Basics of access to medicines for hepatitis programme managers

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Access to Generic Medicines

What is “Access”?

What are the barriers of access?

How to expedite and promote access?
Access: The Five Rights

WHO Definition: The equitable availability and affordability of essential drugs

To provide “Access”, countries need to provide:

- The right *products*
- At the right *price*
- In the right *quantities*
- In the right *places*
- At the right *time*
From Access to Uptake

**Access**

- **High-quality generic** DAAs are now available at affordable prices
- There are **more than 24 generic formulations of DAAs** in LMICs
- By 2015, only **275k patients** in LMICs were treated with DAAs
- By the end of 2016, **more than 1 million** patients were initiated on DAA treatment in LMICs

**Uptake**

- Pricing for DAAs **varies widely** from country-to-country ($100 to $1,200 per treatment course)
- There are still more than **50 million** chronic-HCV untreated in LMICs

Source: WHO Global report on access to hepatitis C treatment, 2016
Why Doesn’t Access Happen Naturally?

Demand-Side Needs

Products that meet the needs of resource-limited settings in terms of quality, formulation, and price, to enable patient scale-up

Supply-Side Needs

A reliable, transparent, marketplace for commodities that provide ongoing growth opportunities

High quality, affordable drugs

Predictable, sustainable volumes
Critical Steps for Product Uptake

- Product Uptake
- Political Buy-in & Stakeholder Engagement
- Product Registration
- Supply Planning & Procurement
- Facility-Level Uptake
- Monitoring

New product available
Product Adoption
Five Lenses Approach

What are the key considerations for introducing a new product?

- Dosing schedule
- Pill burden
- Administration
- Availability as an FDC
- Current pricing
- Future pricing
- Related costs
- Development pipeline
- # of suppliers
- Marketplace concerns
- Efficacy
- Toxicities
- Side effects
- Contraindications
- Durability
- Drug interactions
- Special populations
- HCW training & comfort
- Country capacity
# Political Buy-in & Stakeholder Engagement

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>OVERVIEW</th>
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<tbody>
<tr>
<td>Government and MOH</td>
<td>Lead the uptake effort, develop implementation plans, and coordinate other stakeholders</td>
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<tr>
<td>Global Partners &amp; Donor Agencies</td>
<td>Provide funding and coordination for commodity procurement</td>
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<tr>
<td>Procurement Partners</td>
<td>Coordinate procurement, promote supply security, and ensure product availability</td>
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<tr>
<td>Local Implementing Partners</td>
<td>Assist with treatment at national and local level; coordinate clinical evidence, messaging, and rollout activities</td>
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<tr>
<td>Civil Society &amp; Community Representatives</td>
<td>Provide support for community engagement, generate demand, improve treatment literacy</td>
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## Product Registration

<table>
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<tr>
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<th>LOCAL REGISTRATION</th>
<th>REGISTRATION WAIVERS</th>
<th>EXPEDITED REVIEW PROCESS</th>
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<tr>
<td>1</td>
<td>Suppliers file dossiers with NDRA for registration of new products. Registration enables donors &amp; governments to procure and import the product in-country for use.</td>
<td>Can be used to import products that have SRA-approval but not yet NDRA approval. Waivers help avoid delays in patient access while registration with NDRAs is pending.</td>
<td>Some NDRAs may allow for a reduced approval timeline for products that are a public health priority. MOH should work with NDRA to justify priorities and help prioritize dossiers for review.</td>
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<tr>
<td>Timeline: Depending on country, 6 to 24 months</td>
<td>Timeline: Varies by country</td>
<td>Timeline: Depending on country, ~6 months</td>
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Product Registration
Common Bottlenecks

Quality
- High number of poorly compiled or incomplete applications strain available assessors
- Similar looking packaging as a result of applications submitted during different time periods
- Not providing samples to the NDRA or pharmacy board

Packaging
- Look alike tablets and capsules due to lack of standardized presentation of dosage forms

Samples
- Evaluation delays due to the lack of information on new and novel products, especially by innovators

Process Delays
- Analysis delay due to lack of information on new analytical methods and reference standards provided to local labs
- Lengthy waiver process especially where pharmacy boards/task teams exist (no NDRA)
Supply Planning & Procurement

Quantification Process

Supply Planning & Procurement

Procurement Considerations

Some mechanism and arrangements that countries might consider:

• **Long-term agreements (LTAs)** – Arrangement that locks in pricing but allows flexibility in quantities as needed

• **Split volumes** – Award a contract to multiple suppliers to provide supply security and prevent

• **Incoterms and other associated costs** – Understand what the total cost will be including shipping, customs, storage, distribution

• **Lead times** – Understand past supplier performance and remedial actions available; Factor in transport, clearance, last-mile delivery
## Facility-Level Uptake: Catalysing Product Use

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<tr>
<th>I. Facility-Level Plans &amp; Targets</th>
<th>Government and MOH to define patient groups, eligibility, and targets. Progress against these plans should be monitored.</th>
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<tr>
<td>II. Availability &amp; Supply</td>
<td>Ensure facilities have starting stock of drugs and a process to report and reorder. Closely monitor consumption to minimize stock outs or wastage.</td>
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<td>III. HCW Training &amp; Mentorship</td>
<td>Training can be done using a cascade or training-of-trainers approach. Mentoring should be planned to provide ongoing support and identify questions or issues that arise.</td>
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<tr>
<td>IV. Patient Engagement</td>
<td>Engage HCWs, implementing partners, and community groups to educate patients and create demand. Continue regular communication as program develops.</td>
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Monitoring

**SUPPLY MONITORING**
Ensuring patient consumption and stock availability are coordinated and data is used to revise forecasts on a regular basis.

**PATIENT MONITORING**
Monitoring and engaging patients through the cascade of care to ensure they reach cure. Ensuring quality service delivery.

**PHARMACO-VIGILANCE**
Detection, assessment, understanding, prevention and follow-up of any adverse effects or drug-related problems.