

2017



HIV NEW PRODUCT INTRODUCTION GUIDE

A FRAMEWORK FOR SUPPORTING NEW PRODUCT
INTRODUCTION IN NATIONAL HEALTH SYSTEMS

ABOUT CHAI

Founded in 2002 by President William J. Clinton and Ira Magaziner, the [Clinton Health Access Initiative](#) (CHAI) is a global health organization committed to strengthening integrated health systems around the world and expanding access to care and treatment for HIV/AIDS, malaria and other illnesses. Based on the premise that business-oriented strategy can facilitate solutions to global health challenges, CHAI acts as a catalyst to mobilize new resources and optimize the impact of these resources to save lives via improved organization of commodity markets and more effective local management. By working in association with governments and other non-governmental organization (NGO) partners, CHAI is focused on large scale impact and, to date, CHAI has secured lower pricing agreements for treatment options in more than 70 countries. In addition, CHAI's teams are working side-by-side with over 30 governments to tackle many of the largest barriers to effective HIV treatment and care.



ABOUT CHAI'S HIV ACCESS PROGRAM

Since its start in 2002, CHAI has been a leader in expanding access to HIV treatment, reducing the cost of drugs and diagnostics, and strengthening the capacity in high burden countries to combat HIV/AIDS. [CHAI's Access Program](#) works to address barriers to commodity access and to foster a healthy marketplace, fundamentally changing the economics of global health to ensure the sustainable supply of essential medicines and diagnostics. By securing lower prices for key commodities and improving diagnostic capabilities in the developing world, we are helping patients access the life-saving treatment and care they need. As a result of our portfolio of access program work, CHAI has an extensive network of staff with expertise in drug and diagnostics development and production, technology assessments, public health management, market dynamics, new product introduction, data management, supply chain, and government and civil society partnerships.

ACKNOWLEDGEMENTS

CHAI's work to accelerate access to optimal antiretrovirals (ARVs), and develop this handbook, is made possible by the generous support and partnership of [Unitaid](#) through the CHAI-Unitaid Optimal ARV Project.



Unitaid is an international organization that invests in new ways to prevent, diagnose and treat HIV/AIDS, hepatitis C, tuberculosis and malaria more quickly, more affordably and more effectively. It accelerates access to innovation so that critical health products can reach the people who most need them. Unitaid's work facilitates large-scale introduction of health products through funding by the Global Fund, the United States President's Emergency Plan for AIDS Relief (PEPFAR) and by governments. Learn more about the CHAI-Unitaid collaboration [here](#).

ACRONYMS

| | |
|-----------------|--|
| ADR | Adverse Drug Reaction |
| AFROCAB | African Community Advisory Board |
| AMC | Average Monthly Consumption |
| AMRH | African Medicines Registration Harmonisation Programme |
| API | Active Pharmaceutical Ingredient |
| APIPO | CHAI ARV Phase-In/Phase-Out Tool |
| APWH | ARV Procurement Working Group |
| ART | Antiretroviral Therapy |
| ARV | Antiretroviral |
| ATV/r | Atazanavir/ritonavir |
| CAB | Optimal ARV Community Advisory Board |
| CCM | Country Coordinating Mechanism |
| CHAI | Clinton Health Access Initiative |
| CME | Continuing Medical Education |
| COP | PEPFAR Country Operational Plan |
| CSD | Clearance, Shipping and Distribution |
| DDP | Delivered Duty Paid |
| DTG | Dolutegravir |
| EAC | East African Community |
| EGPAF | Elizabeth Glaser Pediatric AIDS Foundation |
| EMA | European Medicines Agency |
| EOI | Expression of Interest |
| ERP | WHO Expert Review Panel |
| EXW | Ex-Works |
| FDA | United States Food and Drug Administration |
| FDC | Fixed-Dose Combination |
| GHSC-PSM | Global Health Supply Chain Program-Procurement and Supply Management |
| HCW | Healthcare Worker |
| ICW | International Community of Women Living with HIV |
| ITPC | International Treatment Preparedness Coalition |
| KEMSA | Kenya Medical Supplies Authority |
| LFA | Local Fund Agent |
| LMIC | Low- and Middle-Income Countries |
| LPV/r | Lopinavir/ritonavir |
| MOH | Ministry of Health |
| MPP | Medicines Patent Pool |
| MSF | Médecins Sans Frontières |
| NDOH | South Africa National Department of Health |
| NDRA | National Drug Regulatory Authority |
| NEPHAK | National Empowerment Network of People Living with HIV/AIDS in Kenya |
| NGO | Non-Governmental Organization |
| OGAC | U.S. Global AIDS Coordinator and Health Diplomacy |
| PEPFAR | United States President's Emergency Plan for AIDS Relief |
| PFSCM | Partnership for Supply Chain Management |
| PK | Pharmacokinetic |
| PLHIV | People Living with HIV |
| PPP | Public-Private Partnership |

| | |
|----------------|---|
| PPM | Global Fund Pooled Procurement Mechanism |
| PV | Pharmacovigilance |
| R | Ritonavir |
| SADC | South African Development Community |
| SRA | Stringent Regulatory Authority |
| STG | Standard Treatment Guidelines |
| TDF | Tenofovir Disoproxil Fumarate |
| TLD | Tenofovir Disoproxil Fumarate/Lamivudine/Dolutegravir |
| TLE 400 | Lower-dose Efavirenz |
| TWG | Technical Working Group |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| USG | U.S. Government |
| WHO | World Health Organization |
| WHO PQ | WHO Prequalification |

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INTRODUCTION

Over the past two decades, the landscape of medications used to treat HIV has evolved rapidly. Treatment options have improved dramatically with the development and availability of more efficacious, safer, and more tolerable antiretrