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Agenda item 5

Unitaid Strategy 2023-2027

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For Information	For Review and Advice	For Adoption	\leq

I Executive Summary

Unitaid occupies a unique place in global health. We champion equitable access to health tools. We ensure that innovative health solutions are fit-for-purpose, affordable and rapidly available for people and communities who need them most, primarily for the fight against HIV, tuberculosis (TB) and malaria and to improve maternal and child health. Unitaid has also taken up a leadership role in the global COVID-19 response under ACT-A.

For over 15 years, Unitaid has led the way by identifying game-changing health innovations and making them a reality, clearing barriers to access. Key results include: a ground-breaking single-pill antiretroviral treatment, by now the most commonly used HIV regimen; the most effective and cost-effective malaria prevention tools used today; the first ever child-adapted TB and HIV medicines; and effective screen-and-treat solutions for cervical cancer.

Innovations are vital to achieving the health-related Sustainable Development Goals (SDGs). But innovations do not automatically reach people and communities who could benefit most. That only happens if the conditions to achieve equitable access are established rapidly, widely, and sustainably. This is Unitaid's area of focus and expertise. By getting better, more affordable, and more effective lifesaving health innovations to people and communities who need them several years earlier than they otherwise would have, millions of lives and billions of dollars are being saved, and the time to reach global health targets is shortened by several years.

Over the past few years, progress towards achieving Sustainable Development Goal 3 — to ensure healthy lives and promote wellbeing for all, at all ages — has gone severely off track. Even before the COVID-19 pandemic, progress was slowing. The pandemic made it much worse: in 2020, for the first time since the fight against HIV, tuberculosis and malaria began in earnest, key indicators were worse than they were the year before. The COVID-19 pandemic also starkly exposed both the dramatic inequality in access to care between high- and low-income countries and between rich and poor people. Moreover, the effects of climate change are intensifying, threatening the health and livelihoods of hundreds of millions around the world.

The need for faster, equitable access to affordable and effective health products has therefore never been greater. Unitaid's 2023-2027 Strategy addresses this need. The Strategy is the road map for how Unitaid will make an essential contribution to our common challenges. That means regaining lost ground and paving the way for even greater efforts in the remaining years of this decade in order to achieve Universal Health Coverage, as part of SDG3.

The new Strategy builds on the successes of the past, but it encompasses an even stronger engagement and collaboration with communities and products' end users to ensure they are part of every step of Unitaid's work. Equity, partnerships, and community engagement are key to Unitaid's continuing success. Working with affected people and communities throughout the process, Unitaid can make the identification, design, and introduction of key health products better and more effective.

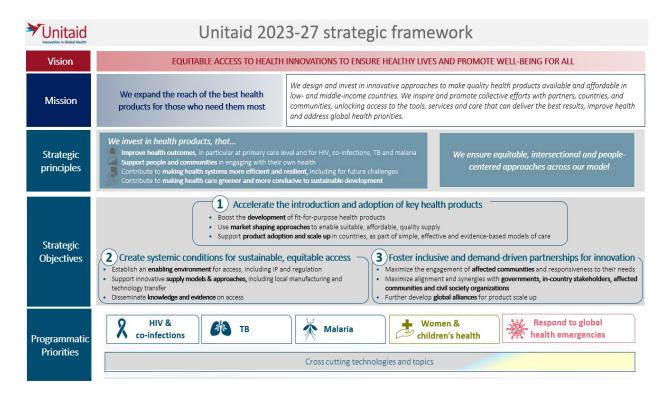
To help "bend the curve" towards progress and success, Unitaid commits to bring at least 30 essential new innovations – products and more effective ways to use them – to all those who need better tools and drugs. The 30 proposed innovations – "30 by 2030" – will deliver significant health

impact in the lead up to 2030 and beyond, harnessing innovation as better, more affordable and more effective health products. The 30 by 2030 highlight the tangible change that Unitaid's work will bring about in the coming years, as a result of the new Strategy.

We forecast that an annual commitment of US\$ 300 million over the course of the Strategy period — US\$ 1.5 billion in total — will allow us to fully execute the Strategy and achieve this "30 by 2030" goal. This level of resourcing is also aligned with Unitaid's historical capacity.

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The Unitaid Strategy for 2023-2027 leverages Unitaid's distinctive comparative advantage — as a pathfinder, investor, and influencer — and will maximize the impact of our interventions. It takes our vision — equitable access to healthcare innovation — and works to turn it into reality by defining what sorts of products we will support to accomplish our three Strategic Objectives.



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The three Strategic Objectives are to: 1) accelerate the introduction and adoption of key health products; 2) create systemic conditions for sustainable, equitable access; and 3) foster inclusive and demand-driven partnerships for innovation.

The Programmatic Priorities are defined by considering the **potential for impact** and **our ability to make a difference**. Key investments will focus on **prevention** (with a focus on access to high-impact preventive tools, particularly for high-risk groups), **testing** (to close the detection gap, reduce the number of missed cases, and link to care), and **treatment** (prioritizing access to simpler, more optimal treatment regimens for adults and children, as well as enhancing adherence to effective treatment to improve outcomes).

Using that framework, and Unitaid's recognized ability to scan the landscape for promising leads, we will find and promote products fighting HIV and co-infections, tuberculosis, and malaria. The Programmatic Priorities also encompass products to improve the health of women and children and respond to emerging or future global health emergencies, as well as products that can work across focus areas.

The Strategy incorporates new elements and new ways of thinking about what we do and how we do it. The Strategy reflects the importance of demand creation and community-led approaches. While Unitaid will continue to focus on health products, our Strategy encourages Unitaid to be even more clear-eyed about tying our priorities to the strategies that work to reach wider targets, not just a product introduced.

The Strategy stresses the importance of equitable access and sets out how we will achieve this to ensure impact for marginalized and at-risk populations. It also commits Unitaid to working with our partners in long-term alliances to define the goals of our interventions and carry the message of equitable access through every level of our strategic partnerships.

To make the shifts outlined in the Strategy, we will need to gain a stronger voice in the global health world. The Strategy pushes us to become a frontstage convenor, taking a more active role in facilitating access to innovative, fit-for-purpose products that are suitable for use in resource-limited settings, coordinating and disseminating knowledge to address barriers in access, and investing to create a sustainable access environment.

The Strategy also focuses on engaging in reducing suppliers' environmental footprint in a more defined way, seeking to minimize the environmental impacts of supported products by moving production closer to need, making production facilities more environmentally friendly, and recognizing that environmental issues play an increasingly important role in many of the health challenges that Unitaid and our partners are confronting.

This Strategy is ambitious, realistic, and achievable. It 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 renewed dedication by the Secretariat, and the resources necessary to support the work. This Strategy is the outline of the story that will be the next five years of Unitaid's vital, life-altering work. Together with our partners, donors, and the rest of the global health community, we will write the story.

II Getting Back on Track

A global crisis

The global health landscape has changed dramatically in the past five years. Twenty years of unbroken progress has ended and partly reversed. The health-related Sustainable Development Goals have become even harder to achieve. The slowdown began even before the COVID-19 pandemic, but in a matter of months, the pandemic erased several years' improvement in the fight against HIV, tuberculosis, malaria, and other health conditions affecting the most vulnerable. The COVID-19 pandemic disrupted access to lifesaving care for millions of people, contributing to an estimated 15 million excess deaths over the two-year period 2020-2021. Some of those deaths were due to HIV and co-infections, tuberculosis, and malaria — preventable and treatable diseases.

Beyond the pandemic, the increasingly acute effects of climate change are affecting, even eroding, previous health gains. Climate change and increasing political instability are driving migration and violent conflict. In the coming years, we will therefore operate in an ever more difficult environment, with an increasing number of challenges emerging to our efforts to maintain progress.

