

UNITAID

STRATEGY 2013-2016



EXECUTIVE SUMMARY



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With this new Strategy 2013-2016, UNITAID enters what could be called the third stage of its development.

The Strategy refines the proven business model of UNITAID

From 2006 to 2009, UNITAID operated mainly as a large scale, procurement group, with the goal of correcting major shortcomings in the markets for drugs and preventive products for HIV, tuberculosis (TB) and malaria. Several major successful initiatives were implemented during this period, notably in the area of paediatric antiretroviral drugs (ARVs), second line ARV drugs for adult HIV infection, long-lasting insecticide-treated bed nets (LLINs) and access to drugs for multi-drug resistant tuberculosis (MDR-TB). During 2006-2009, the Executive Board decided that UNITAID should address market shortcomings through a wide range of actions, rather than only by procuring products. Market transformations lead to long-term improvements that better serve populations of developing countries by encouraging new producers to enter the market, stimulating competition, increasing transparency, improving the quality of medicines and diagnostics, and sustaining these changes. Market-based interventions became the unique feature of UNITAID during the first stage of its development.

During its second strategic phase, from 2010 to 2012, UNITAID built its capacity to describe and analyse the markets for drugs and diagnostic tests for the three diseases, so that it could identify opportunities for market-based intervention at an early stage, focus its efforts, and ensure that UNITAID operations are cost effective. A new proposal review process was set in place, leading to better targeting of projects and improved market impact. A stronger emphasis was placed on innovation and support for the market entry of promising new products. Thanks to this evolving approach, UNITAID entered the field of diagnostic tests for the three diseases, notably at the point-of-care (POC). It also played a major role in increasing access to artemisinin-based combination therapies for malaria, and to drugs for the treatment of MDR TB and paediatric ARVs. The establishment of a market dynamics unit has led to stronger cooperation with other actors in the public health scene and established its reputation as a provider of market intelligence.

In 2012, an independent Five-Year evaluation of UNITAID was conducted, which endorsed the business model of the organization; commended its achievements; and made recommendations for future activities. These recommendations have been incorporated in the 2013-2016 Strategy.

UNITAID is now equipped to analyse market opportunities; define the mechanisms of market interventions; and support selected activities that can have the most significant effect in terms of improving access to key healthcare products for vulnerable populations. Mechanisms for inviting and evaluating proposals have been refined; procedures to finalize grant agreements have been accelerated and streamlined. Market analyses now allow UNITAID to set precise objectives and announce specific goals for its market transformation activities. The current Strategy places great emphasis on innovation, strategic partnerships, performance measurement and value added. The Strategy outlines priorities to improve management of UNITAID operations and the mobilization of resources. The goal is to make UNITAID a reference point for market intelligence, and optimize its ability to implement market-based approaches to improve public health.

Transition from one stage to another has taken place smoothly and seamlessly. Many of the strategic priorities identified for the coming years are already being addressed through grants that were approved in 2012 and this third phase represents an evolution of the successful business model of UNITAID.

The Strategy is based on a clear mission and strict principles

UNITAID's mission has remained constant over the years. It increases access to treatment for HIV/AIDS, TB and malaria for people in developing countries by leveraging price reductions of quality drugs and diagnostics, which currently are unaffordable for most developing countries, and to accelerate the pace at which they are made available.

UNITAID will remain focussed on product markets for the diagnosis and treatment of HIV, TB and malaria, as well as prevention commodities, co-morbidities and co-infections significant to these three diseases. The aim of its interventions is to substantially improve public health outcomes in developing countries. Interventions financed by UNITAID will combine the best market and public health outcomes, and adhere to its guiding principles: innovation, value for money, equity, sustainability, flexibility and transparency. In addition, it will increase and leverage its partnerships, and continue to take a strong 'pro-public-health' approach to intellectual property.

