

Strategy 2010 - 2012



Improving Global Markets to Address HIV/AIDS Tuberculosis and Malaria



Strategy

2010 - 2012

Improving Global
Markets to Address
HIV/AIDS
Tuberculosis and
Malaria



UNITAID STRATEGY 2010-2012

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Purpose of the Strategy:

The purpose of the UNITAID Strategy is to guide the Board and the Secretariat, and to communicate to Partners and Stakeholders the overall direction of the initiative for 2010-2012; to set broad guidelines for funding decisions and project management; and to outline UNITAID's approach to monitoring, evaluating and learning from its projects. The ultimate objective of the Strategy is for UNITAID to achieve its mission.

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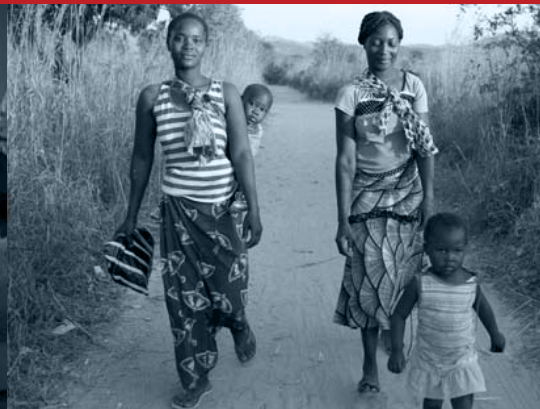
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Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ACT	Artemisinin combination therapy
ARV	Antiretroviral drug
API	Active Pharmaceutical Ingredient
CDC	United States Centers for Disease Control and Prevention
CHAI	Clinton Foundation HIV/AIDS Initiative
ESTHER	Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau
FDC	Fixed dose combination
FIND	Foundation for Innovative New Diagnostics
GDF	Stop TB Partnership Global Drug Facility
Global Fund (GF)	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLI	Global Laboratory Initiative
GMP	Good Manufacturing Practice
HIV	Human Immunodeficiency Virus
IPR	Intellectual Property Rights
IPT	Intermittent Preventive Treatment (for PMTCT of malaria)
IRS	Indoor residual spraying (of insecticides)
KPI	Key performance indicators
LIC	Low income country (World Bank classification)
LLIN	Long-lasting insecticide treated bednet
LMIC	Lower middle income country (World Bank classification)
MDR-TB	Multi drug resistant tuberculosis
M&E	Monitoring and Evaluation
MoU	Memorandum of understanding
MMV	Medicines for Malaria Venture
NGO	Non-governmental organization
OI	Opportunistic infection
PEPFAR	United States President's Emergency Plan for AIDS Relief
PMTCT	Prevention of Mother to Child Transmission of HIV
PRC	Proposal Review Committee of the UNITAID Board
PSC	Policy and Strategy Committee of the UNITAID Board
R&D	Research and Development
RDT	Rapid diagnostic test
RFP	Request for Proposal
RUTF	Ready to Use Therapeutic Food
TB	Tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
TRIPS	World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights
UMIC	Upper middle income country (World Bank classification)
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WTO	World Trade Organization
XDR-TB	Extensively drug resistant tuberculosis

Executive Summary



Executive Summary

1 Mission, Goals and Objectives:

Mission: UNITAID's mission is to contribute to scale up access to treatment for HIV/AIDS, malaria and tuberculosis (TB) 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.

Goal: Using innovative, global market-based approaches to improve public health by increasing access to quality products to treat, diagnose and prevent HIV/AIDS, tuberculosis, malaria and related co-morbidities in developing countries.

UNITAID's four main objectives are to:

- Increase access to efficacious, safe products of assured quality that address public health problems.
- Support adaptation of products targeting specific populations.
- Ensure affordable and sustainably priced products.
- Assure availability in sufficient quantities and timely delivery to patients.

Rationale: Why UNITAID? Markets for products to treat, diagnose and prevent HIV/AIDS, TB and malaria often suffer from multiple points of market failure along the pharmaceutical value chain: from research and development (R&D), formulation, production, registration, and quality assurance to delivery. Each product niche is plagued by a different set of market shortcomings: ranging from insufficient competition to insufficient production; and from information asymmetries to limitations in available technology. In order to address this problem, UNITAID strategically deploys its funds in time-limited interventions to remedy market shortcomings. For example, it may commit to purchasing a medicine for several years in order to create a market where one is absent, or to attract new suppliers to enter a market where the amount produced or the number of suppliers are insufficient. Once a market shortcoming has been addressed, UNITAID will transition out of a particular product market; for example, after prices have fallen or supplies have stabilized, governments or other funders may integrate purchase of the products into their financing, procurement and supply systems.

UNITAID is one of the first innovative health financing mechanisms, and raises additional, sustainable, predictable contributions from low-, middle- and high-income countries, primarily through an air ticket levy. This predictability enables UNITAID to make the credible funding commitments necessary to have sustained market impact. UNITAID adopts innovative approaches and undertakes targeted interventions in global markets in order to improve patient access to health products – a unique focus among global health initiatives. UNITAID seeks to leverage its investments to produce global public goods that generate positive externalities for the benefit of all developing countries and the broader global health community. For example, every dollar invested in increasing competition among pharmaceutical manufacturers aims to result in lower prices and many more dollars of cost savings for governments.

2 Guiding Principles and Role:

UNITAID is guided by twelve principles derived from its Constitution: innovation, effectiveness, leverage, global equity, a pro-public health approach to intellectual property, sustainability, additionality, complementarity, global impact, transparency, flexibility and forward-looking.

Role within the Global Health Landscape: UNITAID aligns its activities with major internationally agreed goals and will contribute to the attainment of goals such as the Millennium Development Goals by improving access to medicines in specific niches. UNITAID itself does not implement projects nor does it work directly with countries; rather, to ensure that it complements the work of other global health actors, UNITAID funds and primarily works through Implementing Partners that are engaged in improving access to health products. Extensive dialogue with non-governmental organizations (NGOs), communities and civil society is essential to ensure that UNITAID is viable and addresses the needs of patients and communities. UNITAID will ensure through the work of its Partners, that its purchases meet country demand and its procedures align with those of national health systems.

3 Scope: Diseases, Products and Position in the Pharmaceutical Value Chain:

The first priority and primary area of focus are products to treat and diagnose HIV/AIDS, TB, and malaria. UNITAID will also fund, on a highly selective basis, prevention products where there is comparable potential for public health and market impact. Products for co-morbidities will also be considered based on the burden of disease, the efficacy and cost-effectiveness of available products, and the opportunity for positive public health and market impact and sustainability after UNITAID support.

For the target diseases and products, UNITAID will address market shortcomings along the pharmaceutical value chain including: formulation, registration, production, quality assurance and global-level delivery issues. UNITAID will not fund actions focused directly on strengthening country systems for supply chain management and logistics, unless they have an impact on global product markets.

4 Approaches and Actions:

UNITAID's approaches are targeted at achieving the public health goals and objectives outlined above. Each objective gives rise to a set of approaches, which are implemented using a range of actions, in order to achieve market impact that ultimately should translate into public health impact. For example, to achieve the objective of affordable and sustainable pricing, UNITAID has adopted an approach of fostering competition among producers. It does so by lowering barriers to entry and introducing new producers in a market through purchase commitments.



5 Priorities and Project Selection:

Within the overall strategy and main priorities, UNITAID will prioritize and select projects through a two-step process based on agreed criteria. The Board solicits expert advice on priorities within the product niches. The area of work is refined through market intelligence and other tools. A targeted Request for Proposal (RFP) is solicited and an expert Proposal Review Committee (PRC) then assesses the proposals before making a recommendation to the Board.

Unsolicited concept notes for market impact projects unrelated to RFPs will also be reviewed, on a highly selective basis, in order to encourage innovative, out-of-the-box thinking. UNITAID will rely on timely market intelligence in order to identify market bottlenecks; devise strategies to improve market conditions; prevent or address market failures; measure the impacts of UNITAID interventions; and help set priorities for future initiatives.

6 Duration for Project Support and Transition:

UNITAID's strategy is to address market shortcomings for priority health products in the short-to-medium term; once the market failure has been remedied, UNITAID will transition out of the specific product niche. In requesting UNITAID's time-limited funding support, Implementing Partners assume the responsibility for ensuring that countries have successfully integrated the targeted products into their national health financing, procurement and supply systems, and Partners are able to sustain the impact of their market intervention within the product niche after UNITAID funding has ended.

7 Monitoring and Evaluation (M&E):

The main goals of M&E are to monitor the achievement of UNITAID's overall goals, promote accountability, effectiveness and encourage learning. M&E will take place at three levels: overall UNITAID performance towards its goals and mission, project implementation, and Secretariat and Board performance.

8 Sustaining Long Term, Predictable Financial Flow:

One of the main principles behind the air tax-based funding model of UNITAID is to provide a constant and predictable funding source, which allows for longer term projects and builds confidence among UNITAID's Partners, countries, and market actors. UNITAID will pursue measures that increase the predictability of its funding stream through strengthened donor

commitments, increased numbers of country contributors, and Voluntary Solidarity Contributions on airline tickets through the Millennium Foundation.

9 Communication Strategy:

UNITAID communications aim to increase global knowledge, understanding and the accountability of UNITAID; consolidate and increase existing members' support; increase understanding in contributing countries of their important contribution to achieved results; maximize Voluntary Solidarity Contributions; advocate for new countries to join UNITAID, introduce the air tax and expand the financial base; and foster good working relations with Implementing Partners and position UNITAID in their communication activities.

10 Future Developments: Challenges and Opportunities

UNITAID's strategy will evolve to adapt to changing challenges and opportunities, while continuing to be guided by its mission and guiding principles. Through partnerships and networks, UNITAID will monitor new developments in: products, guidelines, financing, new actors or activities, access barriers and/or health issues.

Section 1



Mission, Goal, Objectives and Rationale

Section 1: Mission, Goal, Objectives and Rationale

1.1 Mission, Goal and Objectives: What does UNITAID seek to achieve?

1.1.1 Mission: UNITAID's mission is to contribute to scale up access to treatment for HIV/AIDS, malaria and tuberculosis (TB) 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.

1.1.2 Goal: Using innovative, global market based approaches to improve public health by increasing access to quality products to treat, diagnose and prevent HIV/AIDS, tuberculosis, malaria and related co-morbidities in developing countries.

1.1.3 UNITAID's four main objectives are to:

- Increase access to efficacious, safe products of assured quality that address public health problems.
- Support adaptation of products targeting specific populations.
- Ensure affordable and sustainably priced products.
- Assure availability in sufficient quantities and timely delivery to patients.

Mission

- UNITAID's mission is to contribute to scale up access to treatment for HIV/AIDS, malaria and tuberculosis 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.

- [from Constitution]

Goal

- Using innovative, global market based approaches to improve public health by increasing access to quality products to treat, diagnose and prevent HIV/AIDS, tuberculosis, malaria and related co-morbidities in developing countries.

Objectives

- Increase access to efficacious, safe products of assured quality that address public health problems
- Support adaptation of products targeting specific populations
- Ensure affordable and sustainably priced products
- Assure availability in sufficient quantities and timely delivery to patients

1.2 Rationale: Why UNITAID?

Through its innovative and flexible approach, UNITAID is well placed to address the challenges of improving access to products to treat, diagnose and prevent the three diseases. UNITAID supports actions that contribute towards the achievement of the UN Millennium Development Goals:

- To combat HIV/AIDS, tuberculosis and malaria - by providing equitable access to quality medicines, diagnostics and prevention products adapted to patients needs to improve quality of life and reduce the burden of disease (MDG 6).
- To reduce child mortality: by providing a supply of medicines, diagnostics and prevention products specifically adapted to children's needs (MDG 4 and 5).
- To improve maternal health: by ensuring appropriate treatments for mothers and children and products to prevent mother to child transmission.

