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Agenda item 4

Report from the Executive Director

For Information 🛛 For Review and Advice 🗌 For Decision 🗌

Executive Director Report to the Executive Board

Dear Board members,

Unitaid is ready to double down on core health goals. With our new strategy successfully launched, Unitaid is moving into high gear to help countries gain access to vital treatments and diagnostics to fight HIV, co-infections, tuberculosis and malaria and support women and children's health.

To keep ahead of the curve in the global response, we are also addressing broader issues, giving support to communities to engage with their own health and helping to develop health systems that are more efficient, resilient, and sustainable.

As outlined in our new strategy, we are making our interventions more people-centred and better integrated across health systems, while laying foundations for pandemic prevention, preparedness, and response.

Far too many people in low- and middle-income countries (LMICs) are struggling with little or no access to the health products they need.

The COVID-19 pandemic shone a light on many areas, like medical oxygen, where we are intensifying our efforts to address gaps in healthcare. In retrospect, the pandemic highlighted Unitaid's critical role in addressing sharp disparities in access to life-saving drugs and diagnostics between high-income countries and LMICs.

Unitaid has its eye on the long haul. Our partnerships are key to ensuring that access to the health products that we help introduce in low-income countries is both equitable and sustainable.

We are working closely with countries to adopt a risk-management approach to establish how they can make their health systems more flexible and better able to offer ready access to care for those in need.

The way we work, engaging closely with partners and affected communities to develop new models of delivery and care, will put countries on a firmer footing to respond to emergencies and deal with growing challenges such as climate change.

Countries also face a pressing need to develop capacity in other key areas, including a regional capability to manufacture health products.

Bold initiatives are needed that strengthen readiness to deal with disease-bearing pathogens. For example, versatile diagnostics that help us to fight HIV, tuberculosis, and malaria more effectively and efforts to pursue triple elimination of mother-to-child transmission of HIV, syphilis, and hepatitis B.

We also must anticipate new challenges by taking a hard look at future needs, such as a potential cure for HIV, use of monoclonal antibodies to prevent malaria and advanced techniques such as gene therapy.

Unitaid is in the front line of an extraordinary effort to meet the health-related SDGs in the remaining years of the decade. A lot of work needs to be done in HIV and co-infections, TB, malaria, and reproductive, maternal, new-born, child, and adolescent health to meet global objectives by 2030. A flow of new products will be key to getting the world back on track in preventing the spread of HIV, TB, malaria, and other diseases.

Unitaid has a unique combination of skills as: a pathfinder, identifying promising solutions to complex health problems; an investor, mobilizing resources to accelerate equitable access to innovative health solutions; and as an influencer aligning partners behind common health goals.

We have always pushed at the frontiers of global health and have built a strong track record of success. We must intensify our work to stay on track in a fast-evolving global context, in the knowledge that the more financial resources we have as an organization the more we can achieve.

Mobilize funding to fully implement the Strategy

No matter where people live, they should be able to benefit from the highest quality healthcare. We require better and more effective health products and approaches if we are to meet the global goals to end HIV, TB and malaria pandemics and reach other key targets in women and children's health by 2030. Furthermore, equitable access is essential if we are to prepare for preventing and responding to new pandemics, in pursuit of universal health coverage.

Unitaid's impact on global health is significant and more relevant than ever for millions of people, particularly in low- and middle-income countries, where the best health products do not always reach those who need them most. Our unique blend of technical expertise and agility allows us to identify effective tests and medicines, fast-track their development and help make them available at a speed, price, scale, and quality needed to tackle some of the biggest challenges in global public health.

Our efforts save lives, time and money and have proven to maximize the effectiveness of the overall response. Products introduced and supported by Unitaid now reach more than 100 million people each year. These key health tools enable cost reductions and improve efficiencies, critical measures that are projected to generate more than US\$7 billion in savings by 2030.

In continued collaboration with the Executive Board, we are determined to secure resources for all the opportunities in our investment pipeline. To support this ambition, this year we put in place clear plans to ramp up our resource mobilization efforts. Based on a detailed funding analysis and donor mapping we have developed an evidence-based resource mobilization plan for the year with clear objectives, targeted donors, stakeholders, and key events. We have also strengthened the External Relations and Communications team with additional personnel bringing a wealth of knowledge on advocacy, resource mobilization, donor relations, communications, and partnerships expertise.