Reaching many of the targets under SDG 3 will now be very hard to do without an extraordinary effort over the remaining years of this decade.

The pandemic brought into stark relief the extreme inequitable access to necessary healthcare. While tens of millions of people in high-income countries received critical care when infected with COVID-19 — ventilators, supplemental oxygen, and expensive, experimental treatments — billions of others did not have access to even basic tools or treatments. The pandemic stretched health systems beyond capacity and exposed weaknesses, such as the lack of sufficient access to oxygen.

In essence, the pandemic shone a light on areas where attention and future efforts need to be intensified.

We know what to do

The world has long recognized that, in addition to money and commitment, *innovation* is the key to progress. Just as the discovery and deployment of new drugs and vaccines have propelled many of the leaps of progress in global health, from the introduction of antibiotics to success in ending the spread of HIV/AIDS, **new products will be key to getting the world back on track towards success against HIV, TB, malaria and other diseases**. However, innovation means more than new products; it also means collaborating in new ways, bringing additional voices and forging new partnerships to shape the products, ensuring that those who should benefit are also part of the innovation process. Such a holistic approach is necessary to ensure access for all and that people trust and use the new

products. It is equitable access to innovation that will drive progress towards realization of SDG 3.¹ It is therefore fundamental to this Strategy.

Some of the greatest leaps of progress often grow out of a crisis. The creation of antiretroviral drugs for treatment of HIV, as well as the rapid development of vaccines and treatments for COVID-19, and dozens of other products all stem from a crisis response. The broad and challenging crisis health systems all over the globe face today should spur further innovation. Unitaid is ready for that effort.

Innovation is successful only if it reaches all those who can benefit from the new products. Strengthening the pathways from product development to the use of those products by those who need them is an under-prioritized but crucial area of work. It is also Unitaid's core competency and focus. The improvements required — quicker approval of, and access to, new, improved, and affordable treatments, including removing unnecessary regulatory or legal barriers; better supply chain and distribution of diagnostics, treatments, and equipment; better digitalization of diagnostics and treatment data, and improving digital connection — are all investments that will pay off now and into the future. Such investments will increase the resilience of existing efforts to fight infectious diseases and improve health outcomes — and better prepare the world for new pandemics.

Unitaid: Pathfinder, Investor, Influencer for innovation and access

Over the past 15 years, Unitaid's work has enabled safe and effective products to treat HIV, TB, malaria and other global health challenges to become available to <u>all</u> people who can benefit from them in low- and middle-income countries. As a result of our work and investments, such products were in wide use an average of 2 to 3 times faster than they otherwise would have been. Moreover, Unitaid's work typically boosts product adoption between 5- and 50-fold when measured from the beginning of our involvement to the end. Across our portfolio of projects, **the products and innovations we support are adopted, scaled, and used by communities, countries, and our partners, benefitting more than 100 million people each year.** The products Unitaid invests in represent a significant improvement over the previous standard of care. This means better use of resources, better outcomes, and better lives for the people who gain access to those products.

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As the engine for equitable access to innovation of the global health community, Unitaid has and will continue to play a unique role in meeting the challenges of today and tomorrow. Unitaid sits

¹ See, for example, the WHO's "End Malaria Strategy" (2015). More recently, the RBM Partnership the End Malaria noted in their 2019 Annual report that "...to reach eradication, there is an urgent need to significantly step up political will and financing, increase efficiencies through greater collaboration and better use of data, and *invest in developing and expanding access to transformative life-saving tools and innovations*" (p. 12; emphasis added). And the Global Fund stated, in their most recent investment case (2022): "For TB and malaria...it is assumed that the introduction of innovations and new tools considered necessary to achieve the respective Global Plan targets in full will be implemented progressively between 2024 and 2030" (p. 95).

at the intersection of industry, communities, civil society, and the practicalities of global health challenges. Our long-term vision turns the possible into reality by acting in three ways:

- as a Pathfinder, Unitaid identifies, analyses, and frames complex health problems and then scans technology landscapes to identify promising solutions. We help map the pathways for innovative health products to become realities, get to where they are needed, and arrive at the scale required;
- 2) as an **Investor**, Unitaid mobilizes resources to make investments addressing complex global health problems in ways that ensure and accelerate equitable access to better health products and approaches to all. We work to ensure that access commitments and a clear pathway to scale are a part of every intervention and investment; and
- 3) as an **Influencer**, Unitaid relies on its experience, track-record, and recognized role as an innovator and thought leader, to convene, influence, and align partners towards common global health goals. Our unique position in the middle of the value chain allows us to move across a range of ecosystems to ensure that maximum impact is achieved at reasonable cost.

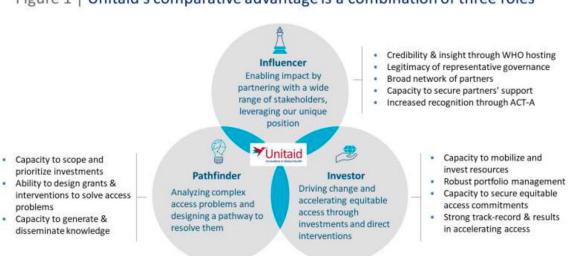


Figure 1 | Unitaid's comparative advantage is a combination of three roles

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Unitaid's track record demonstrates the key role we can play in getting the world back on track to meet the Sustainable Development Goals on health. Since 2006, Unitaid has accelerated the introduction and scale-up of over 150 new products that each made a real difference in the lives of people around the world. By identifying and investing in new, innovative products and establishing their worth, Unitaid enables our partners in the global health community to maximize the impact of their work and increase their efficiency. More than products, Unitaid also invests in innovative ways and works through markets to expand access to affordable, effective treatment. For example, Unitaid founded the Medicines Patent Pool (MPP) in 2010 and remains an active funder and partner. Since its inception, MPP has negotiated non-exclusive voluntary licensing agreements with patent holders to provide more than 18 billion doses of vital treatments and is projected to save over 170,000 lives and US\$ 3.5 billion by 2030. Getting back on track towards the global goals will

therefore have to include the acceleration and efficiency Unitaid has proven to bring into the global health effort.

The world's needs and Unitaid's strengths and experience converge in the 2023-2027 Unitaid Strategy. The Strategy is designed to address both the radical changes to global health prospects and the strains on low- and middle-income health systems that the past years' emergencies have revealed or exacerbated. While the changes over the past years have altered the global health environment, it has only strengthened the need for the services Unitaid provides. If anything, **our work has become even more essential**. The innovation and the acceleration of uptake and access to new technologies that Unitaid drives through its work is now crucial to achieving our global goals in the time that is left before 2030.

III Vision and Mission [infographic to introduce Strategic Objectives and principles section]

Vision

Unitaid's vision is equitable access to health innovations to ensure healthy lives and promote well-being for all.

Mission

Unitaid's mission is to expand the reach of the best health products for those who need them most. We do this by designing and investing in innovative approaches to make the best health products available and affordable in low- and middle-income countries. We nurture and inspire collective efforts with partners, countries, and communities, unlocking access to the tools, services and care that can deliver the best results and improve health.

Strategic Principles

The first Strategic Principle articulates the characteristics of the health products Unitaid will seek to support. These products will:

- 1) Improve health outcomes with prevention, diagnosis, and treatment in particular at primary care level and for HIV and co-infections, TB and malaria
 Unitaid will invest in products that deliver clear health benefits beyond the current standard of care products that offer better protection from diseases, better detection, faster results, better efficacy, and are safer than what currently exists. We will support a range of products, from new breakthroughs to less costly reformulations of existing products, as well as by improving access to important products that are not yet widely available or in use.
- 2) Support people and communities to engage with their own health Unitaid will invest in products and models of care that meet the needs of affected communities, as defined by those communities themselves. We will work to help decentralise tools and care and bring it closer to the communities we serve. And Unitaid will prioritize providing a better experience to people using the products we support, both patients and their care givers. Unitaid will work to increase the ability of people using those products to care for themselves within a supportive environment, without dependence on professional support where appropriate and evidence-based.
- 3) Make health systems more efficient and resilient to future threats

 Unitaid will invest in products and models of care that simplify diagnosis and treatment and optimize the use of health systems' resources. By making health systems more efficient and resilient, we will enable them to provide more care now and be better prepared for future changes like pandemics or climate change.
- 4) Make health care greener and more sustainable

Unitaid will promote practices and products that make the provision of healthcare more sustainable. We will work to reduce the impact on the climate and on the environment of product manufacturing and supply and will mitigate the risk and impact of antimicrobial and other types of resistance.

The second Strategic Principle affirms a commitment to equitable, intersectional and people-centered approaches across Unitaid's model.

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A Strategy based on consultation

To make sure that potential for continuing impact is realized, we recognize the need to refine the way Unitaid works. That is why we commissioned an external review of our past institutional Strategy and work. It is also why we have spent so much time talking to partners, including donors and affected communities, to understand how we can be better, and how our impact can be greater, even in a world where resources are increasingly constrained. Those reflections, consultations, and the lessons we can take from our past informed Unitaid's new Strategy for 2023-2027.

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IV Strategic Objectives

Three **Strategic Objectives** guide Unitaid's work in the next five years:

1. Accelerate the introduction and adoption of key health products				
2. Create systemic conditions for	3. Foster inclusive and demand-driven			
sustainable equitable access	partnerships for innovation			

Strategic Objective 1— accelerate the introduction and adoption of key products —leverages the organization's ability as a pathfinder organization, and as an investor. Timely equitable access to products is at the core of Unitaid's model. The Strategy recognizes this central role that Unitaid has always fulfilled and explicitly calls out the key steps in the continuum to which we directly contribute, from boosting development, shaping the market, through to product adoption at scale.

To meet **Strategic Objective 1**, we first need to **boost the development of fit-for-purpose products**. A 15-year track-record of continuous monitoring of the technology landscape, especially in areas related to HIV, TB and malaria, has given Unitaid the experience and the know-how to spot trends and take smart risks on promising technology that will deliver useful products in the short- to medium-term. Unitaid uses that knowledge and experience to invest in those technologies, particularly at later stages of development. This includes reformulations of products to increase their scalability or accessibility, and new or innovative delivery systems that will aid in wider adoption for people and contexts in low- and middle-income countries. This work typically would involve testing to determine safety and efficacy in resource-constrained settings, as well as advocacy to increase knowledge and awareness and to build trust in new products. It is guided by community-led approaches, in the identification of needs, the creation of demand and the delivery of services, in particular for marginalized and at-risk people.

Beyond identifying and investing in promising products, Unitaid focuses on creating healthy supply conditions and demand, notably through **market shaping**. No matter how good the product is, if it is not accessible for those in need, its promise is unfulfilled. Unitaid has extensive experience in developing markets to ensure that products' potential is realized by preparing relevant conditions for rapid, successful introduction. That means ensuring quality and reach of products (e.g., addressing intellectual property and regulatory issues, quality assurance processes), affordability (e.g., through pricing agreements, intellectual property interventions), and establishing strong supply and delivery conditions (e.g., through product forecasting, incentives, and more effective access conditions). In relation to the latter, the work that Unitaid does – e.g., forecast of demand – increases manufacturer confidence of the viable market, thus strengthening supply. Unitaid's market-shaping role is essential to enable scaled adoption of products and approaches by country governments and scale-up partners such as the Global Fund.

Even when a product is available on the market and in the place where it is needed, Unitaid recognizes the need to **support product introduction**, **adoption**, **demand**, **and scale-up**. We also aid in the development and introduction of simple, effective models of care to ensure delivery of those products. That means working along the full length of the supply chain to generate evidence to demonstrate a given product's effectiveness, suitability, and cost-effectiveness, and working with

partners and country stakeholders to understand how products function in real life and how best to explain their usefulness to a wider audience. It also means working with implementing partners and communities to identify the best models of care for each context, informing the evolution of policy and practices and creating sustainable, community-driven demand. Finally, it means working with country governments, the Global Fund and other scale-up partners to secure political and financial support and introduce and deploy the products properly and effectively.

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Strategic Objective 1 illustration: Preventing TB

It is estimated that a quarter of the world's population has latent tuberculosis (infection without illness or the ability to transmit the disease). Without treatment, up to 10% of those with latent tuberculosis — 190 million people — will develop active tuberculosis. Preventive treatments can help, but traditional regimens require daily pills for 6 months to a year. To make preventive treatment more effective, Unitaid supported the introduction of a 12-week therapy regimen using rifapentine, often referred to as "3HP". Unitaid helped establish the efficacy of 3HP and negotiated a landmark price agreement to reduce the price from US\$ 45 to US\$ 15, successfully encouraging generic manufacturers to offer the same price to meet increased demand. Working with community and civil society partners also helped expand awareness and demand. Thirty-two countries have now adopted 3HP treatments, with the ground prepared for partners, like the Global Fund, to scale up availability even further.

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Strategic Objective 1 illustration: Averting 500,000 malaria deaths

Three-quarters of all malaria deaths are in children under 5, and access to treatment is more difficult to ensure than prevention. For several years already, seasonal malaria chemoprevention (SMC – simply speaking, paediatric doses of malaria medicines for prevention), has shown to be highly effective. Still, until recently, very few children in Africa, where 80% of deaths occur, had access to it.

Unitaid started by laying the groundwork for scale-up of SMC through a feasibility study, which showed that large-scale distribution would be safe, feasible and affordable. From this basis, Unitaid has ensured access and promoted uptake so that the number of children getting access to SMC has increased from one million in 2014 to 33 million in 2020. It is estimated that SMC has averted more than 500,000 deaths and 110 million cases of malaria in children between 2015 and 2020, which means a 20 percent reduction of malaria deaths compared to not having wide application of SMC.

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Strategic Objective 2 — create systemic conditions for sustainable, equitable access — is both a necessary support to the first Objective and an important goal in its own right. To ensure that the

products Unitaid supports are truly available to all, Unitaid's Strategy calls for the creation of systemic conditions for equitable and sustainable access. While support for product access has long been a part of Unitaid's work, this Strategy is a refinement in that it further emphasizes our work on access independent of a specific product. This work will be in support of both current products and future products, positioning Unitaid as an "access champion". Conversely, work and experience gained from working on specific products can help strengthen access more broadly.

Unitaid will work to establish an **enabling environment for access.** We build on our past successes in intellectual property and regulatory processes and systems. Beyond using today's tools, Unitaid proactively identifies access conditions for new technologies and categories of products early in their development, preparing the ground for both the eventual deployment of the product or class of products and access to them when they reach maturity.

Unitaid supports innovative supply models and approaches, including regional and domestic or regional manufacturing. The COVID-19 pandemic brought into stark relief the need for rapid, equitable access to effective tools. During the pandemic, supply constraints, export controls, and national interests showed the limits of having production capacity concentrated in a handful of countries. This highlighted and reinforced the need to review supply models to produce diagnostics, therapeutics and vaccines. Regional/domestic manufacturing can contribute to more resilient supply chains and can bring development and manufacturing closer to customers and people who can benefit from the products. Unitaid believes that widespread access to the resulting products in lowand middle-income countries will be vital in helping the global health community meet the current challenges of existing endemic diseases, as well as providing capacity to respond to future pandemics, and domestic presence and production is an essential element in achieving this. Regional/domestic manufacturing, alongside innovative supply models, can also contribute to reducing the environmental footprint of products and supply chain.

In this area, Unitaid's Strategy builds on the organization's long and growing experience in this space to explore new models with relevant partners. We have already successfully supported the local manufacturing of both malaria therapeutics and diagnostic tests for COVID-19. We also have extensive expertise in product introduction and the creation of viable markets — a critical aspect to any new supply model. Over the strategic period, we will continuously survey the situation and look for opportunities to create transformative change in this area — for instance developing domestic manufacturing capacity and supporting multi-purpose platforms and innovative technologies (mRNA, mAbs, CRISPR, for example). We expect our role to evolve and be refined over time, informed by lessons learned and the evolution of the broader ecosystem of partners.

Unitaid recognizes the importance of thought leadership on access, **disseminating knowledge and evidence.** Unitaid has a long track record of sharing valuable knowledge and useful content — information on access barriers, or evidence from implementation studies — to inform and support governments, health care workers, and the communities they represent and serve. Dissemination of knowledge, evidence, frameworks, and lessons learned is important in supporting stakeholders to understand access issues and inform others, including early-stage funders, to establish or seek conditions conducive to equitable access and to facilitate decisions on accessing products. We will cement our role as a thought leader and build on it by publishing our work more systematically, increasing the availability and visibility of the existing body of knowledge alongside new information.

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Strategic Objective 2 illustration: Increasing access by lowering barriers — the MPP success story.

In 2010, Unitaid founded the Medicines Patent Pool (MPP) to encourage non-exclusive, voluntary licensing, thereby enabling more people in low- and middle-income countries to access affordable, effective treatments for HIV, hepatitis C and tuberculosis. Since then, MPP has negotiated licenses enabling manufacturers to develop quality-assured, generic antiretrovirals to treat HIV, as well as new drugs and treatment regimens that improve the standard of care for both drug-resistant and drug-susceptible tuberculosis. MPP has played a crucial role in the global response to COVID-19 and is a member of the COVID-19 Technology Access Pool initiative and the Access to COVID-19 Tools Accelerator (ACT-A). Looking forward, MPP has widened its mandate to include expanded access to patented small molecules listed on the WHO List of Essential Medicines (EML), as well as new drugs, like new antimicrobials, with strong potential for future inclusion in the EML. In 12 years, MPP revolutionized the access landscape for new and essential treatments in resource-limited settings, thanks to Unitaid's foresight and funding.

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Strategic Objective 3 — foster inclusive and demand-driven partnerships for innovation — recognizes that diversity, equity, and inclusion are central to Unitaid's mission and that integrating those values in every intervention will always yield better outcomes. Acting on this recognition means increasing engagement with everyone, from implementing partners to communities and country stakeholders (governments, civil society, etc.), to invest and build better, more sustainable country- and community-driven programmes and products. It means the starting point for every innovation Unitaid incubates will be seeking out under-represented voices and diverse implementing partners and working with all stakeholders to shift decision-making towards the people and places facing the greatest health inequities.

People are at the center of this new Strategy. People and their communities have driven the identification and implementation of the Programmatic Priorities that realize this Objective.

Seeking the input and participation of communities and civil society — at the local, country, and global levels — helps to ground Unitaid's investments in people's needs and the constraints that the realities of their lives may place on the success of our interventions, e.g., lack of healthcare professionals, difficulty of access, etc. Realistic and practical, Unitaid will work to make countries, communities, and civil society integral to the design and implementation of our programmes. If needs change and strategic or operational realities require adjustments, Unitaid has key community and country partners that are best placed to guide the adaptations required to ensure that our work accomplishes what we intended it to. Community-led approaches are central to ensuring that our work to an even greater extent reaches all who can benefit, especially at-risk and marginalized people.

Alliances will help amplify our work to reach further and do more. The goal of all Unitaid's alliances and partnerships is to scale-up good products and treatments so that they are available to anybody

with a need, anywhere in the world. Unitaid will work at all levels to further develop those alliances. At the global level, Unitaid will coordinate efforts in alignment with donors and strategic partners to identify priority needs, work synergistically so that scarce resources go as far as possible, and bridge the gaps between products and their use and availability at scale and at the lowest possible cost. At the country level, Unitaid will work with governments, civil society, international and regional partners as well as local researchers, local industry, and local communities to ready the ground for successful product scaling. That means working together with those local partners to generate demand, foster grassroots advocacy, and secure both political and financial support at all phases of our projects.

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Strategic Objective 3 illustration: Community Engagement for HIV testing

One in five people living with HIV do not have access to optimal treatment or do not know their status, contributing to premature death and increased transmission rates. Lack of access to diagnostic services, discrimination, and stigma are all barriers that must be overcome. Self-testing is a solution. The tests are easy to use and can return results within 20 minutes.

Unitaid spearheaded the introduction of HIV self-testing by supporting the development and evaluation of effective delivery models, leading to critical policy changes. In parallel, Unitaid worked to build a market for the tests by partnering with scale funders, community organizations and civil society in areas of need. We supported programmes developing locally focused communication strategies and campaigns, as well as Community Advisory Boards to increase self-testing uptake, helping build demand and removing stigma around HIV status. Self-testing has transformed case detection and has proven to be a critical foundation for the diagnostics of other diseases, like COVID-19. Demand for HIV self-testing is expected to reach close to 30 million tests per year by 2025. Self-testing has had a marked impact on rates of testing among men, young people, and certain marginalized populations.

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How the Strategic Objectives work together to realize Unitaid's vision

These three Objectives are the guidance that will allow Unitaid to maintain its comparative advantage from our previous Strategy to this new Strategy, adapted for the current and future global health landscape. In turn, the Objectives will be key factors in selecting Unitaid's future investments and interventions.

The key to Unitaid's work has always been a focus on the practical: key health products that deliver real world impacts in areas of concern for global health. The new Strategy reiterates that core principle. But the new Strategy also recognizes that there are actions that Unitaid can and must take to achieve optimal impact from the products we identify and support. In that sense, the second and third Strategic Objectives are <u>necessary conditions</u> to achieve the first: we must build in sustainable, equitable access and strengthen partnerships if we are to successfully accelerate the introduction and adoption of key products. The explicit focus on equity is therefore a central element of the Strategic Objectives in this Strategy.

Moreover, the second and third Objectives will allow Unitaid to articulate elements that, while incorporated into our operations in previous strategies, are now stated explicitly, reinforcing their importance. For example, as part of Unitaid's push for access, we are engaging in reducing suppliers' environmental footprint in a more defined way, seeking to minimize the environmental impacts of supported products by moving production closer to need, making production facilities more environmentally friendly, and recognizing that environmental issues play an increasingly important role in many of the health challenges Unitaid and our partners are confronting.

Partnerships and community engagement are key to Unitaid's continuing success. By involving affected people and communities throughout the process, Unitaid can help make every part of the identification, design and introduction of key health products better and more effective.

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Unitaid's Commitment and Approach to Equity

Unitaid's vision and mission reflect our goal of providing "equitable access to health innovations to ensure healthy lives and well-being for all" and "expand the reach of the best health products for those who need them most." Underpinning this mission and vision is a set of Strategic Principles, guided by our overarching principle to ensure equitable, intersectional, and people-centered approaches across our model. Equity considerations are central to Unitaid's work and inform all key steps of the operating model, from opportunity scoping and prioritization to project selection, and design and portfolio implementation.

We operate under the principle that equity is the absence of unfair, avoidable, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, geographically, or by other dimensions of inequality (e.g., sex, gender, ethnicity, disability, or sexual orientation)². Equity is central to sustainable development, as demonstrated by the Sustainable Development Goals (SDGs) where equity cuts across several dimensions: SDG 3 – ensure healthy lives and promote well-being for all at all ages; SDG 5 – achieve gender equality and empower all women and girls, and SDG 10 – reduce inequality within and among countries.

