priced and ill-adapted products, limited global manufacturing capacity and lack of a footprint in low-and middle-income

countries are among the barriers that would need to be overcome for this innovative solution to be available in low- and middle-income countries for key diseases where other tools are not sufficient

Unitaid has identified opportunities to address the significant obstacles that prevent broad access to existing and forthcoming mAbs with the potential to advance many of Unitaid's programmatic priorities. There is an urgent need to move forward with this work to avoid reinforcing inequalities in low- and middle-income countries. We are committed to working with partners to anticipate challenges and address systemic issues that prevent access to the most advanced health solutions. We are working with multiple partners including communities and civil society to ensure they participate from the design phase so that mAbs address the needs of patients. We will also continue to collaborate with key partners who are advancing the pipeline for infectious diseases for low- and middle-income countries, including funders supporting the development of mAbs targeting key infectious diseases and industry partners that have shown potential to expand their capacity to include mAbs.

In addition, Unitaid is engaging in regional manufacturing and the related area of pandemic prevention preparedness and response. Currently the majority of health products are manufactured at a significant distance from the people in low- and middle-income countries who need them. This limits timely and reliable supply of products in specific regions and ultimately hinders equitable access. This reality was exposed during the COVID-19 pandemic when global supply chain disruption had a disproportionate impact on access to life-saving products in LMICs.

Reinforcing regional production of medicines in countries where it offers the most impact on equitable access is critical to building a stronger and more resilient health response. Unitaid is demonstrating that we have a unique role to play in this space. Building on our work to date, we will continue to support regional manufacturers, particularly in Africa, and build value chains for key product categories. This will help to ensure that there is a sustainable path for high impact products to be produced and delivered at a competitive market price. The focus of this work will be on products that are not prioritized by global manufacturers but are needed for a more effective global health response. For example, in Kenya and Nigeria manufacturers benefiting from Unitaid's support on Sulfadoxine Pyrimethamine (SP) – an effective and affordable medicine used to prevent malaria in pregnant women and infants, children under five and pregnant women - are now offering comparable prices for SP in their respective regions with products meeting WHO prequalification quality standards, making them eligible to receive Global Fund and World Bank procurement allocations.

As Unitaid moves forward in supporting regional manufacturing, we will target a subset of health products that are outlined in our strategy in the list of thirty products that we aim to introduce by 2030. Many of these products already have active Areas for Investment and therefore Unitaid has planned interventions to address key access barriers and engage scale-up partners, countries, and communities to secure demand. In addition to these regional manufacturing priorities, Unitaid is also developing an oxygen regional manufacturing investment for Executive Board consideration in early 2024. A strong complement to Unitaid's regional manufacturing initiatives will be our partnership with the WHO Regulation and Prequalification Department (WHO RPQ), that we can leverage to stimulate activities within ongoing health product regulatory harmonization initiatives in specific regions and accelerate progress towards strengthening continental and regional regulatory capabilities. Through our support we aim to strengthen regional regulatory authorities and systems to accelerate product approvals without compromising quality.

In addition, the Global Oxygen Alliance (GO2AL), co-chaired by Unitaid, has pivoted from crisis response focused on COVID-19 towards an inclusive long-term partnership focused on cross-cutting systems and operations. Through advocacy, financing and country support, the alliance now serves as a platform to support countries to be self-sufficient in acquiring sustainable and equitable access to medical oxygen. During the UN General Assembly, GO2AL presented the Executive Summary of its Strategy for 2024-2030 which defines the Alliance's five strategic objectives: driving investment consolidation and sustainability; strengthening innovative supply chains and market shaping; supporting robust country planning and implementation; advocating and generating demand; and measuring performance and ensuring accountability. Four dedicated

working groups, each leading one of the first four objectives, are currently being established. The GO2AL Secretariat will lead on the monitoring and evaluation work central to the fifth strategic objective.

Unitaid continues to engage with a broad set of partners and alliances to promote sustainable, equitable access. Since July, Unitaid has joined efforts by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to support regional manufacturing of HIV rapid diagnostic tests (RDTs). Initiatives include supporting the design of the expression of interest for the WHO Expert Review Panel for Diagnostic Products (ERPD) that was announced in August and will allow an expedited regulatory pathway for HIV RDTs manufactured in Africa. In addition, ongoing collaboration with the Foundation for Innovative New Diagnostics (FIND) will provide technical support to African manufacturers that show potential to meet the regulatory and quality requirements of large institutional donors.

