Patients and TB: Improving treatment outcomes through a patient centred approach and access to new treatments

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Funding mechanisms, TB drug procurement, and prospect for the future

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MEDECINS SANS FRONTIERES

OUTLINE

1. Overview of funding for TB and DR-TB
2. Transition from the GFATM
   - GFATM Eligibility Policy
   - GFATM and the EECA region
   - Transition: What we know
   - Transition: Case studies & lessons learned
   - Transition: Concerns
   - Transition: Recommendations
3. Prospects for affordable access to SLD
   - Strategies to lower prices
   - What won't work: drug donations
   - Target prices

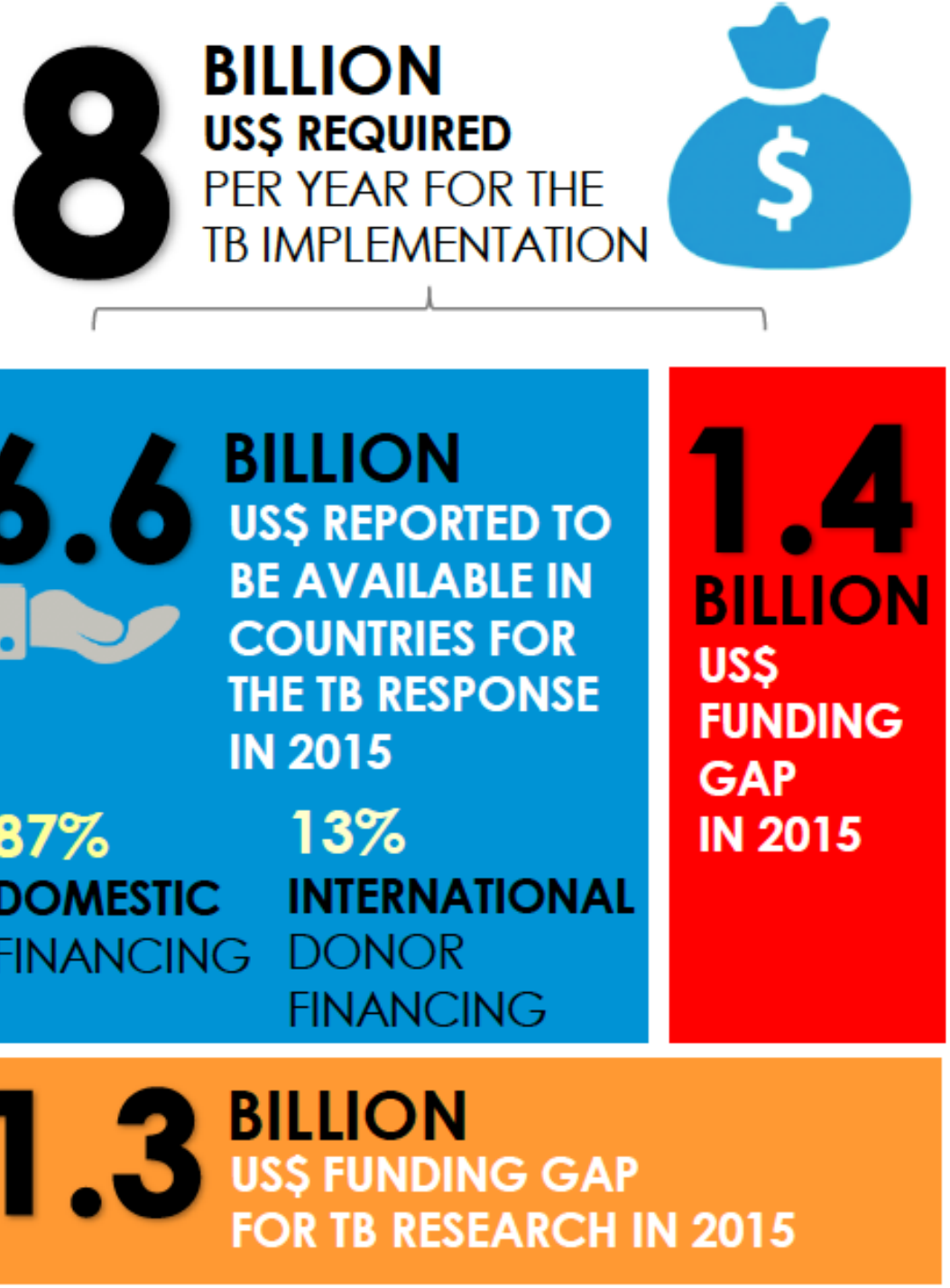
Funding overview

Domestic funding

- 87% (US$ 5.8 billion) of the US$ 6.6 billion available in 2015
- Domestic funding accounts for more than 90% of the total funding in 2015 BRICS

International funding

- 72% of total funding available in HBC (outside of BRICS)
- 81% in LIC
- USD .8 billion
- 77% of this from the Global Fund



