Sustainability, Transition, and Co-financing (STC) of Health Products in EECA

Recommendations for addressing risks and ensuring sustainable access to quality products

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National co-financing targets for second line TB medicines, as based on Global Fund investment guidance

Services		Investment guidance targets	Planned domestic (by end)**	Transition
First line TB drugs				
All countries (regardless of income)		100%		
Second line TB drugs, lab services, adherence support				
Low Income Countries (LIC)	N/A	30%	N/A	
Lower Lower Middle Income Countries (LLMIC)	Kyrgyzstan*	50%	0% (2017)	
	Tajikistan*		0% (2017)	
Upper Lower Middle Income Countries (ULMIC)	Armenia	75%	0% (2017)	2017-2019
	Ukraine		99% (2017)	
Upper Middle Income Countries (UMIC)	Belarus	100%	73% (2018)	
	Georgia*		75% (2018)	

** Country income category (based on GNI per capita) was reclassified by GF during allocation period: Kyrgyzstan reclassified from LIC to LMIC in 2015, Tajikistan reclassified from LIC to LMIC in 2016 and Georgia from ULMIC to UMIC in 2017.*

*** According to country concept notes. 2017 and 2018 target dates reflect the variations in Grant implementation periods for the 2014-2017 allocation period across countries, with end dates ranging from Dec 2017 to 2019.*

Risks: failed procurement

Problem	Info	Strategy
Access to “global” market or does law require competitive national bidding process?	Will national tender limit options?	• Push for waiver from national bidding process in order to continue use of GDF for TB medicines • Delay switch to national procurement • Possible state law change on procurements of commodities
Failed tenders due to a variety of issues including lack of registration	Is there a history of failed tenders? Are there key drugs/diagnostics unregistered? Has country been using GFATM-related waivers?	Country should enrol in the WHO Collaborative Registration and expedite local registration of medicines approved by Stringent Regulatory Authority Provide import waiver

Risks: higher prices

Problem	Info	Strategy
Country could pay more than through GDF for TB health products or other pooled procurements	What is price difference now between nationally procured drugs (HIV, TB, HCV) and global market?	• Cluster or regional pooled negotiation or procurement • Continue procurement through global agenda (e.g. GDF, other) • Use pricing benchmarks to improve negotiation • Remove unnecessary &costly barriers to entry (e.g. diagnostics trials in-country)
Corruption creates perverse incentive to choose more expensive drugs	• Is there a history of corruption? • Is there transparency of procurement systems?	• Transparency of prices, bidders, and selection criteria • Improvement of procurement practices to avert corruption
There are barriers to generic competition	TRIPS flexibilities can be used? LICs are not prematurely WTO TRIPS compliant? What impact of customs union?	

Risks: quality of commodities

Problem	Info	Strategy
Many countries don't systematically require quality-assured medicines (WHO Pre-Qualification or stringent regulatory authority (SRA) approval)	Does country require WHO Prequalified or SRA approved medicines?	• Require WHO pre-qualified drugs and diagnostics or SRA approval • Companies have to be incentivised to file for WHO PQ
Preference for local production or packaging could result in suboptimal formulations or poor or unknown quality	Is there a history of local production and/or quality issues?	
Risk of different formulations or presentation of same drugs	Will there be multiple procurement streams due to co-financing?	

Risks: sustained supply

Problem	Info	Strategy
Country might need continued forecasting support (e.g. by GDF for TB drugs)	• History of stock-outs of nationally procured drugs/diagnostics? • Is the national procurement supply management systems adequately supported? • Is there a history of stock-outs?	• Procurement continues through GFATM or GDF for a transition period while countries adapt system, including use of standardised tools • Funding/training for adequate forecasts from national budgets or technical assistance providers (e.g. KNCV, WHO, UNDP, etc.)
Lack of registration impedes suppliers and supply	Is there a history of local production and/or quality issues?	• Transitory importation waivers: till national procurement systems are ready to manage supply of key health products, importation waivers should remain an option to import health products not yet registered locally.

Persistent problem of lack of registered products

PROBLEM

- TB DRUGS
  - Delamanid: Only 7 out of 30 high-burden DRTB countries already granted marketing authorisation or a dossier submitted for registration
  - Bedaquiline: 21 out of 30 high-burden DRTB countries already granted marketing authorisation or a dossier submitted for registration
- HIV
- HCV

NATIONAL INFO

- Is the national drug regulatory authority (NDRA) well capacitated?
- Is country enrolled in WHO Collaborative Registration Procedure?
- Is there expedite registration of SRA approved medicines?

STRATEGY

→Enrol in WHO Collaborative Registration Procedure

→ Recognition of SRA registered medicines through expedited registration

Examples

- Stock-out of first-line TB drugs due to failed domestic tender in one EECA country
- Xpert MTB/RIF cartridges available for USD 10
  - USD 50 – 3 upper middle-income countries in EECA
- Cost of 3rd Line ARV regimen (DRV+RTV+ETV+RAL) 2016
  - Kenya USD 2,470
  - Ukraine USD 17,083
  - Georgia USD 28,760
- Cost of ARV dolutegravir (50 mg) 2017
  - Belarus USD 1,983
  - Concessionary price USD 44 (Aurobindo)
- Single doses instead of fixed-dose combinations in 2 high MDR-TB burden countries in EECA

What GFATM should do

- Carry out national-level assessment of impact of policy changes on procurement, treatment scale-up and prices
- Until the results are available, the GF should allow for a waiver on co-financing requirement for specific medical commodities and countries
- GF should offer or facilitate technical and legal assistance for countries
- GF & others should develop mitigation strategies
- GF develop a roadmap for scaling up access to optimal new preventive options, diagnostics, and treatments