1.2.1 What is the Problem? Markets for products to treat, diagnose and prevent HIV/AIDS, TB and malaria often suffer from multiple points of market failure along the pharmaceutical value chain (See Figure 1, page 25 for illustration), from formulation, production, registration, and quality assurance to delivery. Each product niche is confronted by a different set of market shortcomings, ranging from insufficient competition to production of substandard quality products, from information asymmetries to limitations in available technology (*See Annex 1 for a list of the most relevant market shortcomings*).

Box 1: Definition of market shortcomings:

Instances where natural market forces do not lead to equilibrium between supply and demand; where there is a need to create a market where one would otherwise not exist; and where a product must be safeguarded such as to reduce emergence of resistance.

1.2.2 What does UNITAID do to address the problem? UNITAID strategically deploys its funds in time-limited interventions to remedy market shortcomings. For example, it may commit to purchasing a medicine for several years in order to create a market where one is absent, or to attract new suppliers to enter a market where production or number of suppliers is insufficient. Once a market shortcoming has been addressed, UNITAID will transition out of a particular product market; for example, after prices have fallen or supplies have stabilized, and governments or other funders integrate

the purchase of these products into their financing, procurement and supply systems.

1.2.3 What enables UNITAID to address the problem? UNITAID is one of the first innovative health financing mechanisms, and raises additional, sustainable and predictable contributions from low, middle and high income countries, primarily through an air ticket levy.

1.2.4 What is unique about UNITAID's contribution? UNITAID adopts innovative approaches and undertakes targeted interventions in global markets in order to improve patient access to health products – a unique focus among global health initiatives. UNITAID seeks to leverage its investments to produce global health products that generate positive externalities for the benefit of all developing countries and the broader global health community.¹

1.2.5 Whom does UNITAID fund? To ensure that it does not duplicate, but rather, complements the work of other global health actors, UNITAID funds and primarily works through Implementing Partners that are engaged in improving access to medicines, diagnostics and prevention products within its niches.

1 UNITAID/EB9/2008/R1

Section 2



Guiding Principles and Roles

Section 2: Guiding Principles and Roles

2.1 Twelve Guiding Principles (*Derived from Constitution*):

1 Innovation: UNITAID will seek to stimulate and adopt innovative approaches to improving global health, in line with its mission. It will stand ready to take risks and support promising but untested approaches.

2 Effectiveness: UNITAID will operate in a pragmatic and evidence-based fashion, with an emphasis on achieving concrete results.

3 Leverage: UNITAID will strive to make cost-effective investments that generate positive externalities, promote efficiency through coordination with other global health initiatives, and run efficient operations via a streamlined Secretariat.

4 Global equity: UNITAID is committed to channelling its resources where needs are greatest and resources most scarce. Therefore, at least 85% of funds dedicated to purchase health products should go to low income countries (LICs), no more than 10% to lower middle income countries (LMICs), and no more than 5% to upper middle income countries (UMICs) with priority given to those with a high disease prevalence, subject to these countries providing co-financing for their projects.²

5 Pro-public-health approach to intellectual property: Where intellectual property barriers hamper competition, affordability and/or development of appropriate formulations (e.g. FDCs), UNITAID will support the use by countries of compulsory licensing or other flexibilities under the framework of the 2001 World Trade Organization (WTO) Declaration on the Trade- Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health (“Doha Declaration”), when applicable.

6 Sustainability: UNITAID will mobilize long-term, predictable, sustainable financing.

² World Bank country classifications, revised annually in July. Income group: Economies are divided according to 2008 GNI per capita, calculated using the World Bank Atlas method. The groups are: low income, \$975 or less; lower middle income, \$976 - \$3,855; upper middle income, \$3,856 - \$11,905; and high income, \$11,906 or more.

7 Additionality: Resources mobilized will be additional to existing financing, and will not compete with other initiatives for funds.

8 Complementarity: In line with the 2005 Paris Declaration on Aid Effectiveness, UNITAID will not duplicate the activities of other global health actors, but rather, coordinate so that it will make a unique contribution and enhance the effectiveness of other global health actors. It will also seek to minimize burdens on national health systems by, for example, by working through Implementing Partners that support countries (and not directly with countries) and using existing reporting mechanisms where possible.

9 Global impact: UNITAID will strive to achieve price decreases and other market improvements that benefit all developing countries.

10 Transparency: UNITAID will be transparent in its governance, agreements and operations (see Transparency policy, UNITAID/EB4/2007/R1).

11 Flexibility: UNITAID will maintain flexibility to be reactive to changing contexts and conditions, and respond quickly to emerging global health needs.

12 Forward-looking: UNITAID will be proactive in identifying and taking action to address future needs.

2.2 Respective Roles of UNITAID and Implementing Partners

2.2.1 UNITAID Implementing Partners³

UNITAID collaborates with a range of Partners who can contribute and add value to its goals and objectives and who have a relevant, successful track record.

Box 2: Adapted from UNITAID Constitution 2006

To meet its objectives, UNITAID will rely on contractual and implementing partners. To date, partners include WHO, UNAIDS, UNICEF, the Global Fund, the Roll Back Malaria Partnership, the Stop TB Partnership, the Clinton Foundation HIV/AIDS Initiative, FIND and ESTHER. UNITAID will work in close cooperation with and eventually rely on organizations that have experience relevant to its operations, such as procurement, price negotiation, shipment and handling, and monitoring. UNITAID will rely on suitable programmatic partners to implement its programs, specifically those that have strong strategies to ensure sustainability of the investment. Strong dialogue with NGOs and civil society is essential to ensure that the initiative is viable and addresses the needs of patients and communities. ...[UNITAID will] ensure through the work of its Partners that its purchases meet country demand and its procedures align with those of national health systems.

At present, the UNITAID Partners responsible for project implementation are international organizations, global health partnerships, and a not-for-profit corporation engaged in humanitarian efforts. Partners' characteristics include: funders, coordination, fulfilling a normative role, or providing technical assistance. With regards to the implementation of projects, the relevant Partners are principally those engaged in the procurement and supply of medicines, diagnostics and prevention products to beneficiary countries. UNITAID is also committed to maintaining a strong dialogue with NGOs and civil society, patients and communities. UNITAID does not provide funding directly to recipient countries.

In the future, UNITAID may collaborate with other Partners for specific purposes, on an as needed basis and in accordance with a project's aims and objectives.

2.2.2 Types of project costs presently funded by UNITAID

The use of UNITAID funds is currently restricted to financing the purchase and supply of high quality medicines, diagnostics and prevention products including reasonable costs for quality control, shipping, insurance and procurement management. Implementation costs are covered by Partners from extra funding sourced separately from other donors. UNITAID funds may

3 Pilot Guidelines for Submission of Concept Notes for Innovative Projects and Proposals

not be used to finance operating costs or to pay for administrative expenses (unless such administrative expenses are the subject of an express provision in the Project Budget).

2.3 UNITAID's Role in the Global Health Landscape

In line with its guiding principle of complementarity, UNITAID will align its activities with the major internationally agreed health goals:

- Millennium Development Goals (UN).
- Universal Access to HIV Prevention, Treatment, Care and Support (UN, G8, African Union).
- Global Malaria Action Plan (Roll Back Malaria).
- Global Plan to Stop TB (Stop TB Partnership).
- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (World Health Organization [WHO]).

In addition, UNITAID affects, and is affected by, the work of many global health actors (in addition to its Implementing Partners); these actors fall into the five main categories listed below.⁴ Building effective collaborations with each type of actor is necessary in order to inform UNITAID's investments, sustain its impact, guide future directions, maintain political support and ultimately achieve UNITAID's mission.

2.3.1 Funding - organizations that mobilize resources at the global level to address public health challenges:

UNITAID will collaborate with major funders to ensure that its market impact can be sustained and it can transition out of product niches (see Section 6: Transition). UNITAID will also keep abreast of global financial flows for the three disease areas, and develop and share strategic market intelligence with funders to facilitate their operations.

2.3.2 In-country operations - organizations that support recipient countries in program implementation, technical assistance and service delivery:

UNITAID will communicate with implementing organizations and governments to ensure that it remains informed of and responsive to country needs and that products are effectively delivered.

4 Many players have several roles.

2.3.3 Research - organizations that fund and/or conduct research to develop new products against the three diseases:

UNITAID will solicit these organizations to monitor the development pipeline for new products and to identify potential future areas for market interventions.

2.3.4 Advocacy - organizations that advocate for political attention, funding and/or action against the three diseases:

UNITAID will collaborate with these organizations to maintain political support for its work and mission.

2.3.5 Standards and norm-setting:

WHO plays a key normative function by establishing standards (e.g. with respect to product quality) and treatment guidelines. UNITAID will collaborate with WHO to remain current on evolving standards and likely future priority product needs.

Section 3



Scope: Diseases,
Products, and
Position in the
Pharmaceutical
Value Chain

Section 3: Scope: Diseases, Products, and Position in the Pharmaceutical Value Chain

UNITAID accounts for a small proportion of total global health spending. In 2007, UNITAID funds comprised only 1.7% of development assistance for health. The current economic climate has resulted in major reductions in the available funding. It is important, therefore, that an organization such as UNITAID continues to focus its efforts on providing funding for the needs of the most vulnerable. Therefore, in the 2010-2012 period, UNITAID will maintain a targeted focus on products for HIV/AIDS, TB, malaria and related co-morbidities. Nevertheless, UNITAID funding affects a relatively large proportion of global donor-funded product markets, and its impact on those markets is considerable.

3.1 Diseases and Products

For 2010-2012, UNITAID's scope of work will focus on the following product areas:

3.1.1 Medicines, diagnostics and prevention products for HIV/AIDS, TB, malaria: Increasing access to quality products to diagnose and/or treat HIV/AIDS, TB, and malaria has the highest priority and is the primary focus. UNITAID will also fund, on a highly selective basis, prevention products where there is comparable potential for public health and market impact (UNITAID/EB9/2008/R1).

3.1.2 Co-morbidities including opportunistic infections: In order to enable a comprehensive impact on the morbidity and mortality rates associated with the three target diseases, UNITAID will also consider supporting access to products for the co-morbidities ⁵ of these diseases- based on the burden of disease, the efficacy and cost-effectiveness of available products, and the opportunity for positive market and public health impact.

