

# TB Alliance's Pediatric Initiative Update

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**USAID**  
FROM THE AMERICAN PEOPLE

# Overview

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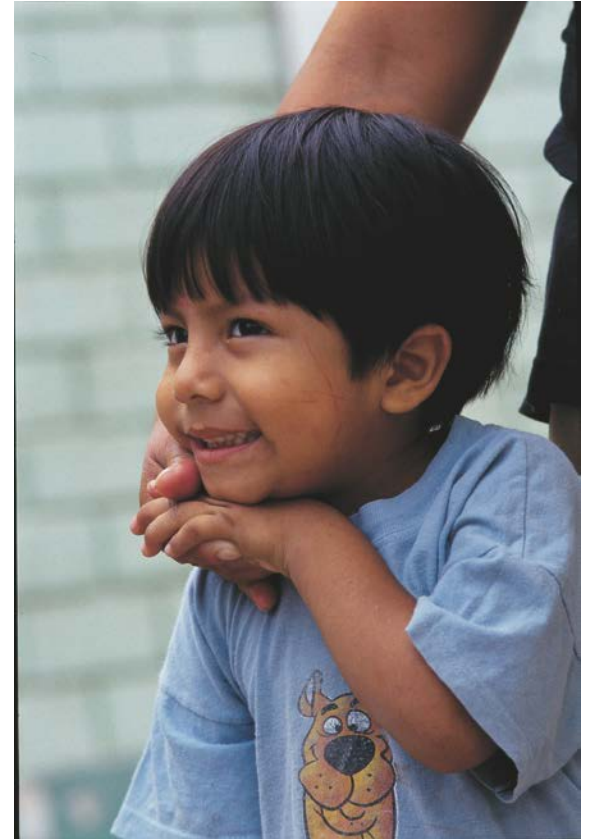
Speeding Treatments to End Pediatric TB

Problem being addressed:

***Not enough kids being treated –  
and not being treated  
appropriately***

Goal & Major Outcome:

***Increase access to optimal pediatric  
TB medicines*** which means  
***Correctly dosed, properly  
formulated, affordable, high  
quality pediatric TB medicines  
available***