Unitaid works to reduce existing inequities in people's access to innovative quality health products through catalytic investments in tools, services, and care models that can deliver the best results, improve health, and address global health priorities. The latest report on the *State of Inequality in HIV*, *TB*, and *Malaria*³ points out that while inequalities in access to care within countries are widespread, gaps in inequality are narrowing through interventions that target disadvantaged population sub-groups. Hence, as an organization, we recognize the need for differentiated, people-centered, and intersectional approaches that are conducive to addressing inequity in two main areas:

² According to WHO's <u>definition of equity</u>

³ State of Inequality: HIV, Tuberculosis and Malaria. WHO/GF, 2021

- Populations or sub-populations that are disproportionately affected and/or lack access to optimal
 care relative to other groups; these inequities are often linked to a person's social and
 demographic characteristics (such as age, gender, vulnerability, stigma, criminalization, economic
 status, place of residence, among others) and a key consideration is the risk of catastrophic cost
 to households; for example, a large part of our portfolio addresses gender-related access issues,
 with a focus on women and girls;
- Low and middle-income countries that lack control over their supply and access to optimal products.

We seek to address existing inequities in how we do our work, by:

- Prioritizing investments and products designed to benefit populations that are most vulnerable or least able to afford and access optimal care these populations are specific to each area of Unitaid's work and need to be defined in the specific context, but can include, for example, key populations in HIV whose risk of acquiring HIV is much higher compared to the general population, such as adolescent girls and young women, pregnant women, people who inject drugs, transgender women, female sex workers, gay men and other men who have sex with men; men and children who have high gaps in testing and treatment for HIV; prisoners who are at much higher risk of acquiring TB; vulnerable children who are at increased risk of developing serious forms of TB; the very poorest children who are more likely to have malaria, and pregnant women in malaria endemic regions. These are an illustrative subset of populations whereby several nuanced socio-demographic elements can determine ease of access to optimal care. We also recognize that there can be co-infections in the different population groups, which accentuates their vulnerability, for example, people living with HIV whose risk of acquiring TB and hepatitis C is higher, or women living with HIV who are at higher risk of developing cervical cancer;
- Promoting more secure and potentially more affordable/faster access to health products
 including through innovative supply models and approaches, domestic manufacturing,
 technology transfer, and by establishing an enabling environment for access, including IP and
 regulation;
- Prioritizing investments and collaboration with organizations and partners that are closest to the
 population with the highest need to ensure our funding supports appropriate and contextspecific solutions. We expect our grant implementers to adhere to similar principles in the
 projects we finance;
- Mainstreaming country, community, and civil society engagement to foster inclusive and demand-driven partnerships while supporting people and communities in engaging with and taking ownership of their health;
- Ensuring that Unitaid fosters an inclusive environment, where diverse perspectives,
 backgrounds, and experiences are valued.

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Unitaid has committed to the call for elimination of cervical cancer and is doing so by addressing the key barriers faced by women and adolescent girls in accessing early diagnosis and treatment in low-resource settings. Unitaid's projects seek to embed an affordable test and treat approach in national governments' health systems in a sustainable way, responding to the differentiated needs of women and adolescent girls⁴.

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⁴ Source: https://unitaid.org/news-blog/unitaid-supports-the-whos-cervical-cancer-elimination-strategy-launch/#en; https://unitaid.org/project/innovative-affordable-screening-and-treatment-to-prevent-cervical-cancer/#en; https://unitaid.org/project/intensifying-and-promoting-cervical-cancer-prevention-in-low-resource-countries/#en)

V Programmatic Priorities

Unitaid's 2023-2027 Strategy includes a new category of **Programmatic Priorities** to help focus resources, tighten our programmatic scope, and create a foundation for clearer impact-based investments. The Programmatic Priorities are based on **potential for impact** and Unitaid's ability to **make a difference**. They emphasize **prevention**, with a focus on access to high-impact preventive tools, particularly for high-risk groups; **testing**, to close the detection gap, thereby reducing the number of missed cases and facilitating linkage to care; and **treatment**, prioritizing access to simpler, optimal treatment regimens for adults and children. Critically, equity considerations have informed the design of Programmatic Priorities. In each of them, specific attention was given to the needs of populations or sub-populations disproportionately affected by diseases or lacking access to optimal care relative to other groups, and those of low- and middle-income countries who lack control over their supply and access to optimal products.



Through the newly honed Programmatic Priorities set out in the Figure above, Unitaid will be more systematic in engaging people in need, ensuring that investments have greater relevance by addressing needs that communities define themselves. While Programmatic Priorities are described by reference to disease focus, our overall approach is holistic. The Strategy also recognizes that many of the priorities have impact beyond a single disease. Identified cross-cutting priorities will contribute to the fight against HIV, tuberculosis, and malaria, and will also impact many more areas, including maternal health and future global health emergencies.

For over 15 years Unitaid has led the way by identifying and introducing game changing health innovations. Through our ongoing work, and new investments in 2023-2027, Unitaid anticipates introducing a broad set of products, including **30 key products by 2030**.

Sustain the effectiveness of HIV prevention and treatment. There are still 1.5m new cases of HIV each year, and high-risk groups such as women and young girls bear a disproportional burden. New cases and deaths due to anti-retroviral therapy (ART) treatment failure are an emerging threat. Unitaid has a critical role to play in ensuring equitable access to new and emerging products and informing optimal approaches to prevention and care.

Unitaid will continue to promote increased uptake and effective use of preventive tools in low- and middle-income countries — notably pre-exposure prophylaxis (PrEP) including new long-acting formulations with integrated care, including for sexually transmitted infections (STIs). Unitaid will optimize regimens for children and adults, supporting the alignment of care options, fixed-dose combinations, and new delivery systems. Beyond this we will support emerging technologies for high-risk groups, such as small molecules and biologics; lead market-shaping interventions in regulation, licensing, pricing, and production for long-acting products; and promote integration across prevention and treatment and rapid uptake of such new approaches.

Diagnostics for HIV and co-infections are an important element in Unitaid's HIV prevention and treatment work and are addressed as a cross cutting intervention.

Optimize and enable scale up of the treatment of advanced HIV disease (AHD) packages of care. Notwithstanding the success of scaling up ARTs, deaths caused by HIV remain high. Our goal is to reduce overall mortality, with particular focus on eliminating meningitis- and TB-related HIV deaths, working to improve affordability, quality, and supply of existing and new products for AHD. This builds on Unitaid's current work addressing affordability, quality, and supply security of existing and emerging products.

The immediate push will be to accelerate access to optimal AHD test-prevent-treat packages for main causes of death, such as TB, cryptococcal meningitis and severe bacterial infections, at the primary health care level. A new focus will be on decentralized AHD care, addressing gaps in preventive tools, correcting market failures, and scaling up use.

Prive hepatitis C virus (HCV) elimination through testing and prevention. HCV continues to exact a heavy toll on the health and well-being of millions of people, with an estimated 58 million people living with chronic hepatitis C as of the end of 2019. Unitaid's priority is to support HCV elimination through testing and prevention, where progress to date has been limited. It is estimated that only one in five people living with HCV in 2019 were diagnosed. Our aim is to reduce the diagnostic gap, targeting the most marginalised and vulnerable populations. We will do this by promoting the development of better tools and the simplification and decentralisation of testing and treatment. This continues and builds on Unitaid's recognized track record of raising the profile of HCV through our investments to develop better tools and the simplification and decentralisation of testing and treatment. We will continue to accelerate the development and deployment of HCV self-tests with a focus on high-risk populations, develop and introduce long-acting formulations of Direct Acting Antiretrovirals (DAAs), and pioneer treatment-as-prevention programmes.