Diverse and result-oriented implementers perform UNITAID's market interventions: they receive time-limited grants to catalyse changes in markets and maximize the public health effects of these projects. The evolution of UNITAID's business model will include the possibility of supporting late stages of product development wherever these activities will have a major impact. UNITAID will also establish a mechanism to provide one-off innovative grants to support the incubation of upstream innovative ideas and initiatives.

The Strategy outlines sound objectives for markets and public health

The purpose of UNITAID is to contribute to the achievement of global long-term goals for HIV, tuberculosis and malaria through its interventions in product markets. These goals have determined the Strategic Objectives described in this Strategy for the coming four years and are shared by the international community at large. The Strategic Objectives have also been guided by the market landscapes, which UNITAID regularly publishes and updates twice a year, and which identify opportunities for market interventions. The Objectives have been divided into three categories: active (UNITAID already supports interventions that will continue throughout the period of the Strategy), potential (clearly identified by the landscapes but not yet considered for funding) and exploratory (identified by experts and stakeholders but not yet vetted through landscape analysis).

STRATEGIC OBJECTIVE 1:

Increase access to simple, POC diagnostics for HIV/AIDS, TB and malaria.

The expected market impact in HIV is to reach 80% coverage for CD4 tests and 50% coverage for viral load and early infant diagnosis; introduce several competing TB diagnostic tests into the market to improve affordable access at the point of care; reach 60% availability of malaria rapid diagnostic tests of assured quality in the private sector and 80% in the public sector of malaria endemic countries. (Estimated impact in countries where UNITAID supports interventions on diagnostics.)

UNITAID'S STRATEGIC OBJECTIVES

1

Simple, point-of care (POC) diagnostics

2

Affordable, adapted paediatric medicines

3

Treatment of HIV/AIDS and co-infections

To achieve this objective, UNITAID already finances interventions to accelerate access to innovative HIV POC diagnostics and to implement their use in sub-Saharan Africa. UNITAID also supports open polyvalent platforms for HIV viral load testing, price reduction and scale-up of the GeneXpert test for TB, and creation of a private sector market for rapid diagnostic tests (RDTs) for malaria, including improved quality monitoring and control of these RDTs. In addition, cross-cutting mechanisms are being implemented via UNITAID funding to improve quality assurance and to harmonize evaluation protocols for diagnostic tests for the three diseases.

Additional interventions will be considered during the 2013-2016 period to expedite market entry of game-changing tests, and to support tests that address specific issues, such as resistance to antiretrovirals in HIV, extrapulmonary TB diagnosis, rapid diagnosis of malaria for asymptomatic pregnant women and for patients infected with *P. vivax*, as well as tests adapted for children. Interventions that can harmonize policies and the regulation of diagnostic products, secure demand for them and reduce their price will also be considered.

STRATEGIC OBJECTIVE 2:

Increase access to affordable, paediatric medicines to treat HIV/AIDS, TB and malaria.

The expected impact is to decrease the price of HIV medicines by at least 20% and to introduce better products; to ensure that coverage of paediatric TB therapy reaches 80%; and prequalified rectal artesunate becomes available for the emergency treatment of malaria in small children to reduce mortality among this age group.

UNITAID already finances interventions that have transformed the market for paediatric treatment of HIV and TB. Grants supporting the development of paediatric formulations including HIV protease inhibitors, the development of appropriate medicines for TB in children and the development of rectal artesunate are currently being implemented.

4

Treatment of
malaria
(ACT)

5

Treatment of
second-line TB

6

Preventatives
for HIV/AIDS, TB
and malaria

Over the Strategy period, other interventions will be identified to consolidate and satisfy demand for paediatric antiretroviral treatment, accelerate market entry of new paediatric drugs for the three diseases, support price reduction of paediatric products and accelerate their registration for widespread use.

STRATEGIC OBJECTIVE 3:

Increase access to emerging medicines and/or regimens as well as new formulations, dosage forms, or strengths of existing medicines that will improve the treatment of HIV/AIDS and co-infections such as viral hepatitis.

