

**Facilitating Policy Decisions for Affordable & Equitable Access to
HCV Treatment in Africa
INHSU Africa 2020**

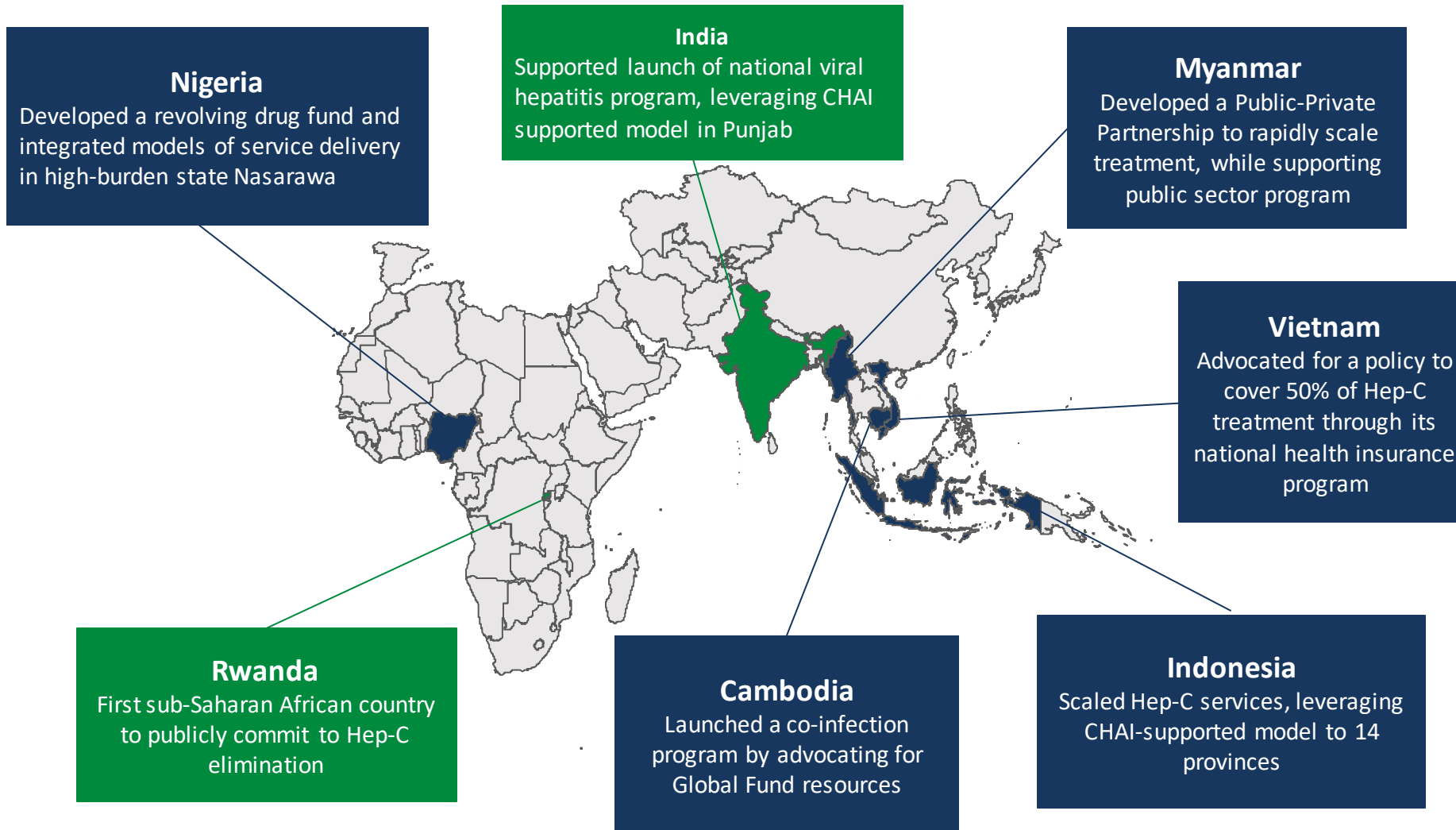
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1. Ensuring Affordability