Since the end of last year, we have increased our engagement with key donors including visits to Brazil, Canada, Chile, Germany, Japan, Korea, Spain, the United Kingdom and held key meetings with the European Commission and the Gates Foundation. We have also expanded engagement with parliamentarians, including developing a partnership with the UNITE Network for political advocacy around key events such as advocacy around Unitaid's role in equitable access during the Multistakeholder Hearings on TB, pandemic prevention, preparedness and response, and universal health coverage held in May by the President of the General Assembly, with clear mention of our unique role and impact in these areas. In addition, we are strengthening our engagement with parliamentarians in key donor countries, including by organizing donor field visits to illustrate the impact of Unitaid's work from the perspective of communities and our implementing partners, including a field visit by UK parliamentarians to Kenya to gain greater insight on Unitaid's investments on women and girls health.

Working closely with communities, civil society organizations and key partners including the Global TB Caucus and Unite, we are further strengthening advocacy networks in support of Unitaid. In April, a strategic meeting on advocacy for resource mobilization took place in Nairobi with our communities and NGO delegations, donors, and advocates from low- and middle-income countries. This important meeting highlighted the critical role that communities and civil society can play in amplifying Unitaid's visibility articulating Unitaid's unique role in the global health response and resource mobilization efforts.

Through the end of this year, we will continue to leverage key global events to raise awareness and engage with donors and advocates. Unitaid will have an active role in the global health agenda at the UN General Assembly in September, as well as the World Health Summit in Berlin and the World Bio Summit in Seoul in October to support advocacy and strategic communications we have prioritized a package of corporate communications products which is in the final stages of completion. Unitaid's Investment Case was issued in May in the lead up to the World Health Assembly and will feature in our communications materials in the coming months. We are also in the process of refreshing Unitaid's organizational narrative, visual identity and branding, as well as our website.

Accelerate the introduction of key health products

In line with our first Strategic Objective, Unitaid continues to be a leader in driving change by bringing innovative solutions to the global health response. In the last six months, with support from the Board, we have moved forward with important investments.

To date, both hepatitis C and harm reduction have been critically underfunded, further marginalizing already vulnerable populations. Unitaid is an important leader in this space. In April at the 27th Harm Reduction International Conference in Melbourne we announced our commitment of \$31 million in harm reduction to prevent hepatitis C among people who inject drugs and other at-risk populations. This is a significant contribution to support harm reduction in low- and middle-income countries, representing a 20% increase in total funding.

Former New Zealand Prime Minister and current Chair of the Global Commission on Drug Policy, Helen Clark, congratulated Unitaid for this investment which supports the integration of hepatitis C testing and treatment within harm reduction programs and trials the use of two products to prevent HIV infection. Our investments will also generate evidence critical to enabling the broader use of low dead space syringes and long-acting buprenorphine. This work includes understanding user preferences, addressing high costs, increasing demand, and demonstrating methods for effective delivery. Both products will be piloted in Egypt, India, Kyrgyzstan, Nigeria, South Africa, Tanzania, Ukraine, and Vietnam. Sites in Armenia and Georgia will trial low dead space syringes. All ten countries will integrate service delivery within harm reduction programs.

We also moved ahead with work to address advanced HIV disease (AHD) as outlined in our strategy. Unitaid is investing in efforts that will further simplify how advanced HIV disease is managed, including for children. This work builds on our previous investments which have significantly improved access to care that include some of the most effective medicines and diagnostics recommended by the WHO. Through this investment Unitaid is working to increase equitable access to the best products for managing advanced HIV disease in adults as well as children. To do this we will support strategies for rapid diagnosis, prevention, and treatment of infections associated with HIV in children, expand access to care for

advanced HIV disease and enable further scale-up. We will also increase the use of newer tools to address the main causes of death, including cryptococcal meningitis and other fungal infections.