The expected outcome is to increase access to medicines for HIV to significantly reduce the price of second line regimens because a growing proportion of patients will require these products; support first-line regimens that can be implemented at community level with decreased overall costs to the health system; and explore the issue of treatment for co-infections, notably viral hepatitis, a major cause of mortality after TB among people living with HIV.

UNITAID already supports projects that aim to decrease the uncertainties linked with the supply of active pharmaceutical ingredients (API) for ARVs, and increasing access to patented innovative products, in particular through the Medicines Patent Pool.

Over the next four years, other interventions will be designed to secure the market and decrease the price of APIs and second-line drugs, and to support market entry of new products and regimens that include better and more cost effective ARVs. In addition, UNITAID will landscape the market of drugs and diagnostics for hepatitis to gain a better understanding of specific challenges related to HIV/hepatitis C (HCV) co-infection in resource-limited settings.

STRATEGIC OBJECTIVE 4:

Increase access to artemisinin-based combination therapies (ACTs) and emerging medicines, which, in combination with appropriate diagnostic testing, will improve the treatment of malaria.

The expected outcome is to contribute to a significant decrease in malaria mortality, notably among infants and children, and to improve the outcome of severe malaria.

UNITAID has already been highly active in this field by being the main funding organization for the AMFm (Affordable Medicines Facility for malaria) and has provided grants to better understand the forecast of ACT demand, the API situation for malaria drugs and to introduce injectable artesunate into the market, as an alternative to quinine for the treatment of severe malaria.

Over the Strategy period, UNITAID will support the market entry of new antimalarials, potentially including for *P. vivax* infections. UNITAID will also support interventions to combine access to rapid diagnostic tests and malaria drugs within the context of integrated management of fever.

STRATEGY OBJECTIVE 5:

Secure supply of second-line tuberculosis medicines, and increase access to emerging medicines and regimens that will improve treatment of both drug-sensitive and MDR TB.

The expected outcome is to stabilize markets to sustain access to safer, simpler, shorter, and more affordable treatment regimens, with particular emphasis on multidrug-resistant and HIV-associated TB. Targets include reduced treatment duration to approximately 4 months for drug sensitive TB and to 9 months for MDR TB; and substantially reduced cost of quality-assured MDR TB treatment of MDR infections, which would lead to more patients accessing treatment.

UNITAID is already active in this field, with on-going grants aiming at gaining better knowledge of the API market for TB drugs and the acceleration of access to MDR TB drugs, notably to avoid stock-outs.

Over the Strategy period, UNITAID aims to develop interventions to improve market intelligence in relation to demand forecasting for TB drugs and their APIs; to facilitate the market entry of new TB drugs approved by the World Health Organisation (WHO); and to harmonize quality standards for MDR TB drugs.

STRATEGY OBJECTIVE 6:

Increase access to products for the prevention of HIV, TB, and malaria, notably to improve the availability of devices for male circumcision and of microbicides, once they are approved; and to increase access to vector control tools to prevent malaria transmission.

UNITAID has supported the market entry of LLINs. This intervention is now completed. It helped create a market that was subsequently supported by Global Fund grants, enabling good coverage of nets in malaria endemic areas.

Over the Strategy period, UNITAID will consider supporting increased access to male circumcision technology and microbicides, once they are available and have been approved for use. Interventions will be explored to support market availability of better and sturdier nets, including the use of new insecticides or combinations of insecticides to address vector resistance; and to make effective and safe medicines available for malaria prophylaxis among pregnant women, infants and children.

The Strategic Objectives are expected to remain constant over the duration of the Strategy period. However, opportunities for each type of product, possibilities for interventions, selection of potential targets will evolve with time, and will also be monitored in relation to epidemiological and disease burden data. Potential and exploratory interventions will be updated regularly and presented to the Board at least once a year.

Strategic objectives will be reached through proven approaches

To achieve the Strategic Objectives, UNITAID works through market interventions that improve access to products for vulnerable populations. To achieve market impact, UNITAID describes and quantifies the access issue and the public health problem that need to be addressed; identifies the market dynamics that contribute to this access problem; provides grants to implementers to carry out market interventions; measures the market impact of the intervention and estimates the extent to which the intervention has improved public health.

The approach includes four phases:

LANDSCAPE ANALYSES AND VETTING

The UNITAID Secretariat compiles research and analyses to publish and regularly update market landscapes for products that are used in the diagnosis, prevention and treatment of the three diseases. These landscapes are discussed in market fora that involve a broad consultation of stakeholders. These consultations allow UNITAID to identify areas where market-based interventions could have considerable public health and market impact. Strategic and practical considerations allow UNITAID to identify the topics that can become the basis of calls for proposals.

PROPOSAL DEVELOPMENT AND TECHNICAL EVALUATION

Based on a review by the Board of potential interventions, UNITAID will issue directed calls for proposals that best correspond to the Strategic Objectives. One open call will also be issued annually to receive proposals that may not correspond to topics identified in the landscape analyses. Proponents send letters of intent, which are reviewed in detail by the UNITAID Secretariat and evaluated against rigorous selection criteria. A limited number of proponents are invited to develop full proposals.

PROPOSAL SELECTION AND PROJECT INITIATION

Proposals deemed suitable, technically sound and feasible by the Proposal Review Committee are recommended to the Executive Board, which makes funding decisions. Approved proposals enter a time-limited process of planning, review of procurement and financial components, review of sustainability and refinement of implementation procedures by the UNITAID Secretariat, and are then formally initiated.

GRANT MANAGEMENT, MONITORING AND EVALUATION OF PERFORMANCE AND IMPACT ASSESSMENT

The success of UNITAID interventions depends on a clear planning process, close monitoring and a strong relationship between UNITAID and its implementers. UNITAID requires annual and semi-annual project reports, through which it monitors grant performance. All grants are externally evaluated at mid-way through the project and at the end of the project. UNITAID summarises its grant and organizational performance annually using a set of Board-identified Key Performance Indicators.

The successful implementation of the Strategy requires a strong and efficient Secretariat

UNITAID's effectiveness depends on the right set of core action areas, carried out to the highest degree of excellence. For the coming four years, five specific areas will contribute most directly to the fulfilment of UNITAID's mission.

MARKET INTELLIGENCE GATHERING AND ANALYSIS

UNITAID will establish a market intelligence system to provide comprehensive and timely information on product markets; identify opportunities from the analysis of landscapes; expand the capacity to analyse information; and share market information and insights internally and with other actors of the international public health scene.

PORTFOLIO AND GRANT MANAGEMENT

Success in reaching the Strategic Objectives will depend on the capacity to manage the process from the call for proposals to the completion of projects. UNITAID is refining its standard operating procedures for grant management. It will monitor the quality of this process through the level of response to calls for proposals, the quality of letters of intent and proposals, the capacity of the Secretariat to recruit new implementers and to reduce the lead time from Board approval to project implementation to less than 120 days.

RESOURCE MOBILIZATION AND FUNDRAISING

UNITAID will work to improve the regularity and predictability of its resource flow and endeavour to broaden its donor base. Securing long-term funding commitments from its current members will remain the main priority for the Secretariat, but it will also seek to attract new donors and increase its funding level, notably through innovative financing mechanisms, budgetary contributions and the development of co-financing. UNITAID recognises the need to maintain and consolidated the current funding level of at least an average of \$300 million per year.

STRONG RELATIONS WITH GLOBAL PARTNERS, COUNTRIES AND CIVIL SOCIETY

Building and maintaining partnerships will be one of the top priorities of UNITAID in the coming four years.