3.2 Position in the Pharmaceutical Value Chain

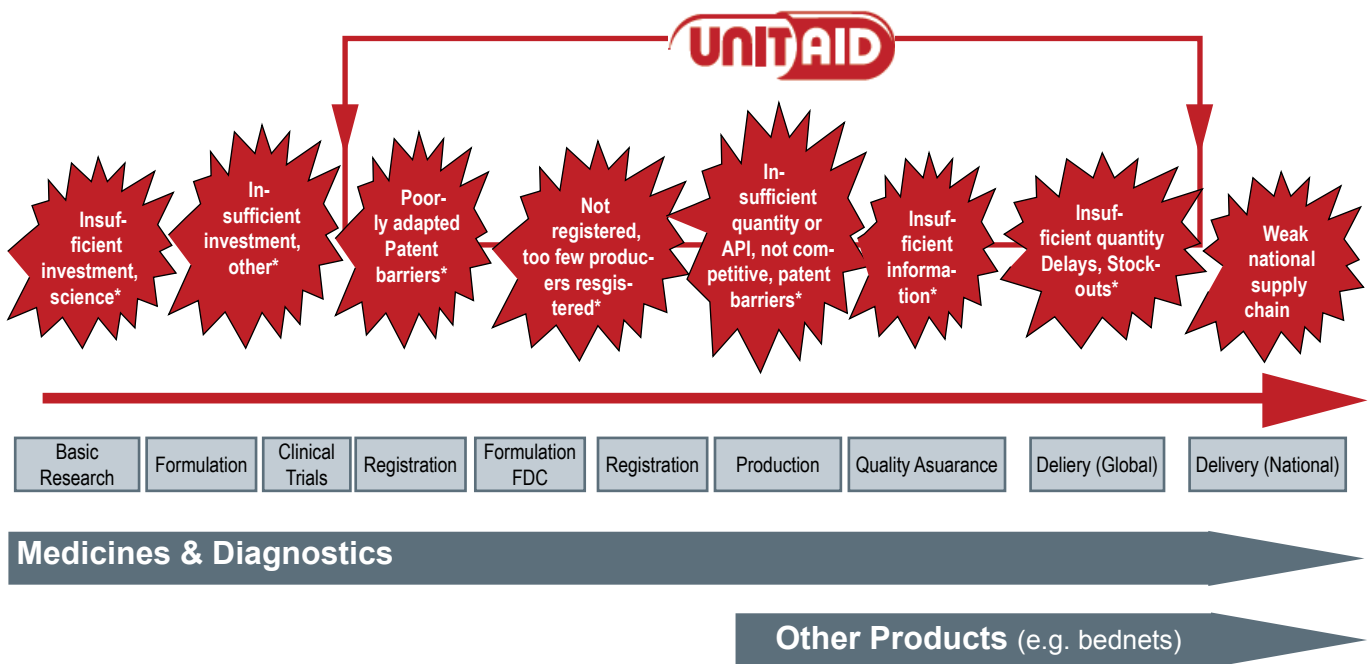
For the target diseases and products, UNITAID will address market shortcomings along the pharmaceutical value chain, starting from the formulation stage through to global level delivery (see Figure 1). For example,

⁵ Co-morbidities: additional conditions with the initially diagnosed illness. Source: Jonas Mosby's Dictionary of Complementary and Alternative Medicine. (c) 2005, Elsevier.

UNITAID may support the development of products adapted for use in low and middle income countries (e.g. FDCs, paediatric formulations, heat stable formulations) through a number of policy tools, including guaranteeing a time-limited market for such products.

UNITAID will not fund actions focused directly on strengthening country systems for supply chain management and logistics, unless they have an impact at a global market level. Nevertheless, in order to ensure that its funded projects provide benefits to patients to the greatest extent possible, UNITAID will evaluate proposals on their ability to ensure delivery and will build effective M&E milestones and targets into legal agreements. (UNITAID/EB9/2008/R1)

Figure 1: Market Shortcoming in Pharmaceutical Value Chain: Scope of UNITAID Work



* Examples of market failure are illustrative and not intended to be exhaustive

Section 4



Approaches and Actions

Section 4: Approaches and Actions

UNITAID's approaches are targeted towards achieving the public health goal and objectives outlined in Section 1. Each objective gives rise to a set of approaches, which are implemented using a range of actions in order to achieve market impact that should ultimately translate into public health impact. See Table 1 for the list of key approaches and actions UNITAID may use to achieve its objectives.

Table 1: Objectives, Approaches and Actions

Objectives:	Approaches:	Actions:
Efficacious, safe products of assured quality	<ul style="list-style-type: none"> Maximize useful lifespan of medicines by reducing the risk of resistance Monitor safety of medicines Support quality assessment initiatives 	<ul style="list-style-type: none"> - Create/expand markets for FDCs - Support quality assurance for diagnostics - Decrease price of diagnostics - Support availability of product while reducing the potential of adverse effects and risk of resistance - Support products aimed at special populations (e.g. pregnant women and children) - Fund WHO Prequalification (PQ) - Expand the market for prequalified products
Affordable and sustainably priced	Price negotiation	<ul style="list-style-type: none"> - Volume price negotiation through pooled procurement/order pooling - Cost-plus pricing
	Stimulate competition:	<ul style="list-style-type: none"> - Support producers in acquiring WHO Prequalification; - Induce new producers to enter market via purchase commitments; - Overcome patent barriers to multi-source production via patent pool; - Support product registration; - Encourage technology sharing
	Encourage economies of scale	<ul style="list-style-type: none"> - Increase export market size through patent pool; - Pooled procurement/order pooling
Available	Stabilize and ensure sufficient global supply	<ul style="list-style-type: none"> - Improve and share demand forecasting, - Reduce volatility in Active Pharmaceutical Ingredient (API) markets through purchase commitment/rotating funds; - Encourage/attract increased number of producers, as appropriate; - Contract manufacturing
	Stabilize demand	<ul style="list-style-type: none"> - Provide bridge grants to countries for product purchase (e.g. to cover gaps between Global Fund grants)
	Accelerate time to delivery	<ul style="list-style-type: none"> - Ensure timely payment; - Risk pooling through the creation of strategic rotating stockpiles
Adapted to the needs of affected populations	Provide incentives for development of well-adapted products	<ul style="list-style-type: none"> - Create markets for improved formulations (paediatric formulations, FDCs, co-packaging) - Overcome patent barriers to formulation production through patent pooling

The approaches and actions listed reflect measures that UNITAID has taken in the past or is currently considering. UNITAID welcomes new ways of achieving the objectives through innovative approaches and policy tools not listed here.

Section 5



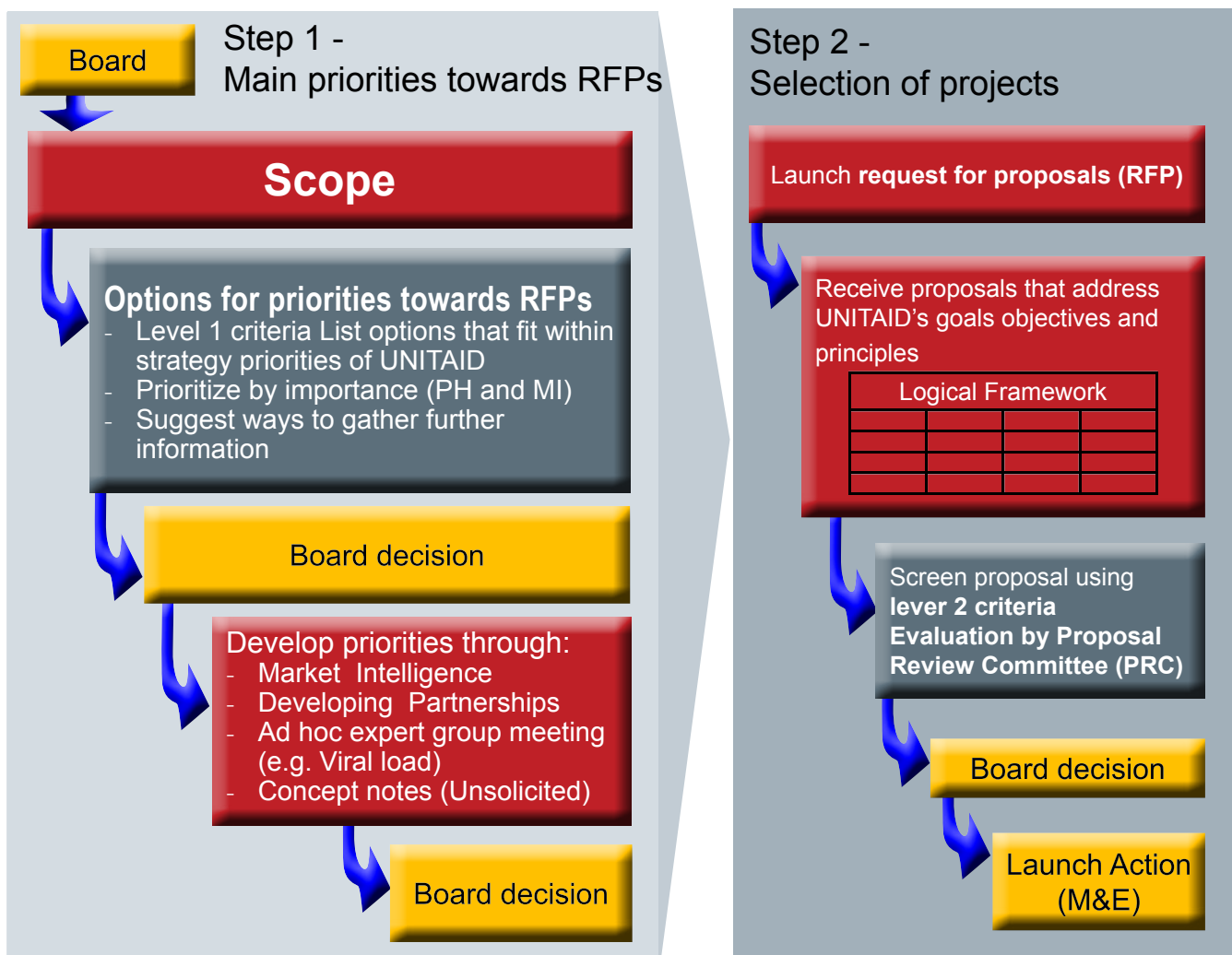
Priorities and Project Selection

Section 5: Priorities and Project Selection

Overview

Within the overall strategy and main priorities, UNITAID will prioritize and select projects through a two-step process. In Step 1, the Board solicits expert advice on priorities for funding for product niches (reference to Annex 2) using Level 1 Criteria; then the Secretariat develops further market intelligence on the priority product niches. Based on this work and with Board approval, in Step 2, the Secretariat issues a targeted RFP, receives proposals, and forwards them to the Proposal Review Committee (PRC) for assessment based on Level 2 Criteria. The Secretariat then sends both proposals and the PRC assessments to the Board for decision. Unsolicited concept notes will also be accepted (see below). These steps are illustrated in Figure 2 and described in further detail below.

Figure 2: UNITAID two step process for prioritising and selection of projects



5.1 Step 1: Priorities for Funding and Criteria

5.1.1 At the earliest stages, the Board delineates the scope of UNITAID's work by disease, product area, and position in the pharmaceutical value chain (See Section 3: Scope). In order to ensure that priorities are based on the best available scientific, economic and technical evidence, the Board will consult with an Expert Advisory Committee⁶, which will provide recommendations on priorities for funding that align with UNITAID's strategy and overall priorities (See Section 3: Scope) based on Annex 2 to this strategy. This Expert Advisory Committee consists of outside experts who will recommend priority options using Level 1 criteria (see Table 2).

5.1.2 Once the Board has set priorities for funding, the Secretariat will develop them further by gathering market intelligence, consulting with Implementing Partners, and consulting with further experts as needed, until a detailed Request for Proposals (RFPs) is issued.

5.1.3 In order to encourage innovation and "out-of-the-box thinking," UNITAID will also consider unsolicited concept notes that are compatible with its mission and goals, and are aligned with its principles. Due to the complexity of product market dynamics, the best opportunities for UNITAID investment may come via unsolicited concept notes. The Secretariat will screen received concept notes based on Level 1 criteria, soliciting advice from the PRC as appropriate. This advice will form the basis of recommendations to the Board⁷ for a decision on whether to invite potential applicants to submit a full proposal, with the clear understanding that doing so does not entail any commitment to fund the project. Final proposals will follow the same assessment and decision process as those received in response to an RFP (process described in Step 2).