2. Ensuring Equity

CHAI provides 7 countries with technical assistance in scaling-up public viral hepatitis programs



 **On a path to**
 **Early scale-up stage**

WHO definition of “Access” and the 5 rights

WHO Definition: The equitable availability and affordability of essential drugs (and diagnostics)

To enable “Access”, countries need to provide:

- ❖ The right products ✓
- ❖ At the right price ✓
- ❖ In the right quantities ✓
- ❖ In the right places ✓
- ❖ At the right time ✓

Why doesn't affordable access to treatment 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

Timely drug and diagnostic registration is essential to accessing products at competitive prices

GOOD PRACTICES: DRUG AND DIAGNOSTIC REGISTRATION

1

PRIORITIZE LOCAL REGISTRATION

Encourage suppliers to file dossiers with NDRA for registration of new products, enabling donors & governments to sustainably procure and import the product.

2

UTILIZE REGISTRATION WAIVERS

Consider issuing waivers to suppliers while their dossiers are under review by NDRA for products that already have SRA approval or WHO PQ.

3

EXPLORE OPTIONS FOR EXPEDITED REVIEW

Advocate for NDRA to prioritize registration of products that are a public health priority or grant approvals based on NDRA partnerships.

Drug Waivers were utilized by Nigeria, Vietnam, Indonesia and Myanmar, to expedite access to daclatasvir, facilitating a simplified public health approach.

Zambia and Botswana have used the WHO's Collaborative Drug Registration System to register sofosbuvir.

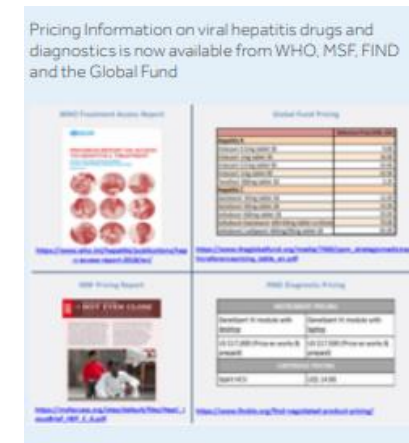
A detailed and transparent quantification and forecast of drug and diagnostic commodity needs facilitates healthy markets and lower pricing

GOOD PRACTICES: COMMODITY QUANTIFICATION AND FORECASTING

- 1 Plan in advance
- 2 Solicit stakeholder input
- 3 Gather latest pricing intel
- 4 Update assumptions/inputs on regular basis
- 5 Share outputs and updates on a regular basis

Commodity Price Transparency

Up to date pricing intel can be found through online resources from WHO, MSF, FIND, and GFATM.



Rwanda Commodity Forecast Example



Optimize procurement to secure the best pricing and ensure supply stability

GOOD PRACTICES: PROCUREMENT

- **Centralized procurement**, as demonstrated in Rwanda, can achieve low pricing
- **Pooled procurement** is an alternative option to leverage volume discounts
- **Communication** to suppliers on procurement plans is key to ensuring participation
- **Long-term agreements (LTAs)** can lock in pricing but allow flexibility in quantities as needed
- **Splitting tenders** can incentivize multiple suppliers to improve service capacity and capabilities

Leveraging pooled procurement of DAAs has been used to lower pricing:

- 1) **UNDP procurement** in Ukraine and Kazakhstan to \$89 per course
- 2) **GFATM procurement** reference pricing is now as low as \$79 per course

Agenda

1. Ensuring Affordability

2. Ensuring Equity

To ensure access equity, specific needs must be represented in program design and roll-out

Technical Working Groups (TWGs) are an important component of policy development and can be effective in influencing MOH decision-making. Substance user representation within viral hepatitis TWGs is important in ensuring that MOH policy reflects their needs.