- UNITAID will, in particular, strengthen its collaboration with the Global Fund to maximize the market impact of our initiatives and secure their sustainability, cooperate on strategic developments in market dynamics and accelerate market entry of new products.
- UNITAID will engage with large international public health organizations, notably the WHO, UNAIDS, the Roll Back Malaria Partnership, the Stop TB Partnership, PEPFAR and other global stakeholders to ensure the alignment of our Strategic Objectives with normative guidelines and to accelerate the impact of our initiatives.
- UNITAID will engage with country authorities to encourage national ownership of new products and market conditions, notably through their incorporation into national policies. Implementers are required to develop agreements with country authorities. Communities and civil society

organizations will be encouraged to observe the public health impact of grants at local level. Together with governments, regulatory authorities, implementers and health professionals, they will participate in regional consultative forums that will guide and inform UNITAID.

- UNITAID will actively consult product development partnerships and private product manufacturers to identify candidate products for UNITAID support, agree on the most effective market entry approaches and share experience and information.
- UNITAID will engage with academia to broaden support and identify collaborations to improve the quality of our market dynamics information.

SECRETARIAT MANAGEMENT AND GOVERNANCE

Hosted by the WHO, the Secretariat will adapt its management mechanisms to the new Strategy, maintaining a lean, nimble and highly skilled staff. It will strengthen the effectiveness of its leadership under the Executive Director through a strong senior management team, who are empowered and accountable. It will streamline its work planning and budgeting process, based on results, with clear responsibilities and risk management procedures. The quality of the human resource management will be enhanced to give staff clear opportunities for professional growth and development.

A quality management system will be implemented across the whole organization and an integrated accountability framework will be built on the existing monitoring, evaluation, benchmarking and review processes. Regular reviews will be conducted to assess the implementation of the management and accountability framework, the satisfaction of stakeholders, the satisfaction of staff and effectiveness of work planning, financial planning and grant management.

The effectiveness and cohesion of governance practices will be enhanced. The mechanisms of independent expertise supporting Board deliberations and ensuring technical excellence of decisions on grants will be revised, notably to mobilize a larger pool of experts. Board composition, membership arrangement and accession, as well as the balance of constituencies, will be addressed to better reflect the commitments of donors to UNITAID and to give a role to new donors who join UNITAID.

The proof of the Strategy will be in its implementation

Funding projections show that the Strategy is feasible, but will require a level of steady funding of at least \$300 million each year. With a greater funding envelope, UNITAID could further increase access to commodities, allowing increased availability of products to those who need them most. Additional funding could be invested in projects further upstream (such as the recently approved project to improve paediatric ARV formulations) or downstream (to enhance the delivery of commodities to beneficiaries). During the implementation of the Strategy, UNITAID will consider options for co-funding to leverage its investments.

Continuous assessment of outputs and outcomes from UNITAID grants enables UNITAID to measure its overall achievement; expand its market intelligence; and filter project data, analytics and learning back into its landscape analyses and evaluation of opportunities for market-based interventions. Frequent assessment and sharing of results support continuous quality improvement and strategic redirection of on-going projects as required. Impact estimates will help UNITAID to better understand its influence on public health through its interventions.

By employing findings from all three levels of assessment (outputs, outcomes, impact), UNITAID will continue to work during the Strategic period to develop and implement an approach to measuring value for money that will guide proposal assessment and resource allocation decisions. As the concept is further elaborated and aligned for UNITAID's unique role in global health, key principles will include equity, efficiency, and effectiveness. UNITAID will continue to engage with other global health stakeholders working to establish methodologies and best practices for measuring and quantifying value for money.

The Secretariat will design an implementation plan with key work streams and responsibilities. It will assess the implications of the Strategy in terms of budget; human resources; Secretariat structure and management; and revise the key performance indicators of UNITAID. A mid-term evaluation of the implementation will be conducted in 2015.

The next four years will be challenging and exciting. At the beginning of this new Strategic period, the Secretariat is empowered to achieve significant market and public health impact aligned to its Strategic Objectives.