6 The Board will determine the selection and TOR of the Expert Advisory Committee

7 The Board will receive information about all unsolicited concept notes received.

Table 2. Level 1 Criteria for Priority Options for funding⁸

Criteria	Rating
1. Does it fit within UNITAID's mission and goals (Section 1)?	- Yes/No
2. What is the importance of the public health problem? - Scope/scale of problem? - Specific (vulnerable) populations? - Severity of problem?	- High/Medium/Low - Large/Medium/Small or specific number - e.g. pregnant women, children, rural population - Life-threatening, disabling, etc. or in DALYs
3. What is/are the priority market shortcomings in this niche? [Identify Market Shortcomings]	- Safe, efficacious and quality product - Adapted to target populations - Affordable and sustainable - Available ⁸
4. What would be the public impact of resolving the market shortcomings? - Scope/scale of impact? - Specific (vulnerable) populations? - Depth of impact?	- High/Medium/Low - Will reduce #s affected by Large/Medium/Small or specific quantity - Will help children, etc - Life-saving, morbidity reducing, etc. or in DALYs
5. How feasible is it to resolve the market shortcomings?	- High/Medium/Low

5.2 Step 2: Project Selection Process and Criteria

5.2.1 Once the Secretariat has gained internal familiarity with a product niche and after the Board has made a decision, a targeted Request for Proposals (RFP) will be developed and issued.

5.2.2 Proposals must clearly describe the public health problem, the market shortcoming(s), the proposed intervention to remedy the market problem, its expected market impact, and the ultimate projected public health impact. Applicants should submit a proposal that reflects robust logical reasoning and a thorough analysis of assumptions, risks and opportunities, including a concise logical framework that summarizes key quantitative targets to facilitate Board consideration. In order to enable UNITAID to make quantitative funding decisions, proposals must present quantitative targets with respect to both market impact and public health impact dimensions.

5.2.3 Once proposals are received, the Secretariat will forward them

⁸ Availability refers to (a) reducing lead times from ordering to country port delivery, (b) reducing the risk of insufficient supply to meet solvent demand. The mere provision of a health product does not qualify as market impact.

Table 3. Level 2 Criteria for Project Selection and Proposal Assessment

Criteria	Rating
1. Does it fit within UNITAID's mission and goals (Section 1)?	- Yes/No
2. What is the importance of the public health problem? - Scope/scale of problem? - Specific (vulnerable) populations? - Severity of problem?	- High/Medium/Low - Large/Medium/Small or specific number - e.g. pregnant women, children, rural population - Life-threatening, disabling, etc. or in DALYs
3. What is/are the priority objective(s)? [Identify Market Shortcomings]	- Safe, efficacious and quality product - Adapted to target populations - Affordable and sustainable - Available
4. To what extent does the project adhere to UNITAID's Guiding Principles?	- i.e. Innovative, Efficient Sustainable, Additional, Complementary, Global impact, Globally equitable, Pro-health approach to intellectual property, Transparent, Effective, Flexible, Forward-looking
5. Accurate identification of a plausible market shortcoming.	- High/Medium/Low
6. Plausibility of intervention having the expected market impact and leverage effect; confidence in quantitative market impact targets and announced leverage potential; post-grant sustainability of Market Impact.	- High/Medium/Low; Large/Medium/Small
7. Plausibility of intervention having the expected public health impact; confidence in quantitative public health targets	- High/Medium/Low, Large/Medium/Small
8 Importance of the desired public health impact: - -Scope/scale of impact? - Specific (vulnerable) populations? - Depth of impact?	- High/Medium/Low - Will reduce #s affected by Large/Medium/Small or specific quantity - Will help children, etc - Life-saving, morbidity reducing, etc. or in DALYs
9. Quality of other proposal components: - Budget and Budget Narrative - Timeline - Monitoring and Evaluation Plan - Risks and risk mitigation - Transition Plan	- High/Medium/Low - High/Medium/Low - High/Medium/Low - High/Medium/Low - High/Medium/Low
10. Value for money: - Projected health benefits per unit of UNITAID expenditure	- TBD

to the Proposal Review Committee (PRC), which will assess the quality and credibility of each proposal's analysis of the:

- Public health problem;
- Market shortcomings in a given niche;
- Feasibility of the proposed intervention; and
- Validity of the applicant's projections regarding the project's quantitative market impact and ultimately, public health impact targets.

The PRC assessment will be based on both specific Level 2 criteria (which are more product and project specific than Level 1, as detailed in Table 3) and a holistic assessment of the strength of logic in the proposal. The PRC will make recommendations to the Board, which will make funding decisions based on prioritisation in light of Level 2 criteria and projected UNITAID resource availability. At this point, once agreements with Implementing Partners have been concluded, actions can be launched and M&E begins.

5.3 Market Intelligence for Priority-Setting, Project Selection and Evaluation

5.3.1 During the 2010-2012 period, UNITAID will support the establishment and maintenance of a market intelligence information system that can describe, monitor and assess the global markets for medicines, diagnostics, and prevention products for HIV/AIDS, TB and malaria. Reliable, timely market intelligence is indispensable to UNITAID in order to:

Identify market bottlenecks;

- Devise strategies to improve market conditions;
- Prevent or address market failures;
- Measure the impacts of UNITAID interventions; and
- Help set priorities for future initiatives.

5.3.2 Market information is especially critical since UNITAID is engaging in multiple innovative approaches whose impact needs to be clearly understood. The system will aggregate data from existing sources into one publicly accessible, user friendly data resource. The UNITAID system will be in the public domain and will require that information produced from analyses of the system's data also be returned to the public domain and made freely available to all users. It is expected that the UNITAID database will facilitate the daily work of donors, international organizations and country programs.

Section 6



Duration of Project Support and Transition Strategy

Section 6: Duration for Project Support and Transition Strategy

6.1 Objectives

While UNITAID's mission is long-term and spans a range of potential products, its objectives for a particular product niche are time-limited and catalytic. UNITAID's strategy is to address market shortcomings for priority health products in the short-to-medium term; once the market failure has been remedied, UNITAID will transition out of the specific product niche. For example, UNITAID has guaranteed a market through large-scale purchase of paediatric antiretroviral drugs (ARVs) in order to induce market entry from suppliers; once the market stabilizes, countries and/or donors are expected to begin purchasing these medicines out of their regular budgets.

6.2 Impact on the Market

Each project is unique in the way it will impact the market. Certain projects will address a specific market failure in a short period of time, and will not require additional funding for transition. One example of such a project is UNITAID's intervention in the insecticide treated bed net market, in which the short-term risk of supply shortages was averted through the commitment of secure funding. It is of utmost importance to avoid any risk of disrupting the procurement of medicines on which patients rely. It is also critical that the market impact benefits that have been achieved throughout a project can be sustained after it has ended. Transitioning out of projects once market shortcomings have been addressed allows UNITAID to address market problems in other product niches. Lessons learnt to date show that most projects follow a three year life cycle. (See also Section 8: UNITAID and international resource flows for HIV/AIDS, TB and malaria.)

6.3 Time Limited Funding

In requesting UNITAID's time-limited funding support, Implementing Partners assume the responsibility for ensuring that, by the time UNITAID support ends:

6.3.1 Countries have successfully integrated the targeted products into their national health financing, procurement and supply systems, including but not limited to having secured sufficient domestic or external funding to continue purchasing the product.

6.3.2 Partners and/or other funding organizations are able to sustain the impact of their market intervention within the product niche.

6.4 Partners to Plan for Transition

UNITAID will require Implementing Partners to plan for transition from project inception, including criteria and milestones for transition and that this is included in all agreements (Note that criteria will be product and niche-specific). Upon request, it will also assist Implementing Partners in securing the early buy-in of other global funders before entering into a new project area. Through its M&E strategy, UNITAID will closely monitor project implementation to ensure problems are addressed as they arise and to achieve timely progress towards successful transition. Project partners are to provide technical assistance to countries to enable them to apply to international donors.

6.5 Bridge Funding

In case an Implementing Partner is unable to secure alternative funding after the end of UNITAID support, and if this failure is putting country programs and patients at risk, UNITAID will consider providing bridge funds for a limited period of up to two years on condition that the Partner demonstrates concerted efforts to secure alternative funding arrangements. UNITAID maintains a



strong commitment to avoiding disruptions in supply of health products to project beneficiaries, which is critical both to avoid treatment interruption and to provide the confidence among countries and Partners necessary to initiate projects in the first place. The potential sustainability of a project's impact after transition needs to be carefully considered before committing to a project.

6.6 Up-front Transition Strategy

On-going discussions with Implementing Partners and beneficiary countries has recommended that up-front identification of a transition strategy either to a national government or to another funding agency (or a mix of both) occur at the very start of the project to facilitate smooth transition of projects from UNITAID funding to other funding sources.

Section 7



Monitoring and Evaluation

Section 7: Monitoring and Evaluation

7.1 Rationale

UNITAID's M&E is aligned with the overall goal and objectives of UNITAID as outlined in this document. Strengthening monitoring and evaluation (M&E) to inform decision making and demonstrate impact is

Box 3: UNITAID defines *monitoring* and *evaluation* in the following manner:

- **Monitoring** is a continuous, systematic process of data collection and information gathering throughout the life of a project. The information collected can be used for regular evaluation of project progress so that adjustment can be made to improve project outcomes;

- **Evaluation** is an assessment of what has taken place during the project's implementation in order to improve the future work of the project, consider new project directions or implement different types of projects.

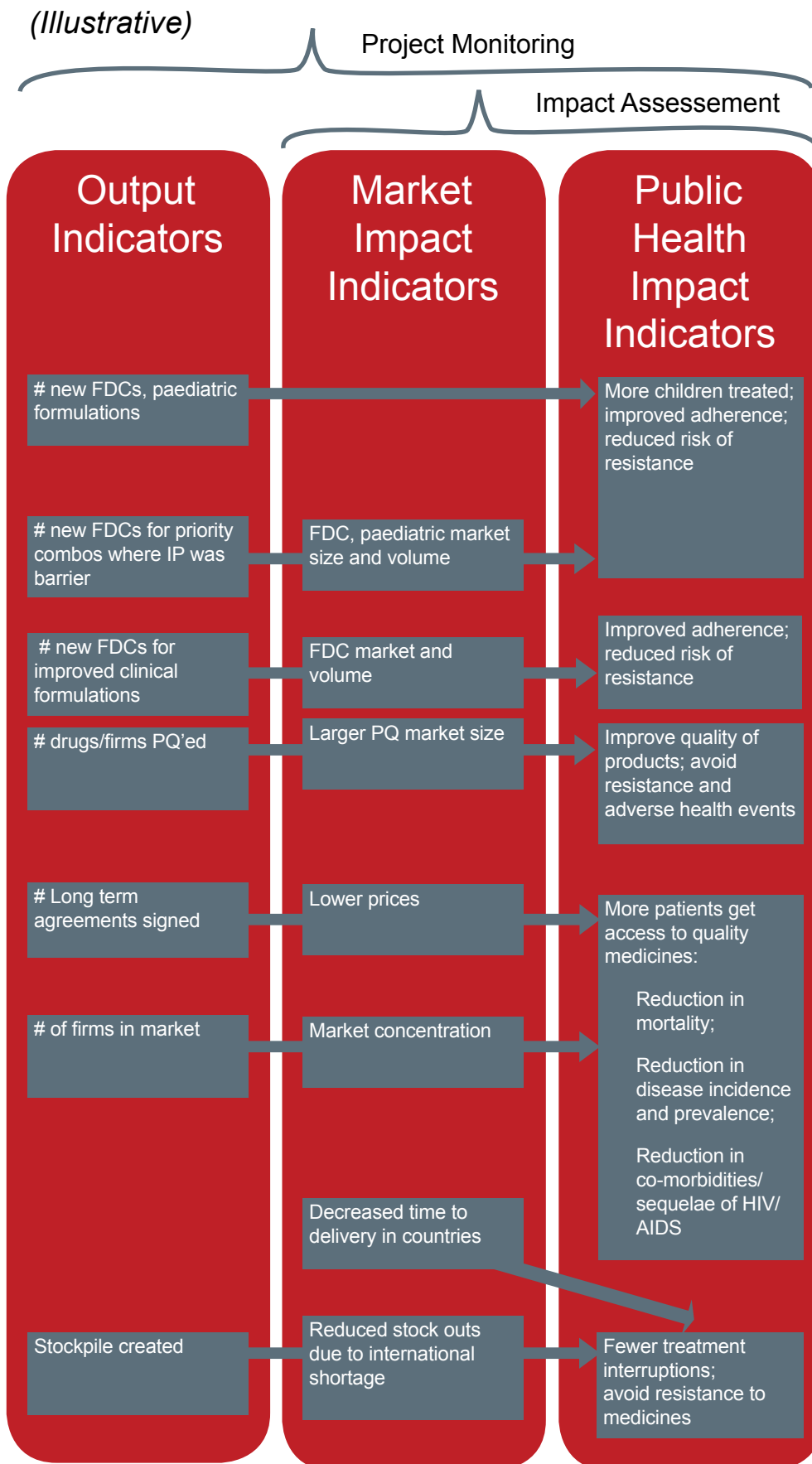
critical to its success. Through M&E, UNITAID aims to promote accountability for its achievements through the assessment of results, effectiveness and performance of its funded projects. M&E are important elements of successful partnerships and UNITAID-funded Partners are more likely to capitalize on their innovative and catalytic role in public health and the market for medicines, diagnostics and preventive products if their results are used to improve project management to achieve common goals and objectives. In this context, M&E processes can help strengthen partnerships and this is a core principle for UNITAID. UNITAID

will ensure that the findings of M&E reports are disseminated widely and that a learning environment is cultivated to build upon project strengths, correct project weaknesses and identify new opportunities.

Measurement of and reporting on, the key performance indicators (KPIs) requires a synthesis of data from a variety of sources. These include Partner progress reports as well as external and internal databases. The results of an analysis of UNITAID's organizational performance will be presented to its Executive Board annually.

An example of how UNITAID aligns its M&E with the data gathered and activities performed by its Partners is shown in Figure 3 (illustrative). This figure shows how information gathered through project monitoring can be used to measure UNITAID's impact on both the market and public health.

Figure 3: Monitoring and Evaluation



M&E addresses three distinct areas:

1. Project monitoring and evaluation;
2. Evaluation of UNITAID's impact in public health and the market for the products it funds; and
3. Evaluation of UNITAID as an organization (through its KPIs).

The processes used for each of these areas are discussed in detail in the sections below.

7.2 Monitoring and Evaluation of Projects

7.2.1 UNITAID uses its Monitoring and Evaluation Toolkit⁹ to guide the collection of relevant project-related monitoring data. A set of monitoring indicators for reporting on individual project-level performance have been developed from the framework used in the M&E toolkit and Partner-produced project plans. The revision of the toolkit will occur in early 2010 to ensure alignment with UNITAID's three year strategy as articulated in this document.

7.2.2 The M&E monitoring indicators developed from the framework provided by the M&E Toolkit are included in UNITAID's legal agreements with its Partners for all funded projects as an M&E annex. The timing and scope of evaluations of UNITAID-funded projects are also included in the legal agreements.



⁹ M&E Toolkit: a collection of questions, forms, checklists and other useful documents that can be used to define indicators to measure the performance and effectiveness of projects.

7.2.3 The Secretariat will monitor Partners on outputs (did grantees do what they said they would?) and evaluate impact (did grantee activities have their projected impact?). The reviews and evaluations are planned in collaboration with Partners, as mentioned above, taking into account the specific disease area, project timeline and Partner restrictions.

UNITAID will avoid, as much as possible, putting additional reporting burdens on beneficiary countries; therefore, UNITAID may join country-level evaluation missions as part of a team with Partners whenever possible.¹⁰

- Outputs: Data will come primarily from Implementing Partner reporting, with ad hoc verification as appropriate.
- Impact: Data will come from external and internal data sources, specifically:
 - For Market impact: Data will come primarily from the market intelligence system and Partner reports, and evaluation will be done by the Secretariat with the help of experts.
 - For Public health impact: Data will come from country reports, Partner reports, international organizations, and other bodies as appropriate. Due to the theoretical and methodological challenges in establishing a robust association or causal link between market impact and public health impact, external experts (e.g. academic institutions or external consultants) may be engaged to carry out this type of evaluation.

7.2.4 As mandated by UNITAID's Constitution, all projects are subject to an independent performance evaluation at the end. Additionally, UNITAID will commission an independent impact assessment, as part of its evaluation of its own impact in public health and the market, for a representative selection of its completed projects.

¹⁰ For a select few countries where it is making the largest funding contribution across a number of partners, UNITAID may carry out country-level evaluations to assess the quality, effectiveness and efficiency of its funded projects.

7.3 Evaluation of UNITAID's impact in public health and the markets

7.3.1 UNITAID has a responsibility to measure its success based on its impact on public health and the markets for medicines and diagnostics to treat HIV/AIDS, TB and malaria. Specifically, UNITAID needs to monitor how markets respond to the provision of additional, secure funding by opening up to more manufacturers of existing and new high quality products, generating sustainable price reductions that are made widely available and ensuring timely delivery of products to countries.

7.3.2 An impact assessment of UNITAID's overall achievements with regard to its mission, goal and objectives will be facilitated by development and use of market intelligence information. The information required should cover:

- The manufacturers that make the medicines/diagnostics/prevention products and their prequalification status;
- The customers who buy these medicines/diagnostics/prevention products;
- The prices paid globally and at the country level for these products;
- The treatment guidelines and registration processes used by countries; and
- Information on new products in the manufacturing pipeline.

Being able to read market conditions and predict market changes with more accuracy will help to achieve a positive impact on the markets for medicines and diagnostics for HIV, TB and malaria. Ultimately, this means that people in low and middle income countries will be able to afford the best possible care and treatment, with the long term result being reduced morbidity and mortality in low and middle income countries from the three diseases.

7.3.3 In addition to information addressed in 7.3.2 there are data sources for the amount of revenue generated by innovator manufacturers and for expenditure on generic products. Taken together, these data can provide a snapshot of a specific product market at a point in time and help UNITAID to track changes to inform new directions and assess the impact of existing interventions. However, UNITAID will need to work with Implementing Partners

to acquire the additional information needed to understand how its funding is impacting both countries and the overall markets which it is trying to improve. Missing pieces of data that will need to be gathered in partnership with others include:

- Specific regimens used in countries;
- Registration status of products in countries;
- Patents on active pharmaceutical ingredients;
- Patents on products;
- Country information on how patent protection is implemented; and
- Country information on whether or how TRIPS flexibilities are employed for some products.



7.4 Key Performance Indicators

7.4.1 Every organization needs to have a standard set of core performance indicators that can be monitored over time to facilitate evidence-based decision making. For UNITAID, the KPIs are used to monitor the performance of the UNITAID Secretariat and its Executive Board. The UNITAID Secretariat reports on KPIs on an annual basis. There are three areas of the UNITAID results framework that will help put the KPIs in context:

- **Area 1:** Performance (overall indicators related to implementation of UNITAID's strategy);
- **Area 2:** Organizational Effectiveness (financial and human resource indicators);
- **Area 3:** Contributions to country outcomes (transparency).

7.4.2 KPIs are set within each of these areas (KPI 2010-2012 see UNITAID web site). An external party should be engaged periodically to evaluate the performance of the Secretariat and the Board with regard to these KPIs. The evaluation should generally indicate the extent to which:

- The Secretariat is implementing Board decisions in a timely, efficient and effective manner that adheres to UNITAID's guiding principles; and
- The Board is setting priorities and providing clear direction for the Secretariat in a manner that adheres to UNITAID's guiding principles and ensures sufficient financial, human, and political resources to achieve UNITAID's mission.

Section 8



Sustaining
Long Term,
Predictable
Financial Flow

Section 8: Sustaining Long-term, Predictable Financial Flows

8.1 Strategic Deployment of Funds

UNITAID strategically deploys funds in time limited interventions that are backed by credible funding commitments to its Implementing Partners, which is necessary for sustained market impact.

8.2 Credible Funding Commitments

For UNITAID to make credible funding commitments to its Implementing Partners a sustainable and predictable funding stream from UNITAID donors is imperative.



8.3 Sustained Market Impact

For UNITAID to successfully develop projects that will achieve sustained market impact, the duration of contributions from donors must be matched with the duration of the funding commitments to Implementing Partners. This will provide the UNITAID Executive Board, Secretariat, Implementing Partners and other key stakeholders with a predictable funding horizon with which to make informed decisions in relation to the funds available to back a project.

8.4 Volume of Funds Available

The total volume of funds available for allocation to projects is an important contributing factor to delivering sustained market impact. Recent indications from stakeholders show that, based on UNITAID's current donor profile, a three year funding horizon of around US\$ 300 million per year is projected.

8.5 Resource Constraints

Despite recent growth in development assistance for health, resources are insufficient to reach internationally agreed targets including the Millennium Development Goals, universal access to HIV/AIDS services, and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. Compounding this problem is the global financial crisis that began in 2008, which has negatively affected both national health budgets and donor contributions.

8.6 Enhancing the Sustainability and Predictability of Contributions

8.6.1 UNITAID will expand the number of low, middle and high income countries that adopt the air tax and/or provide funds to UNITAID in order to diversify its donor base and thereby reduce risk and volatility in funding levels. A contributions policy that would ensure that donor funds match the duration of funding commitments to Implementing Partners is being refined.

8.6.2 The Millennium Foundation¹¹ is working with airline ticketing companies to enable passengers booking tickets online in selected countries to donate two dollars/pounds/euros through a micro voluntary contribution and will provide financing to support UNITAID.

11 The Millennium Foundation: <http://massivegood.org>

8.7 Putting Resources to Work

8.7.1 A key tool for putting the UNITAID strategy into practice is the Budget. The Budget provides a framework by which detailed work plans are linked to the overarching categories identified in the strategy as priorities.

8.7.2 The groupings and sub-groupings used in the Budget form a framework for the allocation of resources and the tracking of performance against those allocations. The categories developed for the allocation of resources and tracking of financial performance must follow the overarching categories identified in the strategy and be interlinked with the Monitoring and Evaluation Strategy.

Section 9



Communication Strategy

Section 9: Communication Strategy

9.1 Sustaining Public and Political Support for UNITAID

The main goal of UNITAID communications is to help achieve UNITAID's mission. UNITAID communications targets multiple audiences, but in particular member countries, government stakeholders and decision makers of existing and prospective members, UN and other international stakeholders and Implementing Partners, and the general public as voters, taxpayers and voluntary contributors. UNITAID communications are closely linked to its resource mobilization efforts, and have adopted the following objectives and strategies:

Objective 1: Increase global knowledge and understanding and accountability of UNITAID.

Strategies: Develop messages, identity branding and communication products that define and reflect UNITAID's activities, contribution and specificity in the global health landscape; increase visibility and transparency of UNITAID's actions, progress and achievements. UNITAID will ensure that it will uphold the transparency policy through all its activities.

Objective 2: Consolidate and increase existing members' support.

Strategies: Increase understanding in contributing countries of their important role in and contribution to achieved results (e.g. 'Thank you' campaign to raise awareness of UNITAID's work and promote a 'sense of achievement' in those constituencies).

Objective 3: Maximize Voluntary Solidarity Contribution.

Strategies: Develop joint communication strategy with Millennium Foundation.

Objective 4: Advocate for new countries to join UNITAID, introduce the air tax and expand the financial base.

Strategies: Increase visibility through media outreach and other communication activities in target countries; widen perception of the urgent need for action; conduct direct government advocacy in target countries.

Objective 5: Foster good working relations with Implementing Partners and position UNITAID in their communication activities.

Strategies: Improve understanding among Implementing Partners of UNITAID's unique contribution to their efforts; foster a sense of shared purpose towards the goals of achieving access among UNITAID's Partners; increase UNITAID participation and visibility in Partners' international events and communication products.

Section 10



Future Developments: Challenges and Opportunities

Section 10: Future Developments: Challenges and Opportunities

In order to remain an innovative, forward-looking and complementary actor in the global health landscape, UNITAID's strategy will evolve to adapt to changing challenges and opportunities, while continuing to be guided by its mission and guiding principles. UNITAID will take pro-active measures to prevent future access barriers, where appropriate. Through partnerships and networks, UNITAID will monitor new developments in the following areas:

10.1 Products

UNITAID will follow markets to ensure that it can assess and rapidly respond to the need for new products needs. UNITAID will consider supporting new products that meet its project selection criteria. In assessing the public health value of new products, UNITAID will consult WHO expertise and guidelines. For example, new ARVs that may offer improved safety and adherence profiles may soon become available in high-income markets; UNITAID will consult with WHO regarding the potential utility of these products in low and middle income countries.

10.2 Guidelines

UNITAID will collaborate with WHO to remain fully informed of the evolution of guidelines, such as treatment protocols (e.g. paediatric TB), in order to overcome access barriers for recommended products as quickly as possible. In addition, UNITAID may identify priority products that could be included in guidelines if their cost was substantially reduced. However, UNITAID does not fund guidelines development directly.

10.3 Players and/or Activities

UNITAID will be mindful of changes in the global health landscape, such as new players or new activities of existing players, to ensure that its contributions remain unique, additional and complementary.

10.4 Access Barriers

UNITAID will watch for and identify potential access barriers (e.g. widespread patents on new medicines, raw materials supply shortages) to take preemptive action to avert access crises, where appropriate.

10.5 Health issues

UNITAID will monitor emerging health issues (e.g. Extensively Drug Resistant [XDR-TB]) in order to be able to respond as quickly as possible to new needs, as appropriate.

Section 11



Annexes

Section 11: Annexes

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Annex 1: Potential Market Shortcomings and Symptoms

Potential market shortcomings could include:

- Inadequate market structure (various inappropriate asymmetries between number of buyers and suppliers):
 - Monopoly/Oligopoly that may fuel financial barriers for access and/or barriers for innovation and appropriate R&D: (only one or a small number of suppliers) which may be due to intellectual property rights (IPR).
 - Monopsony/ Oligopsony: only one or very few buyers may drive prices too low to be guarantee a sustainable and quality supply.
 - High concentration of the API market
- Information asymmetries: about costs (e.g. the fact that buyers do not know true costs of suppliers) and/or quality of products.
- Inappropriate regulation at international level or in significant targeted geographic areas.
- Barriers to market entry: reduces number of suppliers and competition.
- Inappropriate supply chains and delivery channels that may limit access for consumers at the point of delivery (logistic and/or financial barriers).
- Barriers to market entry: reduces suppliers and competition.

Potential symptoms of these market shortcomings include:

- High product prices due to insufficient or no competition.
- Large differences between source prices and consumer prices (e.g. because of intermediaries).
- High product prices due to collusion between suppliers.
- Predation behaviours that deter new entrants and eliminate or reduce competition.
- Insufficient supply due to low number of producers.
- Long delivery lead times due to low number of producers (or other factors).
- Frequency of stock outs.
- Low or no availability of quality assured products.

Annex 2: Needs Assessment and UNITAID's Strategic Responses to Market Shortcomings for HIV/AIDS, TB and Malaria

a. Developed Strategic Responses

Some market shortcomings are common across the three disease areas, while others are more specific. Based on both a transversal and disease-specific needs assessment, UNITAID has made strategic responses to overcoming market failures. The transversal and disease-specific strategies are mutually reinforcing: for example, among other benefits, quality assurance supports competitive markets for malaria medicines; and a patent pool will support well-adapted formulations for HIV/AIDS medicines. In addition, the drivers of, and tools to, influence a product market are complex, interconnected and interdependent. Therefore, UNITAID takes a multi-pronged, integrated and coordinated approach to implementing its transversal and disease-specific strategies.

b. Transversal Market Shortcomings: Needs Assessment and Strategic Response

Some market failures cut across multiple diseases and products, and perhaps can most efficiently be addressed through transversal action.

- i. **Lack of Quality Assurance:** information on quality of health products is often lacking.

UNITAID response ► UNITAID supports the WHO Pre-qualification Programme to carry out multiple activities that strengthen quality assurance processes at national and global levels. UNITAID supports WHO activities to examine pre-qualification applications; provide training to national regulators and quality control personnel (including capacity-building of medicine quality control laboratories); provide technical support to select manufacturers; and set global norms and standards for pre-qualification. WHO Pre-qualification can offer efficiency gains and positive externalities by providing useful information for all countries interested in purchasing from participating producers, not only recipients of donor-funded purchases.

- ii Low availability of co-formulated or co-packaged products:** FDCs offer important public health benefits, including: facilitating patient adherence, reducing the risk of resistance, and simplifying supply.^{12, 13, 14} Comprehensive packaging of diagnostics with equipment, consumables and maintenance is also rarely available in developing countries. In all three disease areas, there are problems securing the availability of FDCs at appropriate dosages, from a sufficient number of quality assured suppliers, at an affordable price.

UNITAID response ► Advance purchase commitments for priority FDCs; funding to develop co-packaging of products for preventing mother-to-child HIV transmission; subsidy for artemisinin-combination therapy with strong encouragement to fund FDCs.

- iii. Pharmaceutical patent barriers:** Granting of pharmaceutical patents in key drug producing countries, such as India, and in many importing low and middle income countries, will create multiple challenges for building competitive markets. First, patents in producing countries may lead to monopolies and the high prices usually associated with them; voluntary price reductions by single-source suppliers have proven far less effective than robust generic competition in reducing prices.¹⁵ Stability of supply is also easier to guarantee with multiple producers, yet patents can hamper market diversification. Second, patents in importing countries will fragment the global market. This can undermine order pooling, increase transaction costs, and limit economies of scale. Third, multiple patents and the failure to license increase the transaction costs of developing FDCs, especially when a separate company owns the patent on each drug in the combination. In addition, production of paediatric formulations may be blocked unless licenses are granted on patented medicines.

UNITAID response ► Patent Pool: The UNITAID Board has supported the principle of establishing a patent pool (UNITAID/EB8/2008/R9), and an implementation plan is in development. The pool's purpose

12 Connor J, Rafter N, Rodgers A (2004) Do fixed-dose combination pills or unit-of-use packaging improve adherence? A systematic review. *Bull World Health Organ* 82: 935–939.

13 Moulding T, Dutt AK, Reichman LB (1995) Fixed-dose combinations of antituberculous medications to prevent drug resistance. *Ann Intern Med* 122: 951–954.

14 Laurent C, Kouanfack C, Koulla-Shiro S, Nkoué N, Bourgeois A, et al. (2004) Effectiveness and safety of a generic fixed-dose combination of nevirapine, stavudine, and lamivudine in HIV-1-infected adults in Cameroon: Open-label multicentre trial. *Lancet* 364: 29–34.

15 Brenda Waning, Warren Kaplan, Alexis C King, Danielle A Lawrence, Hubert G Leufkens and Matthew P Fox. (2009) Global strategies to reduce the price of antiretroviral medicines: evidence from transactional databases. *Bulletin of the World Health Organization* 2009; 87:520-528. doi: 10.2471/BLT.08.058925

will be to reduce barriers to competition, stimulate the development of FDCs and paediatric formulations, and accelerate the availability of medicines. UNITAID will leverage the pool in conjunction with other policy tools, such as guaranteeing a market for the priority FDCs emerging from the pool.

Product safety and efficacy: Many of the products that UNITAID supports are new, and many are for indications, or in populations, that were excluded in clinical trials. For example, drug safety in pregnancy is a major area and limits the use of many medicines. Yet pharmacovigilance systems in many low and middle income countries are under-resourced and/or poorly developed. The global health community has, arguably, both an ethical responsibility and an unprecedented opportunity to support countries in their efforts to collect data to understand better the use, efficacy and safety of these new medicines in the intended populations and special groups for the three diseases.

Area for potential UNITAID action ► To be determined¹⁶

c. Disease-Specific Market Shortcomings: Needs Assessment and Strategic Response

Market dynamics fundamentally differ across the target disease and product areas. Product markets may differ in size, factors driving supply and demand (e.g. price elasticities, availability of substitutes), cost and complexity of production, maturity of the market, severity of information asymmetries, quality issues, degree of competition and barriers to entry, scope and strength of patent monopolies, cost of R&D, potential impact on health outcomes, and scale and urgency of public health need. Therefore, UNITAID's strategies are specific to each product's market niche. Each of the following sections outlines the results of a needs assessment (based on expert consultations), summary of current UNITAID investments, and directions for future action, and is divided by product category (treatment, diagnosis, and prevention products,).

i. HIV/AIDS

a. Needs assessment:

Treatment

- Children: Lack of quality assured paediatric ARVs, especially FDCs.

¹⁶ Inter alia, potential future supported actions could include: verifying treatment efficacy, strengthening post-marketing surveillance, monitoring changes in drug efficacy, side effects and adverse events, and risk-benefit analysis in specific populations.

- First line ARVs: High prices of new, more effective and less toxic first line ARV regimens (e.g. tenofovir based regimens).
- Second line ARVs: High prices and lack of FDCs; patents applied for and/or granted in generics producing countries, severely restricting supply and competition.

Diagnosis: Effective treatment is undermined by a lack of capacity to diagnose and monitor patients. Key diagnostic and monitoring tools such as viral load and DNA PCR are not widely available in all countries. Viral load tests are poorly adapted for large scale use and particularly expensive for low-income countries.

Other health products: other products that are important to ensure effective HIV/AIDS treatment and care, but for which access remains problematic, include:

- Ready to use therapeutic foods (RUTF): malnutrition, particularly among children, undermines the effectiveness of ARV therapy. RUTF can quickly and dramatically improve nutrition and thus enhance treatment outcomes, but is often unavailable and/or costly.
- Treatments for opportunistic infections (OIs): some key products to prevent or treat OIs are not widely available in many countries or are unaffordable. Specific challenges for access to products related to TB, the most prevalent opportunistic infection of HIV, are outlined in the next section (See Section 5.c.ii. Tuberculosis), including those specific to HIV/TB co-infection.

