Programmatic Priority objectives – worked example: preventive TB

PP goal *(mission-level, durable)*

Mission-level PP goal: Contribute to expanding access to effective TB preventive treatment from the current 8.7m (2020, and mostly PLHIV) to 30m people by 2035, including for the most vulnerable groups (household contacts, pregnant women and children)

Strategic Objectives

1	2	3
Accelerate the introduction and adoption of key health products	Create systemic conditions for sustainable, equitable access	Foster inclusive and demand-driven partnerships for innovation

Specific PP objectives, linked to SOs *(linked to outcomes of specific investments or actions, more dynamic, subject to change)*

1

Objective 1: support the introduction of **rifapentine (RPT) based regimens** in line with target access profile, incl. pediatric formulation *[--> refer to TAP on next slide]*

Objective 2: continue market shaping leadership, coordinating manufacturer engagement to secure key access conditions for RPT-based regimens as reflected in target access profile (e.g., quality, supply security, price and ped formulation)

Objective 3: support uptake of RPT-based regimens (delivery models) in high-burden countries & target populations

Learning objective: explore what product adjustments might be needed to respond to changes in drug-susceptible TB context

2

Objective 1: Coordinate with WHO PQ & FDA to establish new acceptable limits for impurities

Objective 2: Support lower-cost production of impurities-free API. Consider potential transition to domestic manufacturing

Objective 3: Develop & disseminate public good on overall market-shaping strategy

3

Objective 1: expand coordinated procurement partnership with key global buyers (incl. selected countries) to consolidate market

Objective 2: establish partnerships with in-country, global and regional CSOs to support demand generation for key pops (PLHIV, HHC)

Objective 3: ensure continuous and meaningful engagement of affected communities & civil society, incl. on ongoing efforts to reduce API impurity levels and advocacy with regulators (e.g., FDA) (linked to obj 2)

Cross-cutting objectives, linked to Strat. Principles

- Apply learning from small CSO grants model to enable local & national advocacy and support people & communities in engaging with their own health beyond TB prevention
- Learning objective: explore the extent to which the carbon / environmental footprint of RPT-based regimens could be optimized

Programmatic Priority: Enable TB prevention tools for high-risk groups

Target Access Profile – RPT

Overall Objective

Contribute to expanding access to effective TB preventive treatment from the current 8.7m (2020, and mostly PLHIV) to 30m people by 2035, including for the most vulnerable groups (household contacts, pregnant women and children)

Key product access conditions		Progress against access condition goals (1 2 3 4 5)	Remaining gaps
Create sustainable access conditions	Target Equity Condition O-1 **Evidence exists** to enable wider uptake of rifapentine- (RPT) based regimens among all target populations, incl. the most vulnerable (HHC, pregnant women, children) & for all use cases	• ***Starting point:*** *Efficacy of 3HP in general pop & PLHIV on TLE (non-inferiority to 6H)* • ***End goal:*** *Evidence on all pops incl. tx-naive* • ***Current status:*** *Evidence on PLHIV (DTG & 3HP)*	• Evidence on 3HP use among vulnerable populations (HHC, pregnant women, children) • *(Long-term)* Evidence on long-acting formulations & interaction w/ DTG**
	O-2 **Global and national guidelines recommend** RPT-based regimens for all target populations (incl. HHC, pregnant women, children)	• ***Starting point:*** *Guidelines do not include 3HP** • ***End goal:*** *Guidelines recommend 3HP use among all target groups (incl HHC, PW & children)* • ***Current status:*** *Gx recommend 3HP use among PLHIV, HHC & children*	• Gx recommendation on 3HP use in PW • Implementation guidance on 3HP use in vulnerable groups (HHC, pregnant women, children (<2 yo / <30 kg))
	O-3 RPT-based formulations meet **quality** standards (WHO PQ, SRA/NRA) & are registered in LMICs	• ***Starting point:*** *Innovator product quality-assured* • ***End goal:*** *Adult & ped form. meet qual standards + limit impurities* • ***Current status:*** *FDC (ERP, WHO PQ pending); singles (WHO PQ pending); registration limited to few countries*	• RPT country registration/marketing authorization • API impurities • Quality-approved pediatric formulation
	O-4 Governments / donors regard RPT-based regimens as **affordable and cost-effective** & demonstrate willingness to pay	• ***Starting point:*** *US$ 72/patient course for 3HP* • ***End goal:*** *US$10 /patient course for 3HP & cost-effective price for 1HP* • ***Current status:*** *US$ 15/patient course for 3HP; anticipated drop to US$ 13.50 by end 2022 for 3HP*	• Further market shaping work to bring price down to US$10 / patient course
	O-5 Adequate and diversified supply base for RPT-based regimens exists (multiple suppliers, sufficient quantities) to ensure **supply security**	• ***Starting point: Innovator (supply of 70K patient courses/year)*** • ***End goal:*** *3 generic suppliers + originator + local manufacturing / local production of API without impurities* • ***Current status:*** *2 generic suppliers + originator (3M+ patient crs/ yr)*	• 1 generic supplier and/or local manufacturing/ local production of API without impurities
	O-6 **Appropriate delivery models** have been demonstrated to effectively and efficiently reach all target populations (incl. HHC, pregnant women and children) with RPT-based regimens	• ***Starting point:*** *Only HICs* • ***End goal:*** *Full set of evidence (feasibility, CE, operational) for all target groups & relevant formulations* • ***Current status:*** *Operational evidence on 3HP use (PLHIV) in 12 LMICs*	• Operational evidence for use of 3HP and/or 1HP in HHC, PW, children & LTBI dx • *(Long-term)* Delivery models for long-acting rollout **
	Target Equity Condition O-7 **Availability of appropriate 3HP/1HP formulations** for all target groups	• ***Starting point:*** *Only singles, adult* • ***End goal:*** *Appropriate formulation available for all target groups and use cases* • ***Current status:*** *Singles & FDC*	• Pediatric formulation (<2yo and <30 kg)

◆ starting point ● current status ◆ w/ current investments scaled up ◆ end goal

** Gx came out 3 months after start of Unitaid investment, incl. HHC*
*** Also addressed in "Long-acting & new technologies" programmatic priority*

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