Call to action on the introduction of bedaquiline and delamanid

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On behalf of 88 signees
Where are we now?

• SDRA approval of bedaquiline (bdq) December 2012, delamanid (dlm) April 2014
• WHO recommended programmatic use of bdq (June 2013) & dlm (Nov 2014)
• USAID donation programme for bdq (April 2015)
• WHO working with Early implementer countries for introduction of new drugs.
Clinical experience to date

– Positive data on bdq from France, Georgia, Armenia, RSA, Latvia (CU programmes)

– 6/12 bdq treatment, amongst patients culture positive at the start of treatment, 77% converted in RSA (33/43), 84% (22/26) in Armenia and 97% (28/29) in France.

– Limited experience of del use outside clinical trials.

Offering hope to patients and clinicians.....
DR-TB drugs – STAT!

Problem:
• Only 600 patients on BDQ outside of clinical trials
• Less than 50 patients on DLM outside of clinical trials
• DLM only currently registered in the European Union, Japan, South Korea
• Minimal use of repurposed companion Group 5 drugs needed to support introduction of new drugs

Potential Solution:
An ‘action team’ comprised of actors committed to meet time-bound goals for increasing access to new and repurposed DR-TB drugs in 50 top high-burden countries through greater collaboration, coordination and accelerated activities
i.e DR-TB STAT!! (Scale-up Treatment Action Team)
Time-bound goals

• ‘Quickstart’
  – 500 patients start BDQ-containing regimens by July 2015
  – 500 patients start DLM-containing regimens by January 2016

• Optimal DR-TB treatment
  – Technical assistance (TA) provided for 27 countries by 2016, 50 countries by 2017 for drafting implementation plans
  – Implementation plans adopted by 27 countries by 2016, 50 countries by 2018
  – BDQ and DLM are routinely used by 27 countries by end of 2016, 50 countries by end of 2019
  – Key repurposed drugs (especially linezolid and clofazimine) are on the national Essential Medicines List (EML), and countries and national TB programmes (NTPs) using these drugs
Time-bound goals cont

- **Regulatory status**
  - BDQ and DLM dossiers submitted for registration in 27 countries by Jan 2016, 50 countries by Jan 2017
  - Import waivers are in place in 27 countries by Jan 2016 while BDQ and DLM are being registered

- **Procurement**
  - Forecasting of drugs is completed
  - Procurement strategies are developed for 50 countries by 2018
  - Drugs procured

- **Pharmacovigilance (PV)**
  - A **flexible approach** for countries implementing BDQ & DLM
  - A set of standardised data for monitoring and reporting adverse events in open access
  - A supranational body to collect, analyse, and disseminate data
Map of DRTB Cases

LEGEND

- Top 10 High DR-TB Burden & Undetected MDR-TB Case
- High MDR-TB Burden
- Remaining DR-TB Countries among top 50 MDR-TB
Map of estimate that 20% of cases are eligible for BDQ or DLM

LEGEND
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Previous example of collaborative mechanisms for access.

- The GF in collaboration with UNITAID and CHAI organized a Consultative Meeting on Coordination of Paediatric ARV Procurement
- Goal: to secure the market to ensure timely and consistent access to paediatric ARVs in order to sustain and scale-up paediatric HIV treatment.
- **Agreed on principles and next steps to coordinate** procurement of paediatric ARVs.
- Regular meetings to **update on progress, assess and align work with all stakeholders contributing, collaborating to improve accessibility** to paed ARV’s. 
- Specified a goal and **worked on operation framework with action lists, responsible leads and timelines to achieve goal**
- is not a legal body, and membership is based on “collaborative spirit”.
What goes in the ACTION list?

• Country focus
  – Funding, whether national or GFATM (GFATM PMs can help)
  – TA & implementing partners identified
  – Procurement/forecasting/stock management (GDF and others)
  – Implementation plan & guidelines in place
  – Clinical & technical trainings planned
  – Implementation partners identified
  – Engagement of affected communities

• Regulatory status of new and Group 5 drugs

• Affordability of the product

• Pharmacovigilance
  – Focus on pragmatic, flexible approach

• Communication strategies
What needs to happen?

Collaboration, coordination, monitoring & accountability is key

- National governments
  - Political will from national governments and NTPs
  - Develop implementation plans and set up compassionate use (CU) programmes as interim access solution
  - Update guidelines
  - Train HCW and disseminate patient education material

- Drug Companies
  - Allow access through CU programmes / import waivers
  - Prioritise registering the drugs in country
  - Ensure pricing transparent and affordable for all countries
  - Ensure adequate plans and access for continuing research into drugs and regimens

- Global Health Actors (WHO, STBP/GDF, USAID, GFATM portfolio managers, implementing NGOs (e.g. endTB))
  - Continue to provide the TA (expand and accelerate)
  - Address supranational barriers and support and encourage countries to address national barriers and implement new and group 5 drugs
  - Provide sustainable funding and look to re-purpose existing funding.
  - Ensure PV is not allowed to become a barrier, consider flexible reporting.
Questions to consider

• Can we achieve these targets?
• How can key actors work together to ensure all patients requiring new drugs have access to them?
• What other barriers need to be addressed?
• What actions need to be taken to achieve these goals
  – Within next 6 months, 12 months?
  – What is your role?

Success is number of patients on treatment.
WHAT NEXT?

• MSF and PIH host first DRTB STAT meeting and invite key actors to participate.
• DRTB STAT convene a (monthly) teleconference,
• A situation report of the priority+ countries is presented (STBP situation room supports)
• Update on the action list and review responsibilities and timelines.
• Report back on progress to STBP Board
• Monitor, report, and ACT with urgency!