Prevention: Areas in which health products can support prevention and where UNITAID may therefore play a role, include:

- Lack of combined product packaging for prevention of mother-to-child transmission (PMTCT), which requires a number of health products, including ARVs, anti-OI drugs, RUTF and diagnostic/monitoring tests;
- High price of female condoms, which is almost the only tool for women to protect themselves from HIV transmission. Currently, there are only two producers of female condoms; and female condoms are significantly more expensive than male condoms.

b. Current UNITAID projects: UNITAID's strategy responds directly to this needs assessment:

- Paediatric ARV treatment (Implementing Partner: Clinton Foundation HIV/AIDS Initiative [CHAI]): UNITAID provides a guaranteed market for paediatric pre-qualified Fixed Dose Combination (FDC) ARVs, and purchases these medicines for children in 39 countries. This funding has facilitated the introduction of triple paediatric FDCs and reduced the average price of leading paediatric regimens by 64%. The funding of diagnostics and key non-ARV health products (anti-OI medicines, diagnostics and RUTF) to support the treatment of children is also making an impact in those markets.
- Second line ARVs (Implementing Partner: CHAI): UNITAID supports volume purchasing, price negotiations, and competition among an increased number of pre-qualified suppliers in order to achieve price reductions, which has thus far reduced prices by up to 43% on leading 2nd line regimens. The objective is to reduce the cost of the most commonly used 2nd line regimen to as low as \$500 per patient per year by 2011. By purchasing large quantities of tenofovir, UNITAID has also reduced the price and increased access to quality 1st line ARV regimens, as tenofovir is now part of both WHO's recommended 1st and 2nd line regimens. UNITAID provided short-term bridge funding for tenofovir-based 1st line treatments for three countries (Namibia, Uganda and Zambia) while they sought funding from other donors.
- PMTCT (Implementing Partners: United Nations Children's Fund [UNICEF] and WHO): UNITAID funds the procurement and delivery of HIV/AIDS medicines, diagnostics and related PMTCT health products, including more efficacious ARV combination regimens to recipients in eight target countries and will be rolled out to a further nine countries. The project aims to accelerate scale-up of PMTCT services and strengthen the link with paediatric HIV care to ensure infected children are promptly diagnosed and treated. UNITAID is also investigating the possibility of combining key products into standardized PMTCT 'bundles'.

c. Areas of potential future contribution UNITAID will support additional projects that fulfil its project selection criteria. Potential future projects are listed here for illustrative purposes only:

Treatment:

- Supporting the adoption of newer, safer, more efficacious and acceptable first-line regimens.
- Ongoing development of paediatric and infant formulations, including FDCs.
- New classes of ARVs, such as raltegravir (integrase inhibitor) and enfuvirtide (fusion inhibitor), are now available in high-income countries but very expensive. Further analysis is required to evaluate needs and opportunities for increased access and identify strategic options for UNITAID; nevertheless, these products merit ongoing monitoring by UNITAID.

Diagnosis:

- Viral load: Increase availability and adaptability of viral load services for HIV/AIDS patients and reducing the price of associated equipment and products (see UNITAID/EB10/2009/R14);
- Point-of-care diagnostics: Creating a market for improved tests through purchase commitments, especially for children (e.g. oral rapid tests), to scale up availability, accelerate delivery, reduce prices and improve quality of treatment.

Other health products (including for co-morbidities (UNITAID/EB9/2008/R1)):

- TB medicines: Rifabutin is a highly effective tuberculostatic when treating HIV/TB co-infection while using a protease inhibitor (usually included in a 2nd line ARV regimen), However, it is not widely used in most developing countries because of its high price. UNITAID could apply its price reduction techniques to improve access to rifabutin in developing countries.
- RUTF: Supporting sustainable local production to increase the availability and quality of RUTF.
- Anti-OI drugs: Investigate targeted action to ensure sustainable, affordable and quality-assured supply of medicines to prevent or treat OIs (e.g. combination of isoniazid and cotrimoxazole as

chemo-prophylaxis, medicines for cytomegalovirus infection, certain quinolones).

Prevention:

Accelerating implementation of comprehensive PMTCT services and including better formulated treatments (for example, triple FDCs); PMTCT will be supported via UNITAID's product based, global market leverage.

Microbicides are currently under development and may become an effective means to prevent HIV transmission. This is an emerging area of interest. However, no effective microbicide has been developed to date. Therefore they may be an area in the future when developed.

- Female condoms.

ii. Tuberculosis

a. Needs assessment:

Treatment:

- First line medicines: stock-outs at country level remain frequent and quality assurance/information is often lacking.
- Children: there is a lack of quality-assured FDCs formulated for children under 15 and easy-to-use formulations for children under 4.
- Multi drug resistant tuberculosis (MDR-TB)¹⁷ medicines: The cost of drugs to treat MDR-TB remains very high, in part due to small volumes which in turn are directly linked to problems with diagnosis.
- XDR-TB¹⁸: No 'good' treatment. XDR-TB is extremely difficult to treat, has very high mortality rates, and has been reported in 45 countries.¹⁹

Diagnosis:

- First line TB: Sputum smear microscopy is the most widely used technology, but only detects about half of TB cases and

17 WHO defines MDR-TB as TB resistant to at least the two main first line drugs, isoniazid and rifampicin.

18 WHO defines extensive drug resistant (XDR) TB as TB that is resistant to three or more of the six existing classes of second-line TB drugs.

19 World Health Organization (WHO) /International Union Against Tuberculosis and Lung Disease (WHO/UNION) Global Project on Anti-Tuberculosis Drug Resistance Surveillance. (2008) Anti-tuberculosis drug resistance in the world. Report No.4. Geneva: WHO. Available: http://www.who.int/tb/publications/mdr_surveillance/en/index.html

an even smaller proportion among children or TB/HIV co-infected patients. LED microscopes are more accurate and can be used to diagnose larger numbers of patients, but are expensive. Point-of-care rapid diagnostic tests, including those that detect TB in HIV positive patients, are urgently needed and currently under development, but not yet available.

- MDR- and XDR-TB: As noted above, current diagnostic technology is a major bottleneck to treatment. Diagnosing either MDR- or XDR-TB requires drug sensitivity testing (DST) to determine which medicines might still be effective against the disease. However, DST is costly, lengthy, and technically complex, and is therefore often only available in capital cities or regional reference laboratories. Diagnosis can take several months, delaying treatment and allowing the disease to spread further. Newer, faster diagnostic methods, such as molecular line probe assays (LPA), have the potential to deliver results within 48 hours, but require upgraded laboratory capacity.

Other health products: No major other products for TB.

Prevention: No major products for TB prevention.

b. Current UNITAID projects: UNITAID's strategy responds directly to this needs assessment:

- First line TB medicines (Implementing Partner Global Drug Facility (GDF)) UNITAID supports the establishment and operations of a Strategic Rotating Stockpile of first line TB medicines to minimize the risk of stock-outs, which can interrupt treatment and thereby increase the risk of resistance. Since the project was launched, GDF has already achieved its short-term cost containment objectives and the introduction of a total of seven (out of the 16) pre-qualified medicines.
- Paediatric TB medicines (Implementing Partner GDF): UNITAID aims to foster the creation of a market for appropriate-strength medicines for children under 15 by the end of 2011. To date, three paediatric TB medicines have been pre-qualified.
- MDR-TB (Implementing Partners: Global Laboratory Initiative (GLI), GDF, Foundation for Innovative New Diagnostics (FIND),

Global Fund): UNITAID is working with several Partners to link diagnostics and treatment:

- UNITAID is supporting the expansion and accelerated access to rapid MDR-TB diagnostics for patients at risk in high burden countries. This state of the art technology will result in diagnosis in two days rather than the standard 2-3 months.
- UNITAID aims to scale-up the number of patients receiving second-line TB treatment, decrease delivery time of medicines and prevent stock-outs. The longer term objective is to achieve price reductions (5-25%) on second line treatments by 2011.
- Through its contribution to Global Fund Round 6, UNITAID is providing access to quality assured MDR-TB treatments in 17 recipient countries.

c. Areas of potential future contribution UNITAID will support additional projects that fulfil its project selection criteria (see Section 5) Potential future projects are listed here for illustrative purposes only.

Treatment:

- Explore options to help stabilize the market for key MDR-TB drug APIs; (UNITAID/EB7/2008/R1).
- Reduce the medicine delivery lead times for access to MDR-TB medicines (UNITAID/EB7/2008/R1).
- Foster the development of a 'fast track' process to rapidly prequalify new and low volume TB products (e.g. through UNITAID support for WHO prequalification program).
- Support access to new medicines that could improve 1st line and MDR treatment.
- Support access to new medicines for treating XDR-TB.

Diagnosis:

- Increase access to LED microscopes to improve quality of diagnosis for 1st line TB.
- Support access to new rapid diagnostic tools for detecting MDR and XDR-TB (products currently in clinical trials; potential to launch in 2009-2011).

iii. Malaria

a. Needs assessment:

Treatment:

- Artemisinin combination therapy (ACTs): There is a lack of pre-qualified ACT FDC producers. ACTs have a relatively short shelf life; long lead times are required to ramp up production due to seasonal planting schedules and consequent risk for farmers, as well as inaccurate demand forecasts. Collectively, these have led to frequent demand imbalances (both excess stock being wasted and stock outs). In addition, ACTs cost more than older, ineffective products.

Diagnosis:

- Most patients are diagnosed with malaria based on clinical symptoms. Point-of-care diagnostic tools exist, including microscopy and rapid diagnostic tests (RDTs). However, microscopy is often unavailable and requires well-trained technicians, while RDTs are of uncertain quality (there is currently no system to prequalify them other than ISO certification based on Good Manufacturing Practice (GMP) criteria). A recently-launched joint project of WHO, FIND, Special Programme for Research and Training in Tropical Diseases (TDR) and United States (US) Centers for Disease Control and Prevention (CDC) is conducting product testing of malaria RDTs to assess the performance of products on the market in detecting malaria parasite at different parasite densities. A full pre-qualification system for malaria RDTs is not yet established.²⁰ WHO estimates that up to 50% of people who receive treatment do not have malaria. The spread of drug resistance, including the first confirmed reports of resistance to artemisinin,²¹ and the relatively higher cost of ACTs, makes accurate diagnosis an urgent priority.

20 WHO/TDR/FIND. (2009) Malaria Rapid Diagnostic Test Performance: Results of WHO Product Testing of Malaria RDTs: Round 1 (2008) Available: <http://www.wpro.who.int/NR/rdonlyres/ED81-BDE9-B812-4B80-8408-3A129A6365C4/0/OMSFINDRapportMalaria200900514v25.pdf>

21 Noedi H, Se Y, Schaecher K, Smith BL, Socheat D, et al. (2008) Evidence of artemisinin-resistant malaria in Western Cambodia. *N Engl J Med* 359: 2619-2620.

Other health products: None.

