



Access to Medicines for Diseases that affect the World's Poor

UNITAID: Making markets work for people

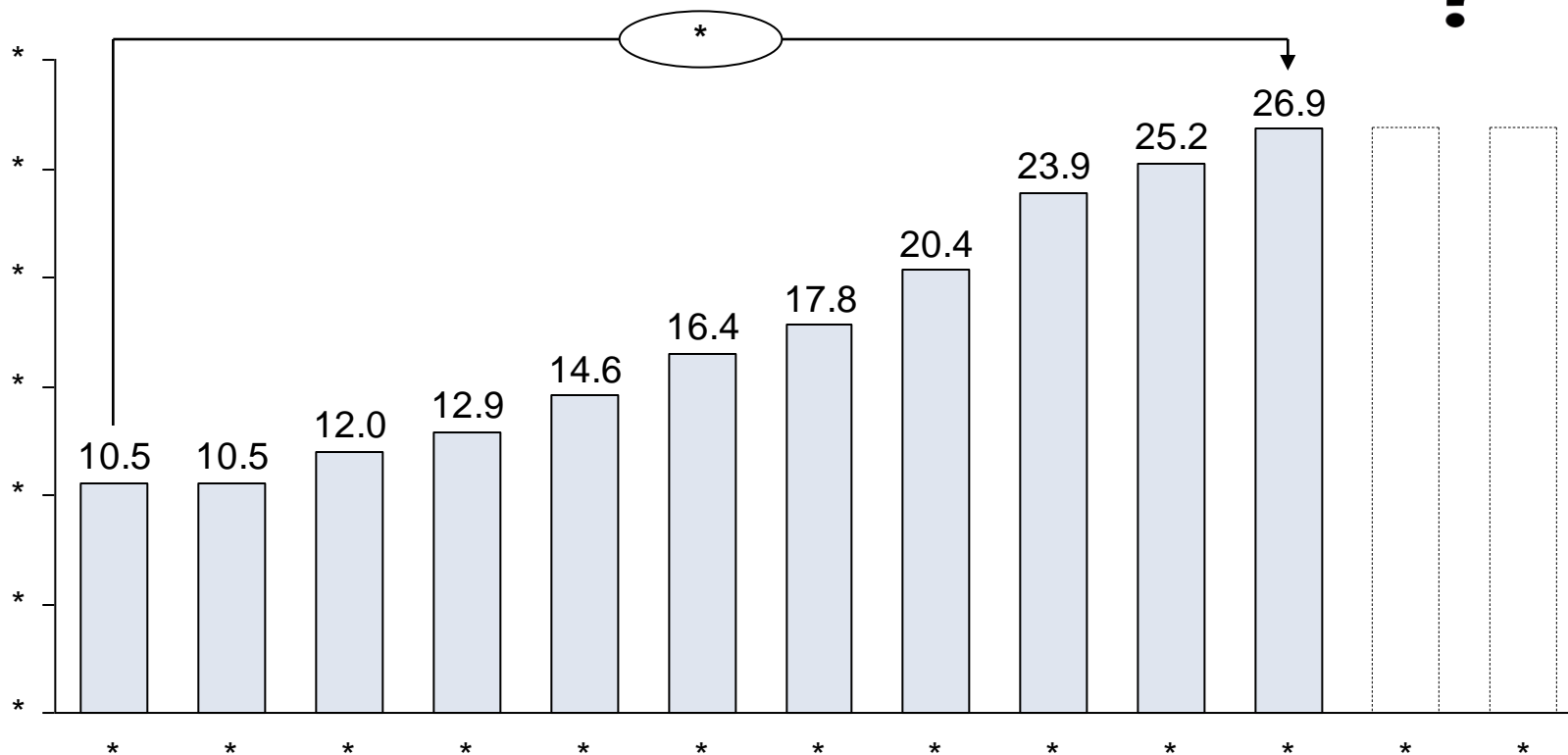
Health Technology Assessment international (HTAi)

Rio de Janeiro, 28 June 2011

Dr. Jorge Bermudez
Executive Director, UNITAID

Funding for global health has grown dramatically, but a funding gap remains...

Development assistance for health, 1998-2010 (\$B)



Source: Institute for Health Metrics and Evaluation. Financing Global Health 2010: Development Assistance and Country Spending in Economic Uncertainty. Seattle, WA: IHME, 2010.

Note: 2009-10 are preliminary estimates based on information from channel of assistance, including budgets, appropriations, and correspondence.

Revisiting the concept of Neglected Tropical Diseases

Diseases covered by WHO NTD Department

- Buruli Ulcer
- Chagas disease (American trypanosomiasis)
- Cysticercosis
- Dengue/dengue haemorrhagic fever
- Dracunculiasis (guinea-worm disease)
- Echinococcosis
- Fascioliasis
- Human African trypanosomiasis
- Leishmaniasis
- Leprosy
- Lymphatic filariasis
- Onchocerciasis
- Rabies
- Schistosomiasis
- Soil transmitted helminthiasis
- Trachoma
- Yaws

Other 'neglected' conditions:

- Podoconiosis
- Snakebite
- Strongyloidiasis

...other conditions?

**Paediatric HIV :
A "Neglected disease" ?**



**ADDITIONAL
PREDICTABLE
SUSTAINABLE**

UNITAID's Essence: The Air Ticket Levy

- Applied to all flights departing from countries
- Amount can vary and decided by government
 - Around \$US 1 or 2 domestic economy
 - Progressive fares, over \$US 40 business international
 - Flat rate for international flights?
- Neutral (all companies)
- No negative impact on tourism and development where applied

Near US\$ 2 billion raised since 2006

UNITAID: an Innovative Financing Mechanism



- Founding countries: BRA, CHI, FRA, NOR, UK
- Contributions from 11 countries to date
- 29 member Countries that are pledging support
- 68% of UNITAID funds from Air ticket levy (2010)
- 32% multi budgetary contributions (as of 2010)

- **68 % of UNITAID funds from the Air ticket Levy**

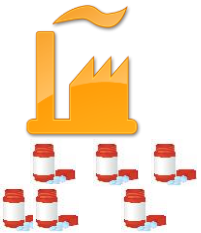
- Chile
- France + **multi year commitment**
- Mauritius
- Madagascar
- Mali
- Niger
- Republic of Korea
- + CO₂ tax from Norway

- **32 % of UNITAID funds from multi budgetary contributions**

- **Brazil + multi year commitment**
- **Law 12.413 passed 31 May**
- UK by **multi year commitment**
- Cyprus
- Spain
- The Gates Foundation

Innovative Spending Mechanism

Value for Money



Value for money

- Money goes further
 - User friendly (FDC) Efficacy/Quality/Price
 - Transaction cost (below 4 per cent)
- Investing in products of proven *public health* benefit
 - More medicines purchased and delivered = **more lives saved**
- Creating and improving *markets*
 - **Incentives** for manufactures to enter or develop market
 - Better **prices negotiated** – purchases made for many countries high volumes
 - Market impact dimensions vary by product; can include:
 - **price,**
 - **quality,**
 - **availability and**
 - **timely delivery**
- Positive Externalities
 - Market benefits and results achieved by **UNITAID available to all**

1 Dollar

=



- One adult or 2 children receive life saving malaria treatment
- One HIV test kit for a pregnant mother
- One week HIV treatment for a child
- One day of treatment for a patient on second line combination
- One week first line TB treatment



UNITAID Market impact framework

Case for intervention

Public health
problem &
commodity
access issue



Market
shortcomings
& their
reasons



Pathway from market to public health impact

Innovative
market
intervention



Sustainable
market impact



Public health
impact &
Value for
money

UNITAID Intervention example: 2nd line ARV market

HIV/AIDS &
poor access to
antiretroviral
(ARV)
medicines



High ARV prices
from low
demand & lack
of competition



Price negotiation,
demand creation,
pooled purchase,
information
sharing, WHO PQ



Lower ARV prices,
more generic
versions, increase
in suppliers,
competition &
awareness



More people
treated with less
money; benefits
extend beyond
country recipients

UNITAID intervention in the health product value chain

Accelerating availability and reducing prices



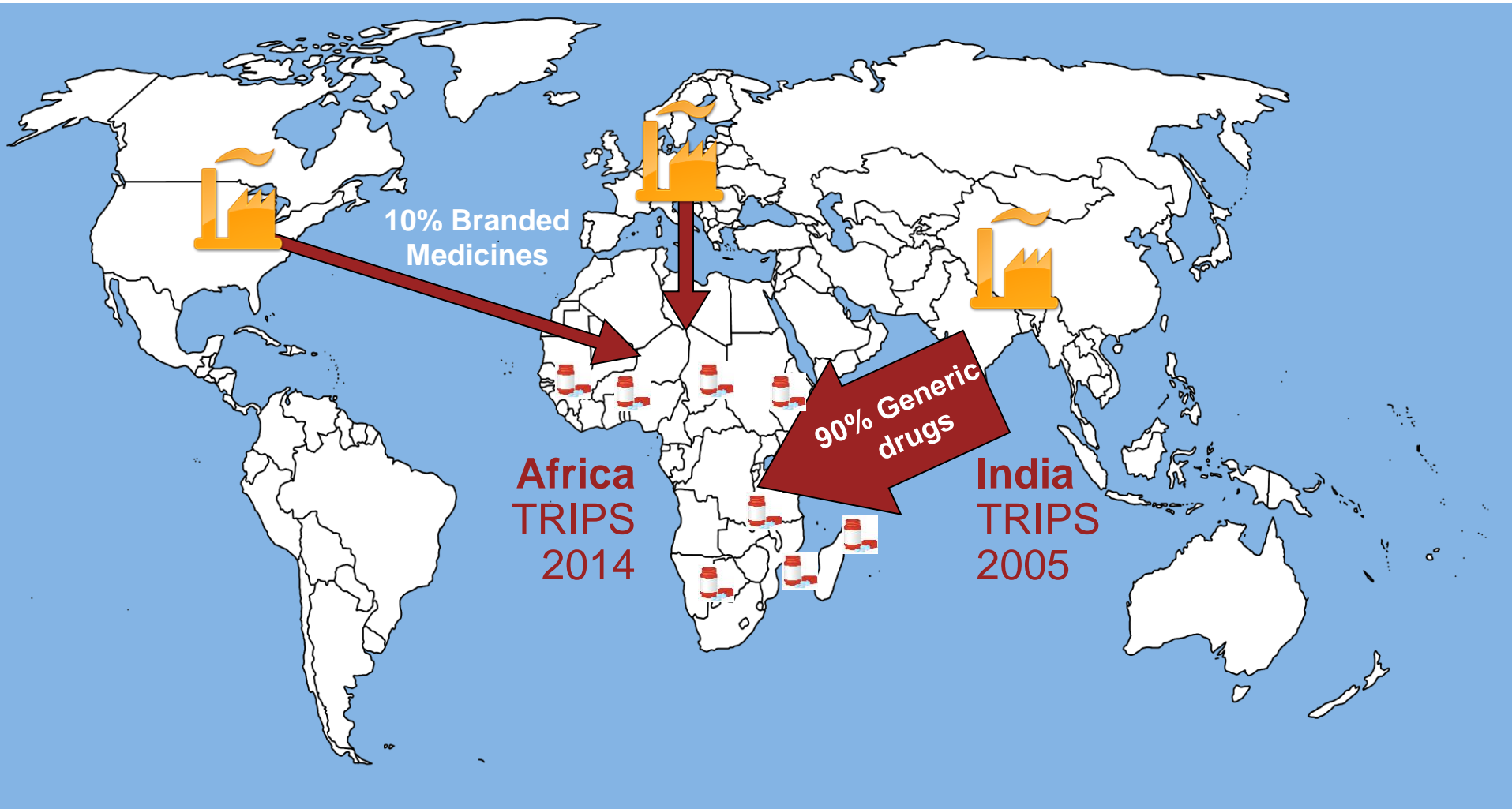
Example activities include:

- Managing IP / other support for re-formulation e.g. FDC and adaptation e.g. pediatric
- Registration
- Pre-qualification
- Treatment guidelines and protocols
- Phase 4 post-marketing studies
- Price negotiation
- Demand forecasting
- Pooled procurement
- Guarantees
- Subsidies
- Rotating stockpiles

AIDS/HIV



HIV-AIDS Medicines provision to low income countries



Pediatric ARVs



Before:

Single dose syrups
16 bottles of syrup monthly
US\$ 200 per patient per year



Now (partnering with CHAI):

Fixed dose combination
3 tablets a day
US\$ 60 per patient per year

Establishing the Medicines Patent Pool

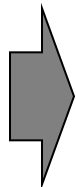
UNITAID funds the operations of the Pool under a 5-year MOU

2006

CIPIH 2006 recommendation:

"Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries."

MSF and KEI proposed to UNITAID to set up a medicines patent pool.



2008

May 2008

WHO Global Strategy and Plan of Action included Voluntary Patent Pools (upstream and downstream)

July 2008

UNITAID Executive Board

Supports the principle of establishing a patent pool and requests the secretariat to undertake all necessary actions for this establishment.



2009

Broad stakeholder consultation

Developed the implementation plan for the medicines patent pool

Ongoing dialogue with patent holders and with other ARV drug manufacturers

Decision by UNITAID Board to fund



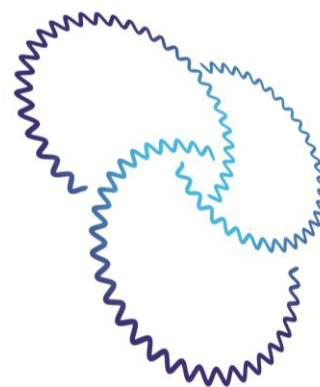
2010

Establishment of the Medicines Patent Pool

Formal licensing negotiations begin

NIH grants first licence to the Pool

- Established in July 2010 with UNITAID financial support



medicines
patent
pool

- Aims:
 - To reduce the price of HIV treatment
 - Encourage development of new formulations
 - Get more people on life saving treatment
- Method:
 - Voluntary licensing of critical intellectual property
 - Making patents work for public health
 - Compensating pharmaceutical innovators for their work

The Medicines Patent Pool: An integral part of UNITAID's strategy

- ***A common goal :***
" improving access to quality, affordable, effective, well-adapted HIV medicines in developing countries "
- ***A common market based approach:***
 - Converging goals through a focus on **market impact** to lower the prices of medicines
 - Influence of global patenting on the medicines' market **dynamics**
 - Market **incentives** to channel the demand
 - Bridging the gap between **accessible** and **affordable**
 - Strategic use of intellectual property (changing international rules that limit competition and lower cost production)

Moving forward: positive synergies

- ***Common areas of work:***

- Fixed doses combinations
- Paediatrics adaptations
- Adequate intervention in the health products value chain

- ***Challenges ahead:***

- Making markets work for people
- Evolving niches
- Evolving treatments
- Evolving economic levers for the pharmaceutical industries

Missing ARVs – Priority setting

UPDATED LIST OF MISSING DRUG FORMULATIONS FOR HIV TREATMENT TO BE REVIEWED BY THE WHO 18TH EXPERT COMMITTEE ON THE SELECTION AND USE OF ESSENTIAL MEDICINES

By the Medicines Patent Pool, UNITAID and the WHO HIV/AIDS Department, endorsed by the following core partners of UNAIDS and WHO's *Treatment 2.0* Initiative:

Agence Nationale de Recherche sur le SIDA (ANRS), AIDS and Rights Alliance for Southern Africa (ARASA), The Global Fund to Fight AIDS, Tuberculosis and Malaria, [HealthGap](#), International AIDS Society (IAS), International Treatment Preparedness Coalition (ITPC), [Médicins Sans Frontières](#) (MSF), Pangaia Global AIDS Foundation, the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Joint United Nations Programme on HIV/AIDS (UNAIDS)

18 February 2011

Background

The 17th meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines, held from 23 to 27 March 2009, reviewed a document on priority drugs missing from the essential medicines list for HIV. The document was jointly submitted by UNITAID and the WHO Secretariat. The document included lists of needed antiretroviral products and formulations for adults and children, with an emphasis on fixed-dose combinations (FDC), based on the 2006 WHO treatment recommendations for HIV-infected adults, adolescents, infants and children. The document was submitted in the context of the possible establishment of the Medicines Patent Pool by UNITAID, which would facilitate the development of missing and needed formulations by making the intellectual property on HIV drugs available to drug developers and manufacturers.

In reviewing the document, the Committee acknowledged the rapidly evolving field of HIV therapy and the "need [for] periodic revision and updating [of these lists] depending on the progress made in clinical research and drug development"¹.

In July 2010, UNAIDS and WHO announced the *Treatment 2.0* initiative as a global platform aimed at dramatically improving the efficiency and effectiveness of quality HIV treatment programmes in resource limited countries. Simplification of treatment regimens and laboratory technologies, cost reduction, adaptation of service delivery and community mobilization are the five priorities of *Treatment 2.0*. The initiative recognizes the urgent need to move from an emergency response towards a long-term, sustainable response that optimizes both HIV-specific and broader health outcomes through HIV programmes. It also recognizes the need for innovation, paradigm shifts, and initial additional investments that will ultimately reduce overall costs of management of the HIV/AIDS epidemic in the medium and long term.

¹ WHO, The Selection and Use of Essential Medicines, Report of the WHO Expert Committee, 2009.

Patent Pool, UNITAID, WHO HIV/AIDS Dept submitted 'Updated List of Missing ARVs submitted to 18th Expert Committee'
- endorsed by 10 Tx 2.0 partners

Next steps:
-Identification of need and opportunities
-Further Prioritization
-MPP, UNITAID, WHO, Tx 2.0 partners working to determine next steps
-7-8 July, Pool, UNITAID, WHO/UNAIDS treatment 2.0 meeting



Let's take the plunge...!

(...)

Today patent pools are a favoured system in technology sectors that require common standards, such as the MPEG-2, DVD-video, DVD-ROM and radio. Medicines, though, are trickier terrain.

(...)

UNITAID may be able to pull it off with some luck and lots of hard work. (...) They have a delicate and onerous task before them. Millions of people are waiting hopefully at the patent poolside."

Latha Jishnu/ New Delhi July 23, 2008

Thank you



Thank you for helping UNITAID save lives