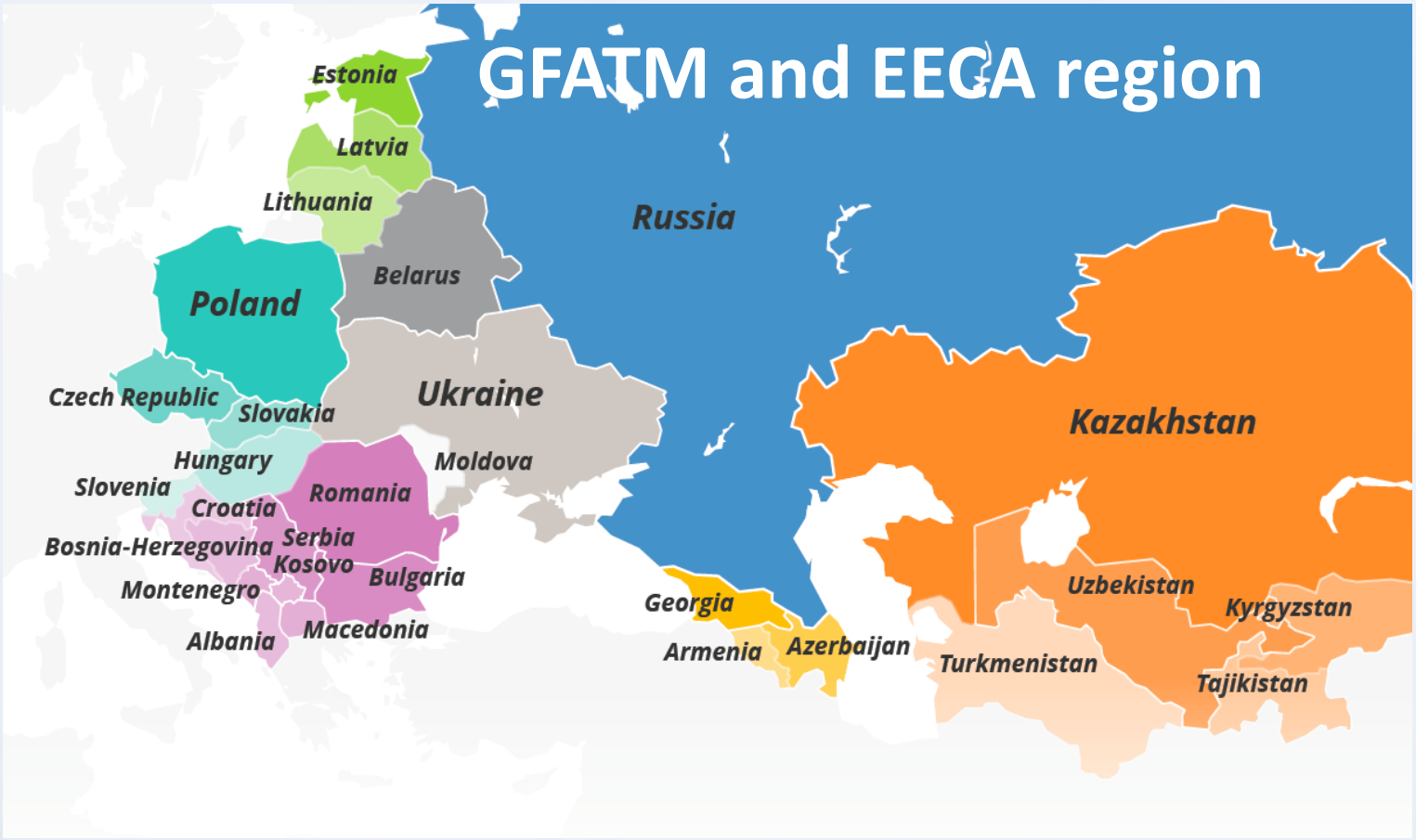
SOURCE: GLOBAL TB REPORT 2015, WHO

Global Fund Eligibility policy

"Global Fund Eligibility policy…is designed to ensure that available resources are allocated to countries with the highest disease burden and lowest economic capacity and to key and vulnerable populations disproportionately affected by the three diseases." (GFATM)

- All LICs and LMICs are eligible for HIV, TB, and malaria funding
- Governments of **upper middle (UMIC) income* countries with a moderate to low disease burden** are no longer eligible for funding
- UMICs are eligible for disease(s) measured as **High, Severe, or Extreme**
- **Disease burden**
  - Combination of TB notification rate per 100,000 population and **WHO list of high burden countries** (TB, TB/HIV or MDR-TB burden)

* Using World Bank (Atlas Method) Income Classification and Gross National Income (GNI)



- The GFATM New Funding Model (NFM) allocation methodology resulted in deeper funding cuts for EECA than any other region: 15% reduction in funding between 2010-2013 and 2014-2017
- According to GFATM it supports: 40% of first-line TB drugs; 66% of second-line TB drugs; 94% GeneXpert
- VISION: To successfully treat at least 90 percent of patients with drug-sensitive TB and at least 75 percent of patients notified as having multidrug-resistant TB (2014-2016)