There are several factors threatening progress in addressing malaria, including insecticide resistance, residual transmission, invasive vector species, and challenges in malaria prevention in specific contexts such as migrant populations and climate-related crises. The introduction of new products is key to preventing resistance and keeping the global malaria response on track. In April, Unitaid launched a call for proposals to drive the uptake of additional tools to address malaria in countries with a high malaria burden and those with an emerging threat of mosquitos that can transmits both Plasmodium falciparum and P. vivax malaria parasites. To enable the rapid adoption and scale-up of new tools, more evidence is needed on how to integrate them within existing malaria control strategies. Work is also needed to develop a viable market for these new products to ensure adequate supply and sustainable pricing. Unitaid is well placed to address these issues in collaboration with key partners.

Create systemic conditions for sustainable, equitable access

To ensure that the products Unitaid supports are truly available to all, Strategic Objective 2 of our Strategy calls for the creation of systemic conditions for equitable and sustainable access. This work includes establishing an enabling access environment, including intellectual property and regulation, and support to innovative supply models and approaches such as regional manufacturing.

The COVID-19 pandemic put a spotlight on intellectual property and its implications for equitable access to health products. Since our inception, Unitaid has been a leader in this space and under our current strategy we are already working to establish an enabling environment for access by building on our past work in intellectual property and regulatory processes.

Overcoming intellectual property barriers to ensure the availability and affordability of the best treatments for HIV, TB, hepatitis C and other diseases is central to meaningful progress towards attaining Sustainable Development Goal 3. Based on proposals put forward earlier this year, Unitaid's Investment Plan includes financing to support capacity building on the use of flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and to expand these efforts to technical support, advocacy, and policy interventions. We also aim to address a range of intellectual property barriers that are particularly relevant for biological products, including trade secrets and regulatory exclusivity.

To help the global health community to address existing health challenges and market failures, as well as provide capacity to respond to future pandemics, broad access to regionally manufactured products in low- and middle-income countries will be essential. Regional production is a key element in establishing capacity at the regional and local level and plays a vital role in addressing significant gaps in the production of region-specific health products that are often not of interest to large manufacturers, based in high-income countries.

Unitaid's work, since inception, includes several examples where manufacturing of quality-assured health products in low- and middle-income countries facilitates increased access to better healthcare. Recent and ongoing projects include the development of child-friendly TB medicines; the technical support to Kenyan and Nigerian companies to develop WHO prequalified sulfadoxine/pyrimethamine to prevent malaria in children and pregnant women; the development of generic pediatric HIV medicine,

dolutegravir; and technology transfer and increased technical and manufacturing capacity of companies in Brazil and Senegal to produce rapid antigen tests for COVID-19.

The COVID-19 pandemic highlighted the need for equitable access to effective health products and the fact that low- and middle-income countries cannot rely disproportionately on manufacturing in high-income countries to meet their needs.

In the inception phase of the new strategy, Unitaid engaged multiple stakeholders across industry, government agencies, and partner organizations to apply lessons learned to regional manufacturing. We also focused on identification of opportunities to strengthen regional manufacturing of medicines and invitro diagnostics, through pathfinder projects, using products from existing and prospective investments in malaria, post-partum hemorrhage, HIV, HCV, and antimicrobial resistance.

Our existing work on intellectual property, including collaboration with the Medicines Patent Pool (MPP) and the WHO regulatory and prequalification programme (WHO RPQ), collaboration with major donors to align on procurement criteria, and strong engagement with regional governing and regulatory institutions, position Unitaid as a natural arbiter to address many of the systemic challenges associated with enhancing regional manufacturing across the global south. Unitaid can leverage our core portfolio to support development, introduction and access to regionally manufactured health tools and our cross-cutting enabler investments will contribute to efforts to promote the development of regional value chains for quality-assured health products, including manufacturing.

Our efforts to date have yielded some immediate and emerging successes, including budding partnerships across African manufacturers and technical and financial support from partner organizations. Unitaid has gained growing recognition as a thought leader on equitable access and regional manufacturing and has strengthened relationships with key players including the G7, the G20, the European Commission, Africa Centers for Disease Control and Prevention, the African Development Bank, the African Union Development Agency-NEPAD and the Pan American Health Organization (PAHO). Unitaid was also invited to join the Medicines Policy and Regulatory Reforms technical committee of the African Medicines Regulatory Harmonization initiative as a technical partner. Building on our experience and expertise in regional manufacturing to date, we have an opportunity to continue to drive progress in this space.

