TB Alliance’s Pediatric Initiative Update

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Childhood TB Subgroup Meeting, Paris, France
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
- Policy and Uptake by Countries
- Information Exchange
- Engaging Countries and Donors
Timeline for FDC of First-Line Pediatric Treatment:

- **Q1 2013:** Project Launch
- **Q4 2013:** MOU signed with first manufacturer
- **Q1 2014:** Web portal launched
- **Q1 2014:** Global Stakeholders Meeting
- **Q2 2015:** Dosage guidelines for children >5kg submitted to WHO PQ
- **Q1 2016:** PmRN endorses pediatric TB regulatory pathway
- **Q1 2016:** WHO PQ approval
- **2016:** Final products available in the market
Market Understanding
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

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

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

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

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