Key Policy Actions/Considerations:

1. Advocate for the MOH to coordinate a national-level TWG on viral hepatitis that meets on a regular basis;
2. Advocate that TWGs include a diverse set of members including representatives from patient groups that support people who use drugs and service providers with experience/expertise in substance user health.

Strategic and operational planning

National Strategic Plans dictate how public programs design, fund and roll-out services...input from the substance user community and SMEs in this process is key to ensuring equitable access.

Key Policy Actions/Considerations:

1. Request input into the National Strategic Plan development process through the national-level TWG;
2. Specify what programmatic provisions must be made to ensure access to services for people who use drugs across the cascade (from surveillance and prevention—including harm reduction—through diagnosis and cure);
3. Provide accurate costing inputs on these activities so that program managers can accurately account for what resources will be needed to provide services.

Clinical guideline development and health care worker training

Published clinical guidelines and training curricula determine how health care workers actually provide services to the population...without proper guidance on providing care to people who use drugs, programs risk of leaving them out of the response altogether.

Key Policy Actions/Considerations:

1. Provide guideline committees with the latest research on the importance of providing treatment and prevention/harm reduction for people who use drugs;
2. Ensure that clinical guidelines include specific language on the safety, efficacy and benefits of DAA therapy for people actively using drugs, including need for treatment of reinfection if necessary
3. Ensure that training modules and job-aides include specific and locally contextualized content for how to provide quality care to people who use drugs.

Monitoring and Evaluation

M&E logframes should include indicators on service provisions for substance users to ensure program accountability and that decision-making is driven by data.

Key Policy Actions/Considerations:

1. Lobby for program M&E logframes to include indicators on service delivery to people who use drugs;
2. Support program data collection efforts (if necessary) to inform decision-making;
3. Ensure that TWGs meet annually with program managers to discuss performance against indicators and adjust programming accordingly.

Including HCV diagnosis and treatment in the GFATM 2020 concept note process is key to increasing access (1/2)

CCMs should include requests for HCV diagnosis and treatment through harm reduction and ART programs within country concept notes submitted to GFATM for approval in 2020.

Key Policy Actions/Considerations:

1. Lobby for country coordinating mechanisms to include provisions for HCV screening, confirmation viral load testing and DAAs through both harm reduction programs and ART programs;
2. If there isn't room within the available allocation, HCV support should be included in the ***Prioritized Above Allocation*** section of the concept note, which will allow GFATM to fund HCV projects with underspend (should it become available) on a rolling basis.

Including HCV diagnosis and treatment in the GFATM 2020 concept note process is key to increasing access (2/2)

Quantification of HCV commodities for concept notes will depend on the country context, but commodity price assumptions should follow the below guidance based on pricing already achieved by countries:

- **Drugs:** Follow the latest GFATM HCV reference pricing of USD \$79 per 12 week course of WHO Prequalified sofosbuvir/daclatasvir fixed dose combination and USD \$93 per 12 week course of WHO Prequalified sofosbuvir/daclatasvir (ref pricing found at https://www.theglobalfund.org/media/7500/ppm_strategicmedicineshivreference_pricing_table_en.pdf)
- **Screening Kits:** USD \$1 or less per WHO Prequalified rapid diagnostic kit
- **Viral Load:** The Global Fund is able to procure HCV viral load kits at **the same price as HIV viral load kits**. Pricing for HCV viral load kits will vary depending on what suppliers and platforms are being used by each country's HIV program.

4 Key Take-Aways

1. Registration of multiple dx and tx suppliers, accurate quantification of commodity needs and a well coordinated procurement process are key components to healthy markets and lower pricing;
2. Representation in TWGs is critical to getting the right policies adopted;
3. Incorporate specific provisions for substance users in strategic planning, clinical guidance and M&E processes to ensure sustained action and accountability.
4. Incorporating HCV diagnosis and treatment in the GFATM 2020 concept note process is critical to expanding access.