UNITAID

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September 2012

UNITAID support for prequalification of medicines

WHO Prequalification

Since 2007 UNITAID support to WHO PQ programme: **US$ 53M**

Objective: to increase the number of prequalified UNITAID priority medicines for HIV/AIDS, TB and malaria and:

1) increasing capacity in production
2) facilitating the development of national regulatory processes
3) Accelerating testing

Achievements

- ❑ 57 products prequalified since 2007 (20 in 2011): 35 for HIV; 14 for TB and 8 ACTs
- ❑ 8 APIs prequalified
- ❑ 90 manufacturing sites, contract research organizations and QCLs inspected
- ❑ Training for approximately 400 regulatory participants, more than 100 QCL participants and over 900 manufacturing company participants

Challenges

- Still too many formulations on current invitations to manufacturers to submit EOIs for which no or too few products have been prequalified.
- Need for acceleration of API prequalification .

UNITAID
Positioning and Strategy

UNITAID Portfolio *(illustrative June 2011)*

R&D	IP Issues	Market Entry	Quality	Availa-bility	Price	Operational Research in country	Delivery	Country Intervention
-	+	+	++	++	++	+/-	+	-

Value Chain

Initiate

- MPP HIV
- PQ C
- RDT M
- CD4/VL HIV
- CD4/VL HIV
- PQ Cross cutting

Create

- Peds TB
- MDR TB TB
- A2S2 M
- 1 line TB
- SRS TB
- Esther HIV
- Expandx TB
- RDT PSI M
- AMFM Malaria
- PMTCT HIV
- Round 6 Cross cutting
- Second line ARV HIV
- ACT Scale up Malaria
- LLIN Malaria
- Pediatric ARVs HIV

Fix

Deliver

Commodity Birth Line

- Diagnostics
- Treatments
- Prevention
- Support

Key area for UNITAID investment
Aspirational Goals 2013-2016

Illustrative

HIV

- Affordable one-pill-a-day treatment without serious side effects that can be started early after diagnosis and keeps viral load of all patients, regardless of drug resistance, to non-detectable levels and contributes to prevent mother to child transmission
- Consolidated and sustained supply of pediatric ARVs

Tuberculosis

- Simpler and shorter TB regimens for first-line and drug resistant tuberculosis
- Easy, affordable and rapid access to diagnostic tests for all forms of TB, allowing for immediate start of treatment and cutting transmission

Malaria

- Rapid diagnostic test that can differentiate malaria from other common causes of acute fever and managed in community setting
- Quality community emergency treatment for severe malaria to reduce infant and child mortality
- New Generation of insecticides for LLINs and novel vector control tools

Key area for UNITAID investment Aspirational Goals 2013-2016

Illustrative

Crosscutting

- Affordable point of care diagnostics bringing high quality of treatment without need of laboratory and/or lab technicians and adapted diagnostic reagents
- Maintain access and insure availability of quality, adapted pediatric treatments
- Shortened courses of treatments or reduced pill burden for the patient across all three disease areas
- Ease regulatory burdens and accelerated registration and entry of quality generics medicines in most developing countries, in particular generics created with licenses from the Patent Pool
- Comprehensive markets monitoring in place

- For consideration:
  - Prevention aspirations
  - Co morbidities Hep C
  - Viral load –CD4 monitoring

Pediatric ARVs

Transition status of CHAI UNITAID pediatric project/GFATM

26 countries have secured transition funding

9 countries have secured funding but PSM issues remain that could mean delays

5 countries have not secured transition funding

Represents between $40 m to $60 m

1. Malawi
2. Mozambique
3. Uganda
4. Zimbabwe
5. Swaziland* (MOh?)

December 2012:

- GFATM decision on pediatrics expected
- Order to be placed by UNITAID/CHAI

Need to Scale up

Tuberculosis Diagnostics

UNITAID scale-up of Gene Xpert MTB/RIF

Evidence to Policy

- December 2010: WHO endorsed **Gene Xpert MTB/RIF** a new rapid molecular diagnostic for simultaneous detection of TB, rifampicin resistance and HIV-associated TB, based on scientific evidence supporting the quality, effectiveness and efficacy of the product.

Market & Public health impact

- August 2012: UNITAID, USAID, PEPAR and the Gates Foundation announced an agreement **reducing the price of Xpert (cartridges) by 40% to US$ 9.98**, valid until 2022.
- The price is available to the **public sector of** more than **145 countries** incl. the BRICs, NGOs and global funding mechanisms, **enabling substantial scale-up** in high burden TB countries.
- **The initiative** will expand the public sector market beyond existing investments for new, rapid molecular Dx in **decentralized settings** and provides an **evidence base for fast followers on a viable Dx market**
- UNITAID will provide **US$ 26M to WHO/STB for scale-up of Xpert in 21 countries** accelerating diagnosis and treatment of particularly MDR-TB and TB-HIV. Detection of an **additional 33,000 MDR-TB cases** is expected under this project over the next 3 years.
- Concessional Xpert **cartridge pricing will be extended to the private (poor) sector** of high burden countries.

ACT Forecasting

Forecasted ACT 'Demand'

Background and methodology

•ACT forecasts produced quarterly by a consortium comprised of BCG, CHAI and MIT-Zaragoza; funded by UNITAID

•Overseen by a Steering Committee: WHO, RBM, GF, AMFm, MMV and UNITAID

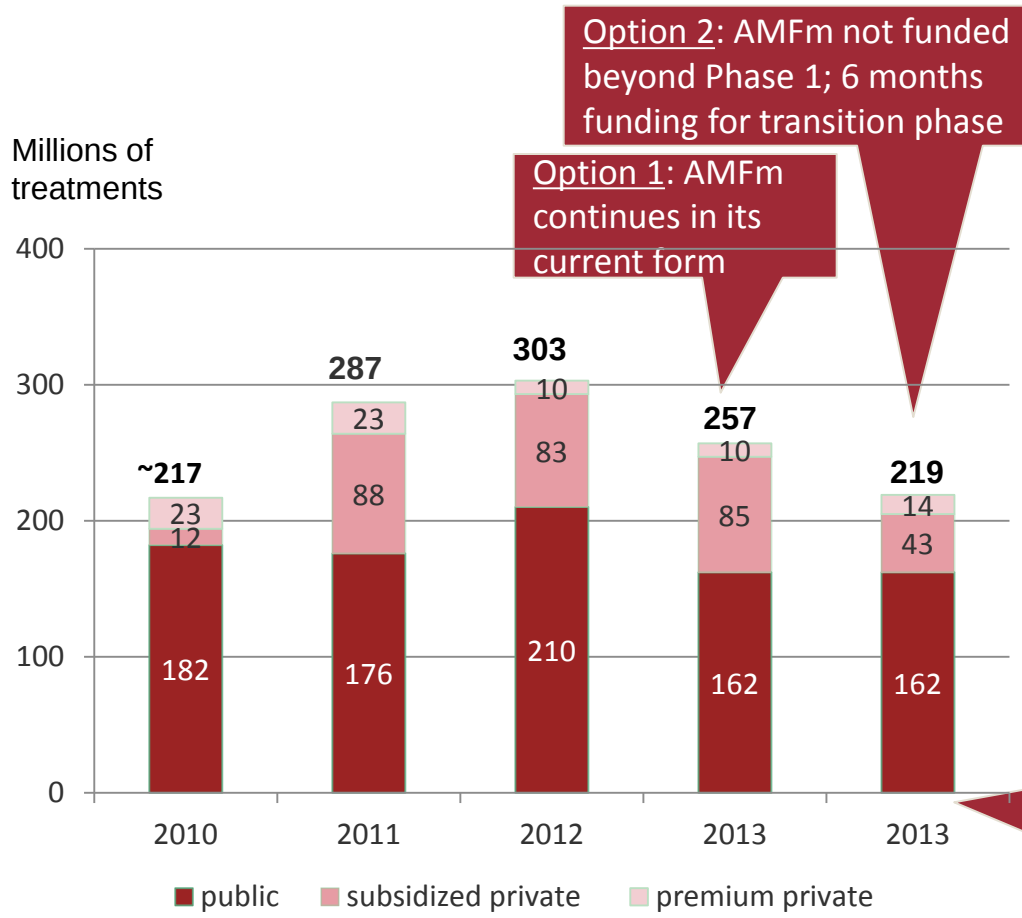
•Forecasts are mainly based on funding available for pre-qualified ACTs rather than 'need' as determined by morbidity, consumption etc.

•2013 forecast scenarios:

- Option 1: AMFm continues largely in its current form in the 8 Phase 1 countries
- Option 2: AMFm not funded beyond Phase 1; 6 months of additional funding during a transition period

Current projections of *available funding* in 2013 would result in a significant decrease in global ACT orders

Global ACT Demand (orders), 2010-2013



Option 2: AMFm not funded beyond Phase 1; 6 months funding for transition phase

Option 1: AMFm continues in its current form

No rationale for a decrease in "need" in 2013

2013 demand could be higher if:

- new international funding emerges
- endemic countries invest more domestic funds to purchase ACTs
- consumers choose pre-qualified ACTs at a higher rate after the AMFm

Public channel:

- Increase in 2012 based largely on timing and volume of procurements planned by countries

•Decrease in 2013 driven by declines in procurement. Transient funding to countries such as Nigeria, Ghana, Tanzania, will end in 2012

Source: ACT consortium forecasts, Q2 2012

Implications and Policy Options

Forecast for 2013 and beyond

- Anticipated decline in ACT projected orders in public and private sectors
- Price increases would decrease the quantity of ACTs procured with available funding

AMFm issues and options

- AMFm not continued beyond a limited transition period
- AMFm continues in its current form
- AMFm expands

Other factors that may influence future ACT orders

- Global fund transition mechanism and new funding model
- New additional international funding for ACTs emerges
- Endemic countries increased national investment to purchase ACTs
- Consumers choose pre-qualified ACTs at a higher rate after the AMFm

Other malaria medicines of interest to UNITAID

- Injectable and rectal artesunate for the treatment of severe malaria

Unitaid Next steps

- Revised Strategy 2013-2016
- Diag POC Hiv TB Malaria
- Pediatric formulations (IP sprinkles/TB and malaria
- New regiments HIV ,TB
- Pre qualification WHO and Countrie Networks
- Develop Market intelligence 3 D