Our work will accelerate the uptake of new tools (HCV self-testing, point-of-care diagnostics, multidisease platforms and integrated diagnostics), and the introduction of new products and approaches, such as core antigen rapid diagnostic tests, long-acting products, and one-stop test-andcure packages.

Recease access to screen and treat for cervical cancer and STIs. Unitaid continues to drive progress towards the elimination of cervical cancer and STIs which are responsible for high levels of morbidity and mortality. Mother-to-child hepatitis B Virus transmission accounts for over 80 million infections a year. There are 87 million cases of gonorrhoea and 6.3 million cases of syphilis, a disease that can cause stillbirth. Cervical cancer kills over 300,000 women annually, 90% in low- and middle-income countries. Women living with HIV are six times more likely to develop cervical cancer when infected with human papillomavirus (HPV).

Unitaid's ability to make a difference lies in our expertise in market interventions to overcome supply and demand barriers. Opportunities to increase the availability of self-screening tools for HPV would overcome barriers to access and reach more women. New tools are available to drive the elimination of mother-to-child transmission of HIV, syphilis, and HBV ('triple elimination'). Emerging diagnostics for gonorrhoea and chlamydia have the potential to improve case management and increase STI surveillance. Unitaid can drive rapid introduction and uptake of these new and promising developments.

Enable TB prevention tools for high-risk groups with improved access for all patients, especially vulnerable groups. Unitaid was instrumental in reducing the price of rifapentine by 60%, which WHO guidance established as a key drug for prevention and treatment of drug susceptible TB. Unitaid's work enabled prevention at scale, reducing the number of cases to be treated, which in turn mitigates the catastrophic costs of TB treatments.

In 2020, 1.1m children and adolescents contracted TB. Unitaid will focus on reducing case numbers by expanding access for these and other vulnerable high-risk populations such as people living with HIV (PLHIV) and children under five. We will continue to expand access to existing prevention tools and will use our market shaping expertise in the introduction of new products including shorter preventive TB treatment regimens.

Accelerate access to new TB detection tools for drug-resistant- and drug-susceptible TB. These tools are vital to identify millions of unreported cases. Unitaid will continue to expand access to existing screening tools and support the introduction of new technologies for TB detection, such as molecular and rapid point-of-care tests. This will build on and extend our previous work in this field. We will support TB education and awareness programmes to promote increased adoption and use.

Future efforts will tackle opportunities for integration such as between TB, HIV and COVID-19, seeking to integrate diagnostic services and products to boost detection.

Accelerate adoption of new TB drugs and regimens. Unitaid is well placed to facilitate access to shorter, less toxic, more effective TB regimens, where barriers to access relate to our core expertise. We will help to realize the full potential of integrated prevention tools, diagnostics, and treatments. This work will also focus on improving standards of comprehensive care for vulnerable high-risk populations.

As WHO recommendations for new drugs and shorter regimens are introduced, there may be a market-shaping role for Unitaid to facilitate equitable and sustainable access. We will use our expertise to promote integrated care with links to patient-centered preventive and curative treatments, and to introduce shorter, affordable, less toxic, and more effective treatments, such as those based on targeted gene-sequencing.

Introduce and optimize malaria prevention tools. New malaria tools are becoming available (e.g., new nets, indoor residual sprays, the first malaria vaccine), as are new approaches to existing interventions (e.g., chemoprevention). More innovations are in the pipeline (e.g., spatial repellents, the drug ivermectin, and attractive targeted sugar baits in the shorter-term and long-acting technologies and monoclonal antibodies (mAbs) in the longer-term). Unitaid, leveraging our expertise and past investments in these innovations, has a critical role in helping to realise the potential, at scale, of these new and evolving tools which could deliver transformational impact.

As part of our efforts to improve access for vulnerable groups, we would continue and expand our work in large-scale implementation pilots to identify the most effective combinations of prevention tools within a given context, and to help guide policy setting. Addressing supply-side barriers, e.g., by boosting local production, will be a key focus.

Improve access to quality case management of malaria. Unitaid will catalyze access to new diagnostics and treatments, enable approaches to mitigate drug resistance and foster integrated, holistic care towards more effective case management in health facilities, communities, and the private sector. We will aim to improve rational drug use through innovative community level test-and-treat strategies, and by addressing pricing and supply challenges.

Antimalarial drug resistance, recently also detected in sub-Saharan Africa, is a growing threat to malaria control. Unitaid will support the adoption of mitigation strategies in the short term and work to ensure the rapid availability of new treatments which may become available later in the 2023-2027 Strategy.

Unitaid will also catalyze access to new diagnostics and treatments and foster integrated, holistic care towards more effective case management in health facilities, communities, and the private sector. We will aim to improve rational drug use through innovative community-level test-and-treat

strategies, and by addressing pricing and supply challenges. In each of these intervention areas, Unitaid is well placed, leveraging past investments, to support early introduction as the tools are recommended.

Improve access to better tools for safe pregnancy and birth, for women and newborns.

Although the global reproductive, maternal, newborn and child health burden has decreased significantly in the last 30 years, progress is now stalling. Currently, maternal and neonatal mortality claims nearly 300,000 and 2.4 million lives per annum respectively, mostly in low- and middle-income countries. More effort is needed to meet the goals of WHO's Global Strategy for Women's, Children's, and Adolescents' Health (2016-2030), as well as Sustainable Development Goals (3.2.1 and 3.2.2).

Unitaid will catalyze access to tools that prevent, diagnose, and treat the conditions that lead to maternal and neonatal deaths. We will accelerate adoption of new tools for post-partum haemorrhage and pre-eclampsia/eclampsia, which together contribute 40% of maternal deaths, through evidence generation, market shaping, and demand generation activities. Unitaid will also support the scale-up of existing tools and market entry of late-stage development products that address maternal and neonatal sepsis more broadly. Unitaid's experience and mandate will enable us to help overcome access barriers through evidence generation, market shaping and demand generation activities.

Improve quality of clinical care packages for COVID-19. The COVID-19 pandemic has shown that — especially in times of acute crisis — access to lifesaving tools is paramount. Unitaid has demonstrated our unique positioning to address many critical bottlenecks with relevant tools and experience, including support for rapid access to diagnostics and medical oxygen, a mainstay of lifesaving inpatient treatment for severe and critical COVID-19. This and the following priority, both of which Unitaid identified early in the COVID-19 pandemic, have proven durable and both remain important. In the event of a future global health emergency on the scale of COVID-19, we may envision similar work to support rapid introduction of effective tools, adapted for equitable global access, to stem transmission, cases, deaths, and new variants.

Decentralize testing and treatment for COVID-19. This work speeds access to tools that enable decentralized test-and-treat strategies, given the potential for these to be implemented at scale, reduce hospitalizations, and ease the burden on health systems. These two emergency-related priorities not only leverage Unitaid's work in COVID-19 but also our long history in supporting quality case management in malaria, optimizing and enabling scale of decentralized testing and care in HIV and improving child survival with triage and treatment tools for the most vulnerable. For both these priorities, potential interventions would be informed by specific circumstances, should a new global health emergency arise during the five-year Strategy period.

C/C Improve child survival with triage and treatment tools. Unitaid will address the leading causes of under-5 mortality (5 million deaths in 2019 according to the UN Interagency Group on Child Mortality Estimation) through expanding access to better tools (e.g., oxygen therapy for under-fives) for integrated management in primary care and community settings. Building on ongoing work introducing pulse oximetry for severe disease triage and our commitment to integrated management of childhood illness, Unitaid can influence care givers, policymakers, and communities to enhance anaemia case management as it is a risk factor of life-threatening childhood illnesses like pneumonia and malaria. Interventions under this cross-cutting priority also directly impact TB and support the early detection of danger signs in children with advanced HIV. This cross-cutting approach is critical to improving child survival and has a focus on equity and targeting those most in need.

