**UNITAID support for prequalification of medicines**

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)

Value Chain

Initiate

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

Create

- Peds TB
- MDR TB
- A2S2 M
- 1 line TB
- SRS TB
- Esther HIV
- Expandx TB

Fix

- RDT PSI M
- Round 6 Cross cutting

Deliver

- AMFM Malaria
- PMTCT HIV
- Second line ARV HIV
- Pediatric ARVs HIV
- LLIN Malaria
- ACT Scale up Malaria

Commodity Birth Line

- R&D
- IP Issues
- Market Entry
- Quality
- Availability
- Price
- Operational Research in country
- Delivery
- Country Intervention
Key area for UNITAID investment
Aspirational Goals 2013-2016

**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

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**
  - 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

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

Option 1: AMFm continues in its current form

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

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 Country Networks
- Develop Market intelligence 3D