The UNITAID Strategy 2013-2016 provides an excellent vision that will guide new investments. It identifies the tools needed to implement the Strategy, of which many are already under development, tried and tested. UNITAID remains creative in its approach, and is ready and able to develop new tools or engage in new partnerships that will ensure its objectives are met. UNITAID's innovative source of income will continue to be well invested, and UNITAID will strive to increase its funding capacity through new and existing donors.

UNITAID looks forward to working with you, our partners, donors, countries and implementers, to make available the best treatments, diagnostic and prevention commodities for those in resource-limited-settings who rely on our combined efforts in the fight against the three diseases.

The Market Dynamics Dashboard was designed to provide a snapshot of the Secretariat's assessment of current market dynamics and opportunities for intervention across all diseases and product categories. It describes:

- the severity of current market shortcomings for all product types, detailed across UNITAID's five standard shortcomings categories and classified as minimal/not present, moderate, or severe;
- the composite severity of all market shortcomings, assessed as mild, moderate, moderate to severe, or severe; and
- the level of current and future opportunity for UNITAID intervention, based on the practical and strategic considerations defined in the 2013-2016 Strategy (see Strategy section 5.2).

The dashboard distils UNITAID's current assessment of the markets into a single page summary that adds context and rationale for the areas of intervention considered 'ready' (or near-ready) for potential UNITAID support and those that are not. This tool will be formatted for presentation on the UNITAID website, and will be updated frequently as market dynamics and opportunities evolve.

UNITAID MARKET DYNAMICS DASHBOARD - (08-MAY-2013)

M = Medicines D = Diagnostics P = Preventives	Product Sub-type	Access	Current Market Shortcomings*					Opportunity for Intervention***			
			Availability	Affordability	Quality	Acceptability/ Adaptability	Delivery	Composite severity of all current market shortcomings** (Apr 2013)	Current (Apr 2013)	Over next 4 years	
HIV/AIDS	M	Adult first-line	54%	x	x	--	x	x		Med-High	High
		Adult second-line	~30%	x	xx	--	x	xx		Med	High
		Paediatric	28%	xx	xx	--	xx	xx		High†	High
		Viral hepatitis C coinfection	TBD ¹	x	xx	x	xx	xx		Low	Med
	D	CD4	<60%	x	xx	xx	x	x		Med-High†	Med
		Viral load (VL)	<30%	xx	xx	xx	xx	xx		High†	High
		Early infant diagnosis (EID)	<30%	xx	xx	xx	xx	xx		High†	High
	P	Male circumcision devices	10% of target	x	xx	x	--	xx		Med	Med
		Female condoms	<1%	--	xx	--	xx	xx		Low	Low
		Microbicides	0%	xx	--	--	xx	--		Low	Low
Pre-exposure prophylaxis (PrEP)		<1%	--	--	--	xx	xx		Low	Low	
Tuberculosis	M	Adult first-line	66%	--	--	xx	xx	xx		Low	Med
		Adult second-line	19%	xx	xx	xx	xx	xx		Med†	High
		Paediatric	<50%	xx	x	xx	xx	xx		High†	High
	D	Near-POC or POC	40% TB Dx 19% MDRTB Dx <5% DST ⁵	x	xx	x	xx	x		Med†	High
Malaria	M	Adult	<20% public <10% private	x	xx	xx	x	xx		Med†	High
		Paediatric	<20% public <10% private	x	xx	xx	xx	xx		Med†	High
	D	Rapid diagnostic tests (RDTs)	77% public Minimal private	x	x	xx	x	xx		High†	High
	P	LLINs	21%	xx	x	x	x	xx		Low	Med
		Indoor residual spraying (IRS)	~5%	x	xx	x	x	x		Low	Low

* Market shortcomings are described as minimal/not present (--), moderate (x), or severe (xx).

** The composite severity of all market shortcomings in each sub-niche is assessed as mild , moderate , moderate to severe , or severe .

*** Level of opportunity for UNITAID market intervention, based on practical & strategic considerations defined in UNITAID 2013-2016 Strategy.

† UNITAID has current ongoing projects



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