Foster inclusive and demand-driven partnerships for innovation

People are at the center of our new Strategy and Unitaid's work, and success is grounded in strong engagement with key partners and our commitment to this approach is stronger than ever. Under Strategic Objective 3, our Strategy recognizes that integration of diversity, equity and inclusion into our work will lead to better results. Therefore, we are working to increase engagement with a breadth of partners including not only implementing partners but also communities and country stakeholders, including governments, communities and civil society. As we strengthen existing partnerships and forge new ones, I would like to highlight a few key successes as we continue to strengthen existing partnerships.

WHO is at the heart of our collaboration with partners. Since our inception WHO has played a central role in informing Unitaid's investment ideas and ensuring that the evidence from our investments is reflected in global health guidance that influences national policies, enabling the scale-up of groundbreaking health products. This work is not always visible and can easily be overlooked but it is what enables millions of people in low-and middle-income countries to use health products that are transforming their lives and the way communities access healthcare. As we begin a new strategic period and mark WHO's 75th Anniversary I would like to acknowledge this unique union.

In the first half of this year Unitaid advanced key partnerships.

Unitaid played a leading role during the COVID-19 pandemic by fostering partnerships to increase access to medical oxygen in low-and middle-income countries. As the world transitions from the acute phase of the pandemic and prepares for future threats, the ACT-A-Oxygen Emergency Taskforce evolved into the Global Oxygen Alliance (GO2AL) - a broader and more inclusive partnership. For the next two years, GO2AL will be co-chaired by Unitaid and the Global Fund to Fight AIDS, Tuberculosis and Malaria, and vice-chaired by the Pan America Health Organization and the Africa Center for Disease Control and Prevention.

With this transition, GO2AL aims to convert the investments made during the pandemic into lives saved and to continue the critical work of the previous Taskforce, including financing to expand production, lowering the price of oxygen and providing technical support to governments. In addition, the alliance will take a more inclusive and planned approach which will emphasize the importance of assessing oxygen and oxygen systems needs at the country, regional and global levels through key partner engagement, particularly with countries, civil society and communities, to facilitate bottom-up planning and programming. Moreover, GO2AL will strongly position and advocate for sustainable oxygen systems as an essential building block for health system strengthening, universal health coverage and pandemic preparedness and response.

Unitaid will continue to lead partner coordination on investment consolidation and sustainability; procurement, supply, and market shaping; country mapping and planning; advocacy, and demand generation, with a focus on low- and middle-income countries. Unitaid will also provide day-to-day management as a co-host of the GO2AL Secretariat, together with WHO and UNICEF. Building on Unitaid's experience leading the ACT-A Oxygen Emergency Taskforce, Unitaid and the other Chairs will oversee and ensure that the work of GO2AL is undertaken through efficient and effective coordination to make high-quality medical oxygen available, affordable, and equitably accessible for those in need.

Optimize Unitaid for Strategy Implementation

The Secretariat is actively implementing the 2023-2027 Strategy. This includes both the work of Unitaid as an investor, pathfinder and influencer, in pursuit of equitable access to affordable and effective health products; activating our new Performance Management Framework; and ensuring the Secretariat is optimized for strategy implementation through a functional review.

Unitaid's Strategy learned from, expanded upon and formalized the strategic shifts and new areas of work that emerged during our previous strategic period. This led to explicit organizational priorities, strategic objectives and targets that build upon past successes, while framing a vision for the next five years that "will guide us and our partners in continuing to drive innovation and equitable access across the global health landscape, helping the world reach its goals and reaching the most vulnerable amongst us. It will require continued guidance by the Executive Board, a sustained dedication by the Secretariat, and the resources necessary to support the work."

