The role of WHO PQP in establishing healthy markets

Lunchtime briefing by WHO Department of Essential Medicines and Health Products on occasion of 66th World Health Assembly

Geneva, 22 May 2013
A Clear Focus

• HIV/AIDS, TB, malaria
  – Specific co-morbidities where burden of disease is high
• Diagnosis and treatment and prevention products
• 85% of funds to products in low income countries

UNITAID aims to **increase access** by **remediying market shortcomings** through making health products:

• **Available** in sufficient quantities
• **Affordable** to governments, donors, individuals or other payers
• **Quality** is assured at each stage
• **Acceptable** and **adapted** to meet specific populations needs
• **Delivery** of the right product for the right person, to the right place at the right time
1. Simple, point of care (POC) diagnostics
2. Affordable, adapted paediatric medicine
3. Treatment of HIV/AIDS and Co-infections
4. Treatment of malaria (ACT)
5. Treatment of Second line Tuberculosis
6. Preventatives for HIV/AIDS TB and malaria
## Market Dynamics Dashboard

Provides a one-page snapshot of the Secretariat’s assessment of current market dynamics and opportunities across diseases and product types...

### UNITAID Market Dynamics Dashboard

<table>
<thead>
<tr>
<th>Product Sub-type</th>
<th>Access</th>
<th>Current Market Shortcomings*</th>
<th>Opportunity for Intervention***</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Availability</td>
<td>Affordability</td>
</tr>
<tr>
<td><strong>M. Medicines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult first-line</td>
<td>54%</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Adult second-line</td>
<td>~30%</td>
<td>X</td>
<td>XX</td>
</tr>
<tr>
<td>Paediatric</td>
<td>28%</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td>Viral hepatitis C co-infection</td>
<td>TBD</td>
<td>X</td>
<td>XX</td>
</tr>
<tr>
<td><strong>HIV/AIDS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4</td>
<td>&lt;60%</td>
<td>X</td>
<td>XX</td>
</tr>
<tr>
<td>Viral load (VL)</td>
<td>&lt;30%</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td>Early infant diagnosis (EID)</td>
<td>&lt;30%</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td>Male circumcision devices</td>
<td>10% of target</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Female condoms</td>
<td>&lt;1%</td>
<td>--</td>
<td>XX</td>
</tr>
<tr>
<td>Microbicides</td>
<td>0%</td>
<td>XX</td>
<td>--</td>
</tr>
<tr>
<td>Pre-exposure prophylaxis (PrEP)</td>
<td>&lt;1%</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td><strong>Tuberculosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult first-line</td>
<td>66%</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Adult second-line</td>
<td>19%</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td>Paediatric</td>
<td>&lt;50%</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td>Near-POC or POC</td>
<td>40% TB Dx 19% MDR-TB Dx &lt;5% DST</td>
<td>X</td>
<td>XX</td>
</tr>
<tr>
<td><strong>Malaria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult</td>
<td>&lt;20% public &lt;10% private</td>
<td>X</td>
<td>XX</td>
</tr>
<tr>
<td>Paediatric</td>
<td>&lt;20% public &lt;10% private</td>
<td>X</td>
<td>XX</td>
</tr>
<tr>
<td><strong>P. Diagnostics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid diagnostic tests (RDTs)</td>
<td>77% public Minimal private</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>LLINs</td>
<td>21%</td>
<td>XX</td>
<td>X</td>
</tr>
<tr>
<td>Indoor residual spraying (IRS)</td>
<td>~5%</td>
<td>X</td>
<td>XX</td>
</tr>
</tbody>
</table>

* Market shortcomings are described as minimal (−), moderate (●), or severe (○).
** The composite severity of all market shortcomings in each sub-niche is assessed as mild (●), moderate (●●), moderate to severe (●●●), or severe (●●●●).
*** Level of opportunity for UNITAID market intervention, based on practical & strategic considerations defined in UNITAID 2013-2016 Strategy.
†† UNITAID has current ongoing projects
Market Dynamics Dashboard in Detail

Four main elements:

• **Commodity access** estimates

• **Severity of individual market shortcomings**, described as minimal/not present (--) moderate (x), or severe (xx)

• **Composite severity** of all market shortcomings, described as mild, moderate, moderate to severe, or severe

• **Level of opportunity** for UNITAID market intervention, based on practical & strategic considerations defined in Section 5 of the Strategy
Quality Assurance Standards 2006-2013

**Medicines:**
- WHO PQ, SRA, ERP, NRA
- WHO PQ, SRA, NRA
- UTD Medicines supply initiated
- Meds. ERP created
- UTD Dx supply initiated
- UTD QA Framework defined as part of new mandate to create a policy infrastructure for portfolio and grant management within UTD’s broader Business Management System

**Diagnostics:**
- WHO PQ Dx + ISO 13485 (or 9000) + rec. by WHO tech. review + GHTF RA
- Modified “a” + ERPD + other

**Preventives:**
- WHO PQ Dx + ERPD + other

**2006**
- Under development

**2010**
- • Meds. ERP created
- • UTD Dx supply initiated

**2013**
- • Medicines: Same
- • Diagnostics: Modified “a” + ERPD + other
- • Preventives: WHO PQ Dx + ERPD + other

(a)+ Under development
## UNITAID support for prequalification of medicines

### WHO Prequalification

- Since 2009 UNITAID support to WHO PQ programme: **US$ 58M**
- **Objective:** to increase the number of prequalified UNITAID priority medicines for HIV/AIDS, TB and malaria and:
  1. increase competition and capacity in production
  2. facilitate the development of NRA capacity
  3. accelerate testing

### Achievements

- Projected **return on investment** of 170:1 US$ spent on PQ
- 89 **FPPs** prequalified since 2009
- 28 **APIs** prequalified
- 19 Medicines **Quality Control Laboratories** prequalified
- Training for > 400 regulatory participants, > 100 QCL participants and > 900 manufacturing company participants

### Challenges

- Still too many formulations on current invitations for EOIs for which no or too few products have been prequalified.
- Need a **sustainable approach** for PQ financing and national regulation in the medium to long term