Looking ahead, we are working to develop collaborative agreements with existing and new partners that are central to the implementation of our regional manufacturing initiative strategy, including the Pan American Health Organization (PAHO), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the African Union Development Agency-NEPAD, Africa Pharmaceutical Technology Foundation, Africa Society for Laboratory Medicine, and the Governments of Brazil, Kenya, Nigeria and South Africa to name a few concrete examples.

Mobilizing funding required to fully implement the 2023-2027 Strategy

With a number of promising investments in our pipeline with potential to advance access to new products that can save lives and money for the global health response, we must collectively be determined to mobilize the resources that we need. Using funding approved by the Board in December 2022, Unitaid has strengthened its resource mobilization, strategic communications and advocacy capacity and has operationalized a resource mobilization strategy for 2023 and 2024.

We continue to adapt to a complex environment where competition for resources is intense and funding can be unpredictable. Considering the rapid changes in the funding environment in recent years, we continue to develop our resource mobilization model. We are engaging more actively with existing donors to push for multi-year funding agreements. We are also deepening engagement with a growing number of stakeholders in new donor countries throughout the budget process to keep Unitaid on the radar and advocate for multiple funding channels and opportunities.

Core funding and multi-year agreements for Unitaid are essential for the long-term viability of the organization. I am pleased to report that we are closing the year with every Executive Board member having a confirmed core contribution to Unitaid in 2023. This is the first time this has happened since 2017. I hope this provides a platform for a sustained increase in core contributions as we seek to attract new core and specific funders. Furthermore, since we last met, I would like to acknowledge that we have confirmed contributions from Chile, Japan, Korea, Portugal, and Spain. If we can sustain the core income growth trajectory we achieved in 2023 (12%), especially with multi-year agreements, we will start to make significant inroads in 2024 on the 2025 funding shortfall. At the same time, specified funding can assist us in realizing our objectives sooner, as demonstrated by Unitaid's recent achievements in the response to COVID-19. In the current overseas aid environment, it is unlikely that traditional sources of funding alone will allow Unitaid to reach a target of \$1.5 billion for the 2023-2027 strategic period and therefore we are exploring other funding models, including blended financing.

In spite of the challenges, Unitaid continues to build on a strong track record, and we will leverage our unique expertise to bring forward promising opportunities that have the potential to change people's lives and advance the global health response. With the prioritized opportunities recommended in the current investment plan, Unitaid investments will protect children and other vulnerable populations from malaria, reduce neonatal deaths, address drug resistance, ensure the continued effectiveness of lifesaving medicines, improve access to better tools for Advanced HIV Disease, and support access to promising innovations, including long-acting

technologies and monoclonal antibodies in low- and middle-income countries. However, based on our current funding Unitaid will not be able to support all the high-impact investment opportunities we have identified which are critical to achieving the global health targets. Opportunities that may not be funded include crucial efforts to address malaria, increased access to screening and treatment for cervical cancer and sexually transmitted infections, integrated diagnostics, and antimicrobial resistance (AMR).

Therefore, to further strengthen our resource mobilization and advocacy efforts, we are leveraging communications to better articulate the critical role innovations play in the health response and Unitaid's unique value proposition. Since my last report, the team launched the organization's updated visual identity, branding, and a series of strategic communications products. An update of the organization's website is also underway.

To raise awareness on strategic areas of Unitaid's work and to engage with donors and partners, we have used the opportunity of high-profile global events including the UN General Assembly, the World Health Assembly in Berlin, the World Local Production Forum in the Netherlands, the World Bio Summit in Seoul, and we are looking forward to participating in the upcoming United Nations Climate Change Conference, where we will launch Unitaid's climate strategy.

Unitaid was highly visible at the UN General Assembly this year. Key elements of our portfolio cut across the UN General Assembly High-Level Meetings focused on TB, pandemic preparedness prevention and response as well as universal health coverage. There was recognition amongst global leaders, partners, and stakeholders of the significant contribution Unitaid has been able to make to the global health response. In addition, the announcement from the Bill & Melinda Gates Foundation to double its contribution to Unitaid over five years represented a huge vote of confidence in Unitaid by a leading health player. It drew significant attention to Unitaid's work and was a mark of appreciation and recognition of our contribution to the global health response, particularly in the area of women and children's health.