C/C Accelerate access to self-testing, self-sampling and integrated diagnostics. It is a Unitaid priority to accelerate access to affordable self-testing/self-care and integrated products. Unitaid can make a difference due to our experience, gained through existing investments, in implementation of testing programmes, development of guidance, and support for our cross-cutting work linking multiple diseases through molecular testing platforms (for TB, HPV, HCV and COVID-19). We will leverage our successes with HIV self-tests for self-testing/self-sampling modalities across multiple diseases, starting with HCV and STIs. Unitaid will support late-stage development of new diagnostics for key HIV, TB and co-infection priority areas (e.g., triple elimination) and will work to introduce new products to the market as they emerge (laboratory-based, device-based point-of-care and device-free point-of-care). Unitaid sees these critical diagnostic tools as a significant means of closing the testing gap and will work to establish availability and access in the market.

C/C Long-acting and new technologies. The effectiveness of safe and efficacious medicines can be compromised by poor treatment completion. Long-acting and other new technologies can improve adherence and therefore clinical outcomes, leading to reduced mortality, lower disease transmission, and prevention of drug resistance. Unitaid's current investments in long-acting and new technologies will inform future efforts paving the way for their expanded use. Through licensing and negotiation of terms conducive to equitable access, these emerging treatments can be guided through the development pipeline and into the market, a process that Unitaid is uniquely qualified to advance.

Unitaid will continue to work to secure early commitments on access and commercialization and prepare markets for the rapid access to new technologies. We will also work to accelerate the uptake and scale-up of long-acting medicines. Unitaid will continue to engage with developers and manufacturers on favourable access terms (including licensing, pricing, and production) for emerging prevention and treatment innovations across HIV, TB, malaria, and hepatitis C.

C/C Intellectual property, regulatory and innovative supply models. Patents and other intellectual property rights can incentivize innovation, but also limit competition that can stabilize supply and

reduce prices. While Unitaid's work has primarily addressed intellectual property and regulatory hurdles, our emphasis will extend under the new Strategy to supply models (e.g., domestic manufacturing) and to climate impact of health products and supply chains. Regulatory work and support for quality assurance — for example through WHO prequalification — is also paramount.

The COVID-19 pandemic revealed two key areas where Unitaid can make a difference. Firstly, intellectual property (IP) protections were exposed as an obstacle to equitable access to health products. Unitaid's flagship investment in the Medicines Patent Pool (MPP) has led to the supply of over 50 million patient-years of treatment, saved around US \$1 billion, and saved thousands of lives. The MPP's work is complemented by other investments to remove unwarranted IP barriers on a range of products (PrEP, HIV, TB, and HCV medicines) to improve access to better, affordable formulations. We are working to expand the number of countries benefitting from IP solutions or covered by price agreements. Going forward, IP interventions will remain a Unitaid priority.

Secondly, COVID-19 revealed that low- and middle-income countries cannot rely entirely on manufacturing in high-income countries to meet their needs. Unitaid's product-focused investments have incentivized lower cost manufacturing in established pharmaceutical manufacturing low- and middle-income countries such as India. Other interventions (e.g., malaria medicines and COVID-19 antigen tests) focused on establishing cost-effective, quality-assured manufacturing in underserved regions such as Africa and South America. To strengthen regional value chains, Unitaid will continue to prioritize investments to support improved domestic manufacturing and regulation.

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Oxygen: an essential health product

Medical oxygen is a mainstay of lifesaving treatment, but it is often unavailable where needed most. With the COVID-19 pandemic having exposed broad failures in access to medical oxygen, Unitaid built on existing work to address acute needs and support more sustainable access. By scaling-up access to oxygen, Unitaid supports the treatment of many conditions affecting newborns, children, and adults including severe malaria, advanced HIV disease and tuberculosis. Oxygen therapy is a critical treatment for severe COVID-19 and improving access now will prepare countries for future health emergencies. Given that oxygen is a lifesaving essential medicine for multiple diseases, Unitaid's oxygen work will enhance efforts across several programmatic priorities.

For example, with clear links between oxygen, pneumonia, and childhood mortality, increasing the availability of oxygen will enable greater impact of Unitaid's work to improve child survival with triage and treatment tools.

Building on the gains made during the pandemic, Unitaid will leverage its strong comparative advantage to ensure countries access a suitable mix of oxygen delivery solutions tailored to local capacity and needs. In parallel, Unitaid will catalyze the uptake of oxygen innovations (e.g., solarized oxygen generation systems) so that countries have access to appropriately designed equipment that

can withstand rugged conditions and environmental challenges in low- and middle-income countries.

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30 by 2030: Unitaid's commitment to bring essential new innovations – products and more effective ways to use them

The Programmatic Priorities that Unitaid will focus on during the 2023-2027 Strategy period will provide a rich crop of results. The outcome from this focus and Unitaid's ongoing investments includes in particular a suite of **30 key products for introduction by 2030.** These innovations — products and more effective ways to use them — will deliver significant health impact, harnessing innovation to bring better, more affordable and more effective health innovations to those who need them, much as Unitaid has done in the past. These products and innovations will be the consequence of ongoing funded initiatives and proposed new investments pursuant to resources secured for the 2023-2027 Strategy period. They will come in addition to the systemic and crosscutting work that is also emphasized in the Strategy.

Investments initiated by Unitaid in recent years will continue to be monitored, supported, and nurtured as they transition to the point of adoption and scale-up. These will begin to deliver impact in the years ahead as they gain acceptance and scale and will also spur new formulations and variations. The new investments arising from the Programmatic Priority focus over the 2023-2027 Strategy period will deliver impact in the lead up to 2030 and beyond. These investments will be prioritized based on their impact potential and Unitaid's ability to make a difference. The future portfolio will by necessity remain dynamic and flexible to capitalise on new opportunities and respond to emerging needs.

HIV & co-infections	ТВ	Malaria	Women & children's health	Respond to global health emergencies	
Sustain effectiveness of prevention & treatment	Enable TB prevention tools for high- risk groups	Introduce & optimize prevention tools	Improve access to better tools for safe pregnancy & birth for women & newborns	Improve quality of clinical care packages for COVID-19	
- Long-acting PCEP - Long-acting HIV treatment - HIV medicines for children - Optimized HIV medicines for adults	- Shorter and more effective TB preventive treatments, including long-acting formulations	New vector control tools, including ivermectin MDA, spatial repellents Next-generation LLINS Malaria vaccines Chemoprevention tools and approaches	- Better medicines for prevention and treatment of post-partum <u>haemorrhage</u> - Tools to detect pre-eclampsia/eclampsia	 Innovations to increase access to oxygen therapy—see also: child survival - COVID-19 therapeutics, in particular oral antivirals for mild/moderate cases, such as nirmatrelvir/ritonavir 	
Optimize and enable scale of AHD packages of care	Accelerate access to new detection tools	Improve access to quality case management		Decentralize testing & treatment for COVID-19	
- New tools to test, treat, and prevent main opportunistic infections	New point-of-care TB tests Next-generation sequencing Medical imaging to diagnose TB (and other respiratory diseases), including artificial intelligencenabled, mobile-based, or point-of-care	Single-dose radical cure for P. www and accompanying diagnostics Anaemia diagnostics New malaria treatments, including non-artemisinin-based drugs		- Antigen rapid diagnostic tests	
Drive HCV elimination through testing and prevention	Accelerate adoption of new drugs and regimens				
- Long-acting HCV treatment - Innovative HCV prevention - HCV rapid diagnostic tests, including self-test	- Paediatric formulations for MDR-TB - Shorter / better regimen for DS- or DR-TB				
Increase access to screen & treat for cervical cancer and STIs	Improve child survival with triage and treatment tools				
- True point-of-care HPV screening for cervical cancer, with HPV self-collection tools - Cervical cancer treatment devices - Point-of-care screen-and-treat for other STIS	 Innovations to increase occess to oxyg New diagnostics and treatments for r 	en therapy – see also: global health threa neonatal sepsis	ts		
Accelerate access to self-testing & integra	ated diagnostics				
	ic disease areas. <u>However</u> several of the flo		for integrated management specific to self-test stics, etc.)	ing & integrated diagnostics as a	
Long acting and new technologies					
Relevant products are shown under specifi priority.	c disease areas. <u>However</u> several of the flo	agship products above offer opportunities	for integrated management specific to long act	ing and new technologies as a programmatic	
IP, regulatory and innovative supply mod		rk but would support equitable access to t			