At the same time that Unitaid adopted its 2023-2027 Strategy, we also adopted a revised performance framework including a revised set of Key Performance Indicators (KPIs). The performance framework is the set of systems, processes and plans that translate organizational goals into results by making use of qualitative and quantitative performance information to support the performance management of Unitaid over time. The framework assists framing how Unitaid defines, measures and manages performance. The revised Framework not only contains several new KPIs that better reflect Unitaid's current strategy, but there is also greater emphasis on approaching performance management in a more holistic manner. In practice, this means that KPIs not only support accountability, but also support organizational learning and identifying successes to promote and advocate Unitaid's work. A few headline examples presented for the first time at this Executive Board meeting include the feedback received from the first Unitaid Partner Survey (linked to Strategic Objective 3 and KPI 3.1), where the responses from four stakeholders – i) Community based organizations, ii) Civil Society organizations, iii) Countries and iv) Scale Funders, provide important learnings, which will help us shape forward-looking actions around partnerships. In addition, the new scale-up dashboard (linked to Strategic Objective 1, and KPI 1.3) provides a high-level summary of how Unitaid-supported health products are being scaled, with reference to 'Magnitude' of scale, 'Speed' of scale and 'Equity' of scale. This helps to clarify where Unitaid is delivering upon its Mission to expand the reach of the best health products for those who need them most.

While Unitaid's scope, ambition, and mission have evolved, the Secretariat currently remains structured, resourced, and measured against the original organizational model. It was in this context that Unitaid launched a Functional Review in 2022. The review provided an opportunity for us to reflect and ensure we are optimally structured to deliver on our ambitious strategy. The objectives of the Functional Review were three-fold: 1) lay the foundation for the successful operationalization of Unitaid's 2023-2027 strategy; 2) ensure that the organization is fit-for-purpose and properly resourced to deliver on the strategic objectives in an efficient and effective manner; and 3) help foster a positive workplace culture conducive to development and growth.

The Final Report on the Functional 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 Functional Review did not recommend any change to Unitaid's Operating Model.

Within the Secretariat, the Review found "Strong cross-functional collaboration and flexibility. Highly dedicated staff, driven by a strong belief in Unitaid's vision, mission and values." While observing the 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. The Report did highlight, however, the need "to review resourcing of non-grant work to enable implementation of new Strategy."

As described in the Final Report, the Functional Review explored and identified potential efficiencies that could be realized within the Unitaid Secretariat's existing business areas, such as optimizing ways of working including investment planning, making and management and by eliminating functions that are no longer essential. The aim of this was to maximize available resources, contribute to addressing chronic workload and, where appropriate, free up resources that could be redeployed.

Based on an in-depth analysis of work practices across the Secretariat in 2022, the review identified efficiencies that could be realized within the Unitaid Secretariat's existing business areas, making work practices more efficient. The Secretariat has already begun to implement some of these recommendations, which will save staff time and effort.

At the same time, the Functional Review assessed and identified where existing business areas need greater resourcing, either to address significantly increased workload or to reflect new tasks and areas of work required to optimize the business of the Secretariat. This analysis identified several new functions needed to optimize the business of the Secretariat and enable it to deliver on the new Strategy effectively and efficiently.

The Functional Review also assessed the Secretariat's current capacity to implement areas of work strengthened in the new Strategy, concluding there is a need to increase staffing to support enhanced roles in Access; Engagement with communities, civil society, countries, and strategic partners; Regional manufacturing; Global Health Emergencies, including work related to pandemic prevention, preparedness and response (PPPR); and Health and Climate Change. The review identified new functions needed to implement these areas of work, which were initiated prior to the new Strategy but which the Secretariat had never been sufficiently resourced for.

The Secretariat has prepared a pragmatic, phased approach that will make the necessary staffing changes efficiently, while mitigating any associated risks and delivering the results needed to fully implement the 2023-2027 Strategy. This approach was reviewed, discussed and endorsed by the Joint Finance and Audit Committee and Policy and Strategy Committee in May 2023.

We have an ambitious agenda ahead of us. I am confident that in collaboration with the Executive Board, our partners and staff we will continue to push boundaries to help ensure sustainable equitable access to the best health products for all.

With my best regards,

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Philippe Duneton Executive Director Unitaid