Prevention:

- Long lasting insecticide treated bed-nets (LLINs): Delays in fund disbursement and procurement has significantly limited the delivery and distribution of LLINs in some countries. There is also uncertainty about the quality of many nets.
- Indoor residual spraying (IRS): Mosquito sprays and indoor residual spraying is a relatively expensive intervention and some products are beginning to lose their efficacy. While there may be potential to reduce the price of existing products, there is also a key need to accelerate the development and production of new, more efficacious formulations and application equipment.
- Prevention of Mother to Child Transmission (Intermittent preventive treatment (IPT)): There is growing resistance to Sulfadoxine-Pyrimethamine, the primary drug used for IPT. It is currently unclear what the WHO will recommend to address this.

b. Current UNITAID projects: UNITAID's strategy responds directly to this needs assessment:

- ACT Scale-up (Implementing Partners: UNICEF and the Global Fund): UNITAID supports pre-qualification and large volume purchasing of ACTs in order to help stabilize and spur competition within the ACT market. The UNITAID Board has also committed a ceiling of US\$ 9.28 million over 2 years to a revolving Artemisinin Pre-finance Facility for artemisinin raw material extractors, with the aim of increasing artemisinin supply to meet projected increases in ACT needs in 2010/2011.
- LLIN Scale-up (Implementing Partner: UNICEF): UNITAID is funding the provision of 20 million nets from 2008-10 to accelerate access to LLINs. This is designed both to improve LLIN availability and to maintain the short term sustainability of the market given the short-term funding gap identified above. Without UNITAID intervention, there was a risk that manufacturers might scale down production in 2008, which could have resulted in major supply shortages as the global community has committed to purchase a significant increase in bed nets from 2009. By

stabilizing the market, UNITAID aims to ensure long term supply security, and to help contain or reduce prices.

- Affordable Medicines Facility – malaria (AMFm): UNITAID is committing up to US\$ 130 million to help reduce the price of ACTs through a producer level subsidy, which will be available to both public and private sector distribution networks. The AMFm is also intended to improve delivery by helping to develop more robust demand forecasts.

c. Areas of potential future contribution UNITAID will support additional projects that fulfil its project selection criteria (see Section 5). Potential future projects are listed here for illustrative purposes only.

Treatment:

- Funding new ACTs to scale-up availability and reduce prices.
- A pipeline of ACT products is in development through the Medicines for Malaria Venture (MMV). Dihydroartemisinin-piperaquine has been submitted for registration in July 2009, and pyronaridine-artesunate is to be submitted for registration in mid-2009. UNITAID could consider supporting these products if they are registered.

Diagnosis:

- Support existing quality assurance services for RDTs; incentivize development of improved RDTs. (UNITAID/EB8/2008/R4).

Other health products: None

Prevention:

- IRS: Lowering the price of insecticides for indoor residual spraying, and improving their effectiveness by supporting the accelerated development of new products, including by exploring options like advance purchase commitments, contract R&D (open source technologies), prize funds, and contract manufacturing.

Annex 3: Existing Projects: Positive Externalities and UNITAID Market Interventions

(non-exhaustive list of externalities, provided for illustrative purposes)

Project	Positive Externalities (Benefits to Countries and Global Health Community)	UNITAID Market Interventions
1. Second line ARV	Price reductions Quality assurance	Product procurement Support to WHO PQ
2. Pediatric ARV	Price reductions Adapted formulations FDC Quality assurance	Product procurement Support to WHO PQ
3. PMTCT	Paediatric ARV quality assurance Price reductions Development of Mother-and-Baby pack	Support to WHO PQ Product procurement
4. Pediatric TB	Paediatric TB meds quality assurance Extended shelf life for medicines Added ETH 100mg to GDF catalogue Formulations for children <4yrs	Support to WHO PQ Product procurement
5. 1st line TB	TB medicines quality assurance Strategic Rotating Stockpile (risk pooling for all countries)	Support to WHO PQ Transitional country grants to prevent stock-out.
6. MDR-TB Scale up	Strategic Rotating Stockpile (risk pooling for all countries) Address global product shortage	Support stockpile creation Product procurement
7. MDR-TB Diagnostics	Price reductions Stimulate increased number of producers	Product procurement
8. ACT scale up	Quality assurance	Support to WHO PQ Product procurement
9. Full format LLIN	Stabilize global LLIN market to avert shortages Price reduction	Product procurement
10. WHO Pre qualification	Verify the quality of products Set technical norms and standards Increase capacity of producers to control quality	Support to WHO PQ
11. GF Round 6	(linked to 2nd line and pediatric ARVs, see above)	Product purchase
12. Patent pool	FDCs Adapted formulations Price reductions	Support new mechanism to help overcome patent barriers to adapted formulations and affordable prices.
13. AMFm	Price reduction Stabilize supply Reduce global risk of resistance	Subsidize prices at wholesaler or manufacturer level.

Annex 4: Challenges in Effecting and Measuring Market Impact

Market impact for UNITAID

This section provides an overview of the meaning of market impact. It is the basis for continued work on refining and prioritizing criteria (price, availability, quality, number of manufactures and delivery) for market impact.

Markets for medicines and diagnostics in low resource settings have undergone growth and evolution over the past 10 years, largely due to unprecedented financial investments by international donors. The resulting markets are dynamic, requiring continuous monitoring and strategic planning to address the ever changing market conditions.

Market definition and complexity

Market chains for medicines, diagnostics and prevention products are long and complex. For medicines, the market begins with R&D to identify new active principle ingredients and ends with consumers who eventually take the medicine for a particular condition. In between the R&D and the end user, however, there are numerous steps that involve API producers and distributors, intermediary producers and distributors, pharmaceutical manufacturers that produce the final pharmaceutical product, organizations that package the final product, wholesale distributors, and finally retail outlets, drug sellers and facilities that provide consumers with the final product. A given product will not only travel along the many steps of the market chain, but will also travel across many different companies at various steps in the market chain.

Demand and supply side drivers of market

Markets for medicines, diagnostics and prevention products are reactive to drivers that determine the supply and demand side characteristics of the market. Both the supply and demand sides of these markets have changed dramatically over the past several years.

On the supply side, for example, we have witnessed a dramatic shift in global market share of ARVs from large multinational producers to Indian-based generic producers. Other clear supply side shifts include mergers and acquisitions, as well as license-sharing arrangements across multiple pharmaceutical manufacturers. Today, there is clear movement among some Indian-based generic manufacturers to work more upstream in the development

and production of APIs rather than purchasing the API from a supplier and producing the final pharmaceutical product. Vertical integration, whereby producers also play the role of distributors and retailers, is becoming more common in medicines. These changing roles of pharmaceutical producers, therefore, cause a responsive shift in business models for wholesalers and distributors who previously competed only among themselves but now find themselves in direct competition with producers. Business arrangements between large donors and international procurement agencies for purchase, distribution and storage of medicines in countries receiving donor aid are now being made. In addition to these constant shifts at the producer and distributor levels, patents and other intellectual property issues present themselves daily and limit the number of producers that can provide supplies of medicines and diagnostics. Most notable, perhaps, are patent and implications that result in virtually no supply of fixed dose combination ARVs needed today, whereby the supply of ARVs in FDC for previously used HIV/AIDS regimens was widely available.

The demand side of medicines and diagnostic markets also exhibits constant flux. In HIV/AIDS, the demand for ARVs is currently changing from 1st generation ARVs recommended by the World Health Organization (WHO) in 2002 to newer 2nd generation 1st line ARVs more recently recommended by WHO in 2006. The introduction of the Affordable Medicines Facility for Malaria (AMFm) will, hopefully, result in demand shifts towards increased consumption of artemisinin-combination therapies (ACTs) for the treatment of malaria. Again, patents and intellectual property issues present an ever-changing landscape around demand for various medicines, diagnostics and prevention products at country level.

Market niches and segmentation

Pharmaceutical and diagnostic markets are intentionally segmented into niche markets such that each product exists in a market with its own unique characteristics and drivers. Therefore, one must have product-specific market intelligence to guide decision making. For example, a segmented market for ACTs where the majority supply of anti-malaria medicines is currently provided by the private sector and demand driven by consumers will require different interventions from a segmented market for paediatric ARVs where supply is almost entirely provided through the public sector and demand is largely influenced by health care providers and national guidelines.

Product life cycles

Market interventions must also take into account each product's unique life cycle which consists of four phases, namely: market introduction, growth, maturation, and decline.

For example, the life cycle for stavudine 40mg is clearly nearing its end, with use declining sharply after WHO decreased dosing recommendations from 40 mg to 30 mg. Fixed dose combinations of stavudine/nevirapine/lamivudine have matured and are just beginning to decline, being replaced with tenofovir and other 2nd generation first line ARVs that are just entering in a growth stage.

Price elasticity

Each product differs with regards to price elasticity of demand. Some products exhibit no elasticity whereby consumers will pay virtually any price for the product, whereas other products exhibit high elasticity with consumers' willingness to pay falling within a very narrow range of prices. For products such as ACTs, intelligence on price sensitivity is critical to the development and monitoring of subsidies and other access interventions.

Each product exhibits unique price elasticity of supply, whereby price changes for some products result in large (elastic) changes in supply and other products exhibit no effect (inelastic) on supply.

Annex 5: Proposed Framework for UNITAID Proposal Guidelines

Part 1: The Problem

A. Describe the specific public health problem that the project wants to address. According to each specific project, this should include:

- Description of the issue in terms of morbidity and mortality (in the relevant geographic areas).
- Size of the affected population (or, where relevant, sub group of the population e.g. pregnant women, children).
- Urgency of the public health problem.
- Coverage of the population that the proposal is intending to reach.
- Potential evolution of the problem with and without the proposed intervention(s).
- Description of the problem in terms of quality, efficacy and safety of preventive and/or therapeutic and/or care interventions considered, and the potential impact in terms of increasing the quality, efficacy, cost-effectiveness, tolerance, acceptability of these interventions (e.g. drug regimens or other health products), including (if appropriate) reduction of the risks of pharmaco-resistance, adverse reactions or misuse by prescribing health professionals or patients.

B. Identify the market shortcomings that contribute to the public health problem (including market absence, failures, dysfunction, and/or the symptoms associated with them). (*See Annex 1 for examples*)

Note: Projects do not need to address simultaneously all market shortcomings that affect a particular public health issue, but the proponent should detail the type of market shortcomings to be addressed in the project.

Part 2. Project Proposal

C. Describe the proposed market intervention:

- How will your proposal achieve its intended market impact (e.g. increase competition to generate price reductions)?
- What are the goal, objectives and activities of the project proposal and how are these aligned with UNITAID's goal?

D. Describe the expected market impact:

- What kind of market impact will your proposal achieve (e.g. reduction in prices, improvement in supply, improvement in quality)?
- What are its scale, scope, and duration (e.g. reduce prices for drug X by 15% for three years)?

Note: Applicants are required to provide quantitative targets. In some cases, the proposal should discuss and clarify potential trade-offs between these objectives (price reduction, improved supply and quality assurance). In some cases, stabilization rather than reduction in price may be needed to increase opportunities for new suppliers entering the market, etc.

E. Project the public health impact: the proposal should provide a rationale for how the market intervention will yield the public health impact.

Potential public health impacts could include:

- Increased coverage.
- More equitable access.
- Increased access to improved technology.
- Increased adherence.
- Reduced risk of resistance.
- Reduced frequency of adverse events.
- Number of life-years, DALYs/QALYs potentially saved, (if relevant or feasible).
- Improvement of the cost-effectiveness ratio of public health intervention (if relevant or feasible).

Part 3: Relevance for UNITAID

- Why should the project be funded or co-funded by UNITAID (rather than other funders)?
- How does it fit within UNITAID's goal, objectives and broader strategy?
- How is it aligned with UNITAID's principles (additionality, complementarity, etc, see Figure 1 p 25)?

Part 4:

- Budget and Budget Narrative.
- Timeline.
- Monitoring and Evaluation Plan.
- Risks and Risk Mitigation.
- Transition Strategy.



The purpose of the UNITAID Strategy is to guide the Board and the Secretariat, and to communicate to Partners and Stakeholders the overall direction of the initiative for 2010-2012; to set broad guidelines for funding decisions and project management; and to outline UNITAID's approach to monitoring, evaluating and learning from its projects. The ultimate objective of the Strategy is for UNITAID to achieve its mission.

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