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)

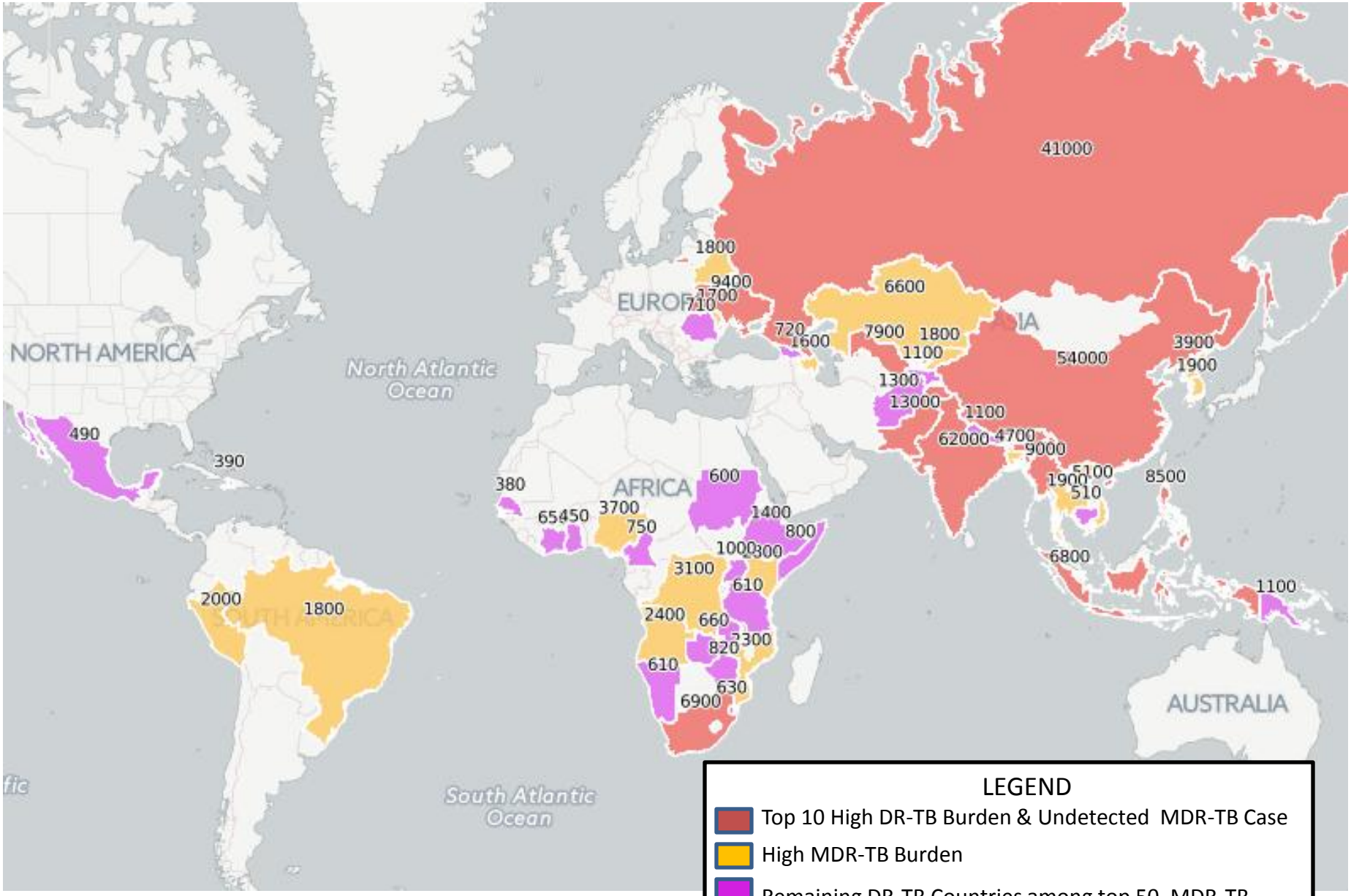
Time-bound goals

- **'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

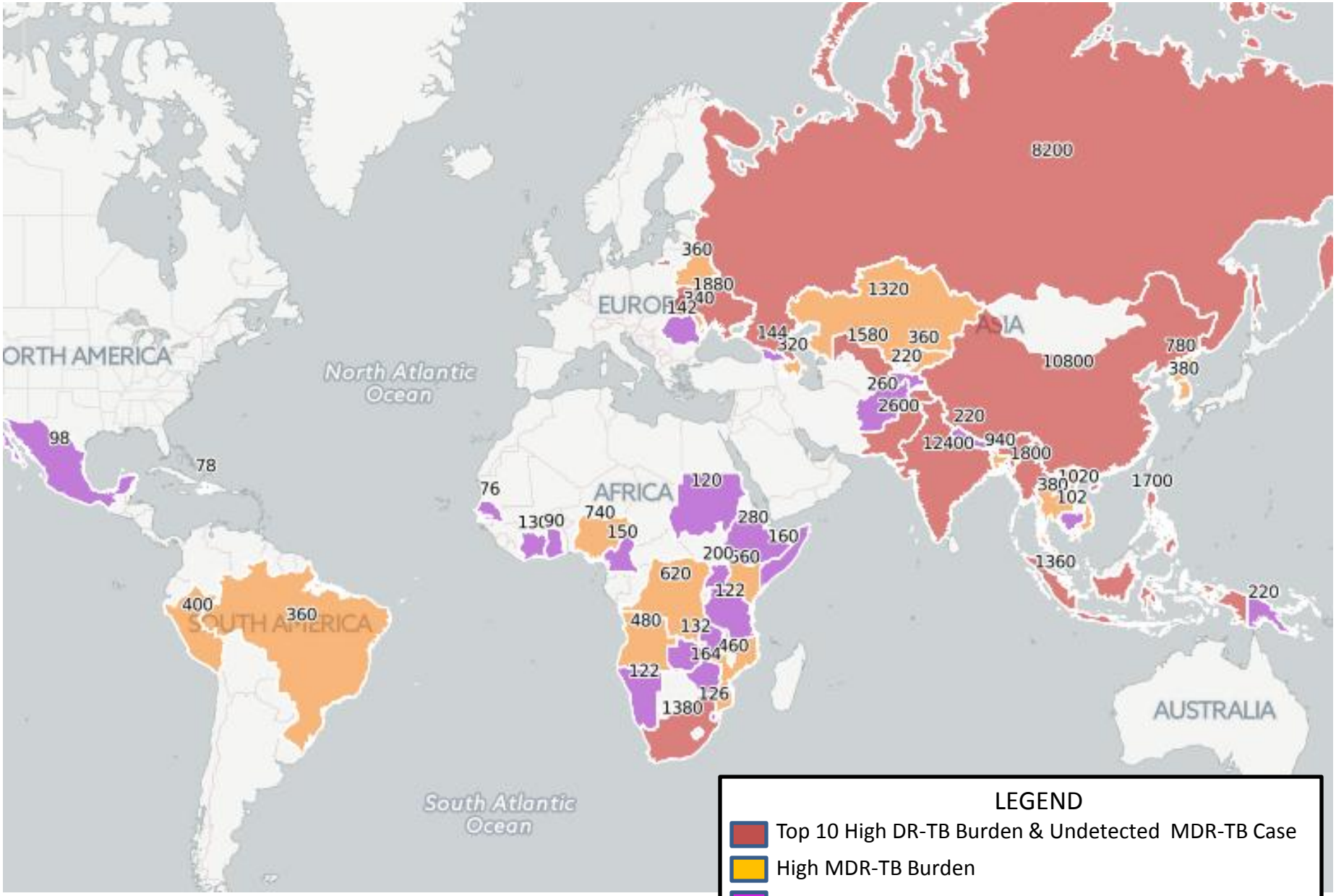
Time-bound goals cont

- **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



Map of estimate that 20% of cases are eligible for BDQ or DLM



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 accessability** to pead 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 acheive these goals
  - Within next 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!