As we move into 2024 and lay the groundwork for 2025 and beyond, I would like to acknowledge the significant support and contribution that the Board has made to Unitaid's success to date. We count on your continued collaboration in investing in Unitaid to ensure we leverage the full potential of our unique expertise and positioning in the global health response.

Optimizing Unitaid for strategy implementation

To lay the foundation for the successful delivery of Unitaid's Strategy for 2023-2027, a Functional Review of the Secretariat was completed in early 2023. The review concluded that "building on its universal recognition as a key player in access to health innovations in HIV, Malaria, TB, Unitaid has responded effectively to new challenges, e.g., women and children's health, global health emergencies. A strong investment planning process ensures Unitaid focuses on areas of highest impact." The Review did not recommend any change to Unitaid's operating model. Within the Secretariat, analysis by SEEK found "Strong cross-functional collaboration and flexibility. Highly dedicated staff, driven by a strong belief in Unitaid's vision, mission, and values." While observing potential to clarify end-to-end accountabilities and responsibilities across thematic issues, their report recommended an organizational design that "optimizes for a lean and balanced organizational structure" without radically changing it.

At the same time, the Review noted the need to address insufficient resourcing for the Secretariat. This included staffing for core functions, as well as for five areas of work strengthened in the new strategy: Access; Engagement with communities, civil society, countries, and strategic partners; Regional manufacturing; Global Health Emergencies (PPPR); and Climate and Health. In response, in June 2023, the Executive Board approved a pragmatic, risk-based approach to resourcing the Secretariat. This approach called for a two-phased approach: a first phase to provide the resources needed to address core staffing shortfalls more permanently and to temporarily resource the five strengthened areas of work at their lowest levels of ambition, followed by a second phase (if approved by the Board in June 2024) to fully resource the five areas.

The Secretariat has been actively implementing the recommendations of the Functional Review and related Executive Board decisions. Key recommendations from the Functional Review related to changes in ways of working, such as establishing organizational planning and development as a key function of a learning organization, are in advanced stages of development and the Secretariat plans for these to be institutionalized by mid-2024. Regarding Phase 1 of the activation and resourcing of the five areas of work strengthened in the Strategy, both the resourcing efforts and the associated programmatic progress is well underway and we are on track to report on progress to the Board in early 2024.

Unitaid's staff are the driving force behind our success and therefore well-being will remain a high priority as an integral part of the workplace culture we want to create together. We will build on efforts we have nurtured this past year. Through a series of all staff meetings and related initiatives we have consulted colleagues on key areas of work. This has included various engagements throughout the functional review process to ensure Secretariat staff were informed of the findings, outcomes, and recommendations of the Review; an all-staff workshop to consult colleagues on the draft Staff and Management Charter; as well as an all-staff session to introduce Unitaid's new brand identity and related strategic communications tools that can be leveraged. In addition, an Action Plan for the implementation of the Staff and Management Charter has been developed and shared with all staff, with interactive learning and development opportunities scheduled for all staff, and specifically for staff with people management responsibilities. A Monitoring and Evaluation framework is also being drafted to ensure we can track progress and adjust efforts where needed.

Looking ahead, we have a clear vision for 2024. Four high-level priorities will guide the Secretariat: implementation of the strategy, focus on impact, resource mobilization and improving ways of working. The concrete outcomes we expect to achieve under these priorities by the end of the next year include being on track for the mid-term review of the strategy and formalized agreements with key scale-up partners; elevated results and impact from our active and closing investments; resources needed for all 2025 investments secured; one strategic vision for Unitaid, driven by substance and impact and a positive workplace culture grounded in effective annual planning, monitoring of organizational work and a consolidated approach to all investments.

Unitaid's strategy stands as a beacon of ambition and thoughtful planning, reinforced by a dedicated team of professionals and strong partnerships that are more than capable of bringing it to life. In close collaboration with the Board, we are committed to not only meet but exceed the strategy's demanding objectives, leaving an enduring mark on the global health landscape.