The 30 proposed innovations reflect a mix of specific products and product categories that in both cases are meant to illustrate the change in available tools that Unitaid's work will bring about in the coming years. They include front-runner prevention technologies for HIV and coinfections, such as hepatitis C, as well as innovative delivery mechanisms such as long-acting injectables and implants. They include a number of new HIV, TB, and malaria formulations for children, and simpler, more effective TB prevention and treatments for adults. There is a significant focus on prevention, testing, and screening tools, to prevent or ensure early treatment of hepatitis C, other sexually transmitted diseases, cervical cancer, deadly conditions during pregnancy and birth, as well as for HIV, TB, and malaria.

VI Implementation through Partnerships

Unitaid has a 15-year track-record of extraordinary success. We have built a broad and deep expertise in how to ensure that innovations go from development to actually reaching those who need them and are used in an efficient way. We have built a deep understanding of market shaping approaches, of public health needs and of the development pipeline of health products that can be relevant in low-resource settings, and we have also developed a set of tools and collaborations, such as the Medicines Patent Pool, and partnerships with the Global Fund as well as other scale-up and technical partners, including WHO, that give us the ability to pursue ambitious ideas and projects and address the end-to-end work necessary to achieve impact.

The new Strategy will build on these strengths and in that sense be a continuation of Unitaid's past work. However, the new Strategic Objectives demand a broader, more systemic approach to partnerships and to how equity is pursued.

Partnerships are a central avenue for Unitaid to translate our expertise into impact that solves problems and helps people. This new Strategy envisions a phased increase in engagement with both country stakeholders and community and civil society partners over the next five years. These partnerships will encompass all aspects of the development process, including partnerships with organizations and partners that are closest to the population with the highest need to ensure our funding supports appropriate and context-specific solutions. Unitaid will adopt key performance indicators to measure the depth and effectiveness of our partnerships, allowing us to monitor how our ability to build lasting, diverse partnerships all the way to the end user and patient is impacting performance and results.

Similarly, the new Strategy will emphasize equity aspects of all steps of the process. In practice, this means that Unitaid will prioritize investments and products designed to benefit populations that are most vulnerable or least able to afford and access optimal care. We will also promote innovative supply models and approaches, domestic manufacturing, technology transfer, and will strive to establish an enabling environment for access, including intellectual property and regulation to accelerate more secure and potentially more affordable/faster access to health products.

The commitment to equity merges with the partnership approach as Unitaid integrates country, community, and civil society engagement to foster inclusive and demand-driven partnerships while supporting people and communities in taking ownership of their health.

Unitaid is in the process of building an implementation plan for the 2023-2027 Strategy. The thinking that has shaped the 2023-2027 Strategy is therefore already informing the investment choices and priority-setting of the organization.

Unitaid also aims to internalize the Strategic Principles and Programmatic Priorities by ensuring that Unitaid fosters an inclusive environment, where diverse perspectives, backgrounds, and experiences are valued.

The 2023-2027 Strategy is expected to require an investment of US\$ 300 million per year, which is in line with investment levels of the past six years of Unitaid's activities.

VII Mobilizing resources to deliver

This Strategy is ambitious, realistic, and achievable. To implement it and realize our potential, Unitaid forecasts an annual need of US\$ 300 million per year. This is consistent with the funding levels across the previous Strategy period and would allow us to achieve the optimized results envisioned by the Strategy. This investment would see Unitaid construct and maintain a pipeline of new products, including 30 key products by 2030, as well as systemic and cross-cutting investments. It will also maintain an activity level that will ensure continued momentum for the next Strategy period from 2028 onwards.

Unitaid's Investment Case describes its unique position and contribution in the global health architecture and offers examples of both innovations we have already pioneered and prospects for future innovations. The Investment Case emphasizes Unitaid's role as an "impact multiplier." Its work has already contributed new products and treatments that have saved millions of lives, billions of dollars, and sped up the global health response by years. Without the innovations championed by Unitaid, it will take years longer to reach several SDG 3 targets than with these innovations in place and widely used. In a world of constrained resources and unprecedented uncertainties, Unitaid enhances, through increased efficiencies, other donors' and countries' own investments in global health, with an anticipated cost saving of US\$ 5 billion by 2030 for the broad market uptake of DTG-based regimens of ARVs alone. Overall, Unitaid's Strategy will reduce costs by 2030, not only in the HIV/AIDS response but also those of tuberculosis, malaria and maternal and child health.

Unitaid will use this Investment Case to engage and diversify its donor community in an ongoing dialogue over the coming five-year period to secure an adequate level of commitments to maintain the aspired funding level of US\$ 300 million per year.

With success, Unitaid will continue to operate at current levels and continue to advance the cause of equitable access to game changing health care. It will allow Unitaid to realize our goal to bring 30 key products to those who need them by 2030. And it will set Unitaid up to maintain our position as an accelerator of progress in global health and in that position being able to transform lives, make communities more resilient, and help humanity care for the most vulnerable among us.

Annex 1

Strategy development process

Unitaid's 2023-2027 Strategy reflects the diversity of perspectives and depth and breadth of thought that went into its development. It builds on the past and sets the tone for the future.

This new Strategy is driven by a sharpened focus on the Programmatic Priorities of highest impact and seeks to leverage Unitaid's unique skills and position in the global health landscape. It strengthens emphasis on access to health products, on enhancing care, and ensuring the resilience of care pathways to build quality and sustainable health outcomes. It builds on the past, extending partnerships critical to Unitaid's successes, and looks to the future, bringing more voices and perspectives as it seeks to find and amplify interventions that will make measurable, lasting differences to communities after Unitaid's part is done. And, recognizing that the Sustainable Development Goals deadline of 2030 is only 7 years away, this Strategy reflects both urgency and resolve.

The document is the result of an in-depth consultative process, in three phases. The first phase included an external evaluation of Unitaid's work in the previous Strategy period (2017-2021) as well as a wide variety of consultations with scale-up partners, grant implementers, key technical and strategic partners, including country stakeholders, representatives of the communities most impacted by our interventions and civil society. Based on that foundational work, the second phase built a strategic framework and a set of Programmatic Priorities that was improved iteratively, based on feedback from the Unitaid Executive Board and external partners. The third phase translated this framework and Programmatic Priorities into a fully-fledged Strategy and built-up key tools for operationalizing the Strategy – such as a prioritization approach and key performance indicators (KPIs).

The issue of equity was one area where the consultations were essential to shaping the new Strategy. This Strategy reflects our efforts to better articulate our commitment and approach to equity and our goal of providing "equitable access to health innovations to ensure healthy lives and well-being for all" and "expand the reach of the best health products for those who need them most.