Programmatic Priority objectives – worked example: preventive TB

**PP goal**
(mission-level, durable)

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

**Cross-cutting objectives, linked to Strat. Principles**

**1. Accelerate the introduction and adoption of key health products**

- **Objective 1:** Support the introduction of rifapentine (RPT) based regimens in line with target access profile, incl. pediatric formulation [\(\rightarrow\) 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. Create systemic conditions for sustainable, equitable access**

- **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. Foster inclusive and demand-driven partnerships for innovation**

- **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)

**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**
  - 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

**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**

- **Create sustainable access conditions**
  - **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
  - **O-2** Global and national guidelines recommend RPT-based regimens for all target populations (incl. HHC, pregnant women, children)
  - **O-3** RPT-based formulations meet quality standards (WHO PQ, SRA/NRA) & are registered in LMICs
  - **O-4** Governments / donors regard RPT-based regimens as affordable and cost-effective & demonstrate willingness to pay
  - **O-5** Adequate and diversified supply base for RPT-based regimens exists (multiple suppliers, sufficient quantities) to ensure supply security
  - **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
  - **O-7** Availability of appropriate 3HP/1HP formulations for all target groups

**Target Access Profile – RPT**

<table>
<thead>
<tr>
<th>Objective</th>
<th>Progress against access condition goals</th>
<th>Remaining gaps</th>
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<tbody>
<tr>
<td><strong>O-1</strong> Evidence exists</td>
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* | **Starting point:** Efficacy of 3HP in general pop & PLHIV on TLE (non-inferiority to 6H)
* **End goal:** Evidence on all pops incl. tx-naïve
* **Current status:** Evidence on PLHIV (DTG & 3HP) |
| **Evidence on 3HP use among vulnerable populations (HHC, pregnant women, 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-2** Global and national guidelines | 
* | **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 |
| **Evidence on 3HP use among vulnerable populations (HHC, pregnant women, children)** |
| **RPT country registration/marketing authorization** |
| **API impurities** |
| **Quality-approved pediatric formulation** |

| **O-3** RPT-based formulations meet quality standards | 
* | **Starting point:** US$ 72/patient course for 3HP
* **End goal:** US$51/patient course for 3HP & cost-effective price for 1HP
* **Current status:** US$ 15/patient course for 3HP; anticipated drop to US$ 13.50 by end 2023 for 3HP |
| **1 generic supplier and/or local manufacturing/ local production of API without impurities** |
| **Operational evidence for use of 3HP and/or 1HP in HHC, PW, children & LTBI dx** |

| **O-4** Governments / donors regard RPT-based regimens as affordable and cost-effective & demonstrate willingness to pay | 
* | **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** |

| **O-5** Adequate and diversified supply base for RPT-based regimens exists (multiple suppliers, sufficient quantities) to ensure supply security | 
* | **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)** |

| **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 singles, adult
* **End goal:** Appropriate formulation available for all target groups and use cases
* **Current status:** Singles & FDC |

| **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 |

* **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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**Notes:**
- **Starting point:** No clear start date provided.
- **End goal:** Target dates specified for all conditions.
- **Current status:** Progress against specific goals.
- **w/ current investments scaled up:** Indicators suggesting progress with investment.

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**Additional Information:**
- **Unitaid**
- **WHO PQ, SRA/NRA**
- **PLHIV**
- **HHC**
- **PW**
- **LMICs**
- **API impurities**
- **Feasibility, CE, operational**
- **Long-acting & new technologies**

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**References:**
- Global Guidelines.
- Local Guidelines.
- Implementation Reports.
- Market Analysis Reports.

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**Key Points:**
- Need for expanded access to effective TB preventive treatment.
- Focus on high-risk groups (HHC, pregnant women, children).
- Importance of guidelines, formulations, and supply security.
- Evidence on efficacy and affordability of RPT-based regimens.
- Challenges and gaps in access conditions.
- Strategies and actions to address gaps.

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**Impact:**
- Increased access to TB preventive treatment for high-risk groups.
- Reduced TB incidence among vulnerable populations.
- Improved health outcomes.

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**Next Steps:**
- Continue to monitor progress.
- Address remaining gaps.
- Scale up current investments.
- Explore additional funding opportunities.

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**Assumptions:**
- Data availability.
- Policy and regulatory environment.
- Resource allocation.

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**Limitations:**
- Data limitations.
- Scope and depth of investigation.
- Future external factors.