GFATM and EECA

Investment guidance for EECA (2014-2016)

- Diagnostic and treatment for DS-TB in all countries is covered by domestic or alternative sources of funding
- Funding for second-line drugs, lab services and adherence support to be covered by domestic sources before the end of the allocation (2014-2016)
  - Low-income countries: Minimum 30% domestic funding
  - Lower LMIC: Minimum 50% domestic funding
  - Upper LMIC: Minimum 75% domestic funding
  - UMIC: 100% domestic funding
  - Transitioning countries: 100% domestic funding

NOTE → Updated guidance is in development now

GFATM Transition: What we know

- "Countries or components funded under an existing grant that become ineligible may receive funding for up to one additional allocation period following their change in eligibility"
- "The Secretariat, based on country context and existing portfolio considerations, will determine the appropriate period and amount of funding."
- "The Secretariat may adjust the level of funding and require specific time-bound actions for transitioning to other sources of financing..."

- Currently developing strategy for 2017-2022
  - Formal policy on Sustainability, Transition, and Co-Financing Methodological tools, including an assessment framework
  - The GFATM plans to track country transitions via Operational Key Performance Indicators (KPI) of development and implementation of transition plans in eligible countries

GFATM Transition: Lessons learned

Review of 8 UMICs/HICs that completed transition or finishing last grant

- Romania (funding ended in 2010): In 2013, about 30% of new HIV cases were linked to injection drug use compared with 3% in 2010
- Croatia, Argentina, & Uruguay: AIDS incidence and AIDS deaths increased
- Uruguay TB incidence went up
- Brazil, Ecuador, Mexico, Romania, Uruguay: TB case detection rates increased only modestly and went down in Croatia and Estonia
- Estonia faced drug shortages due to poor forecasting
- All reviewed countries showed “lack of adequate planning and preparedness for transition”, “lack of clear guidance and technical support”

GFATM Transition: Concerns

- Economic growth in transition-eligible countries has not been accompanied by similar scale-up and strengthening of TB and HIV programs
  - Fastest-growing HIV epidemic and highest prevalence of MDR-TB (15 of the 27 high-burden countries)
- Procurement
  - We risk losing the benefits over the years
    - Quality assuredness
    - Lower prices
    - Markey dynamics: pull factor for generic manufacturers
    - Less market segmentation
    - Forecasting
    - Lead times

GFATM Transition: Recommendations

- **GFATM** (from Curatio International Foundation)
  - Begin transition planning with countries earlier
  - Ensure that planning leads to a legally binding “Transition Plan”
  - Program transition elements as early earlier rather than the end of the grant cycle
  - Assign national responsibilities for coordination, implementation, and monitoring
  - Improve technical guidance and provision of resources needed for transition
  - Align grant cycles with national budget cycles
  - Create sources of continuous support for CSOs
- **MSF recommendations**
  - GFATM: allocation periods until countries upgrade to WHO guidelines & allow countries to continue to procure from GFATM

Strategies to lower prices

- More quality-assured suppliers
  - Finished products
  - Active pharmaceutical ingredients
- Generic competition
  - Including through voluntary licenses
- Consolidating demand by GDF
- Better drug forecasting
- Better negotiation resulting in lower prices
- WHO streamlining the number of second-line options
  - Less market segmentation and fewer options
  - Bangladesh 9 month regimen
- GDF bid in national tenders

What won't work: drug donations

"The negative impact that donations may have on sustainable access to medicines is often not well appreciated, especially where it concerns expensive medicines with few alternatives. Donations of these products may influence the market and suppress competition. The donation may eliminate or greatly delay the import of cheaper alternatives, which will be necessary once the donation programme has ended and regular provision from public health budgets is necessary." (WHO 2010)

- Unsustainable
- Insufficient scale
- Challenging indication restrictions
- Inadequate consultation with recipient countries
- Country eligibility concerns
- Burdensome requirements for recipients
- Time delays
- Costs incurred by recipient countries
- Anti-competitive impacts on drug markets
- Potential distortion of rational use
- Market priming

Target prices

Cost of goods + reasonable profit margin

	Clofazamine	Linezolid	Bedaquiline	Delamanid
Duration (months)	**20 months**	**20 months**	**6 months**	**6 months**
Target price	**$328**	**$256**	**$100**	**$52**
Lowest global price (GDF)	$666 (procured on a named-patient basis only) 100mg	$3253	• $900 LIC • $3000 MIC • $30000 UIC	• $1,700 (GDF) • $28,000 UK, $33,600 Japan

SOURCE: Gotham D et al. Target generic prices for novel treatments for drug-resistant tuberculosis.15thEuropean AIDS Conference, Barcelona, abstract PS2/4, 2015.

THANK YOU