# Multi-faceted Approach

Speeding Treatments to End Pediatric TB

**Market  
Understanding**

**Engaging  
Manufacturers**

**Clinical and  
Regulatory  
Understanding**



**TB ALLIANCE**



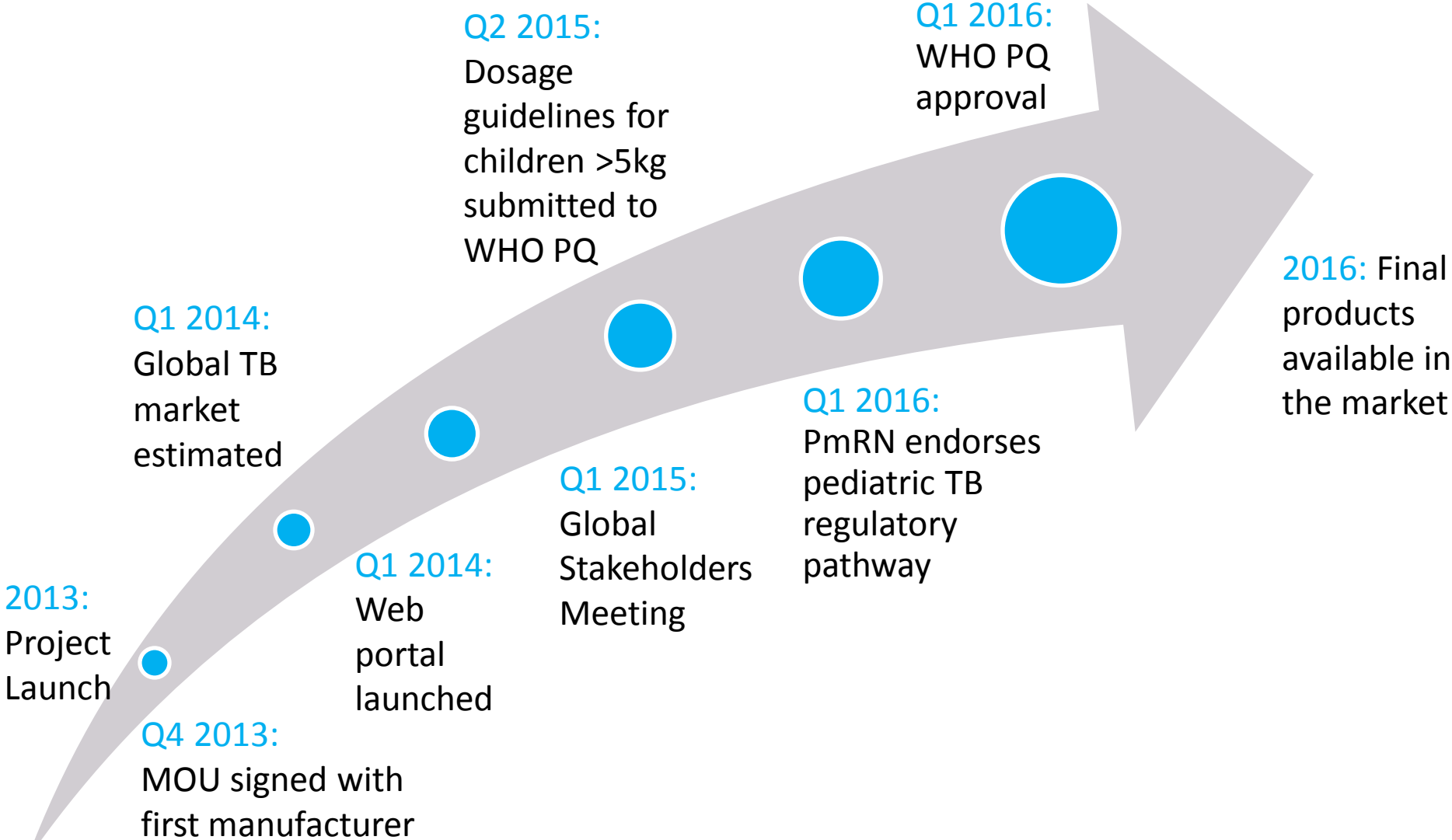
**World Health  
Organization**

**Policy and  
Uptake by  
Countries**

**Information  
Exchange**

**Engaging  
Countries and  
Donors**

# Timeline for FDC of First-Line Pediatric Treatment:



# Market Understanding

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Know how many patients there are and where

## Plan

- Numbers of patients being treated in public and private sectors – existing & potential
- Location of markets
- Current treatment policies and practices
- Cross tabulate procurement with manufacturers' products & sales

## Update

- Global Consultation on Pediatric TB held September 2013
- 1 Literature Review; 3 Rapid Assessments (Indonesia, Nigeria, and Pakistan); Survey of Policy and Practice; Analysis of GDF Procurement from 2007-2012; Modeling Pediatric Burden

# Clinical

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Collect clinical data necessary for new formulations

## Plan

- HRZE dosing for children >5 kg--determining if there is sufficient data for regulatory approval of new formulations
- Conduct of pK study for children <5 kg
- Deciding on and planning for use of new regimens in children (REMox, PaMZ)

## Update

- Finalizing protocol and contracts for pK study in infants and newborns under 5 kg; in partnership with Stellenbosch Univ. and the Univ. of Cape Town
- Results from adult clinical trials of REMox and PaMZ will be released between now and Q1 2014

# Regulatory

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Clarify and accelerate regulatory pathway

## **Plan**

- Discuss design of BE/BA for HRZE
- Understand regulatory needs for pediatrics
- Propose ways to shorten clinical development pathway for new drugs
- Combine regulatory and clinical expert advice into a guidance for pediatric development of TB drugs/regimens

## **Update**

- Initiated discussions with FDA, WHO PQ, manufacturers with experience with pediatric TB drugs

# Manufacturer Engagement

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Engage manufacturers to create competition in pediatric TB markets

## **Plan**

- Collaborate with 2 to 3 manufacturers to produce HRZE in the correct dosages and formulations for children
- Link to markets (countries and global purchaser Global Drug Facility)
- Reduce barriers to product uptake

## **Update**

- In discussions with several potential manufacturing partners about interest and commitment to make optimal medicines for pediatric TB patients



# Adoption & Use

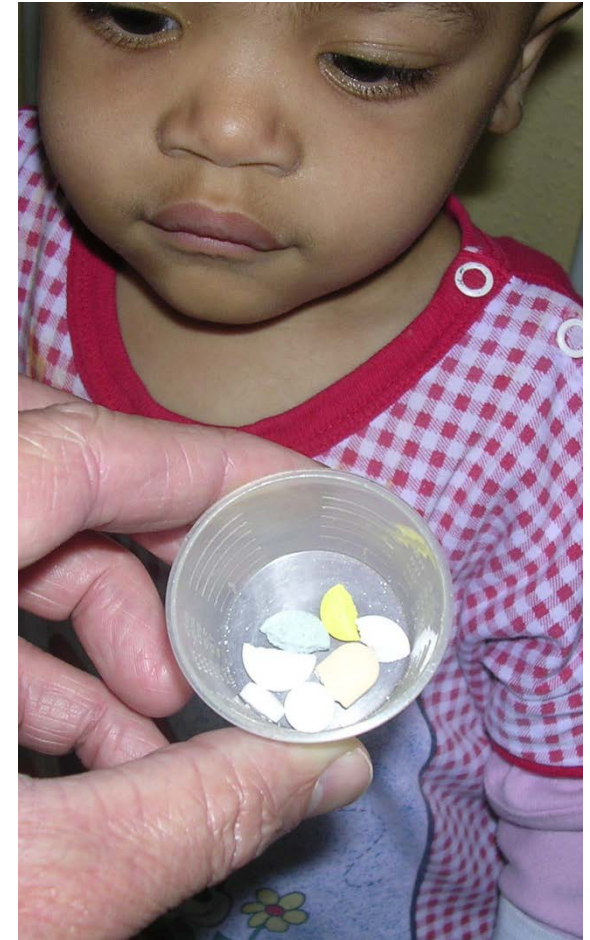
Encourage change in policy & practice

## Plan

- Speed HRZE policy change at the country level
- Encourage use of new formulations
- Identify funding to support procurement of new formulations
  - Donors
  - Country budgets

## Update

- WHO is finalizing a comprehensive guide for pediatric TB management



Credit: Desmond Tutu TB Centre, Department of Paediatrics and Child Health, Stellenbosch University

# Disseminate information

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Create pediatric medicines information exchange platform

## **Plan**

- Make information on pediatrics widely known
- Disseminate market data & regulatory pathway findings to countries, researchers, manufacturers
- Exchange information and approaches with other pediatric disease areas (i.e., DNDi, CHAI, MMV)

## **Update**

- Web-portal in development with anticipated launch by end of 2013
- Initial discussions held with DNDi, CHAI, and others

Thank you!



**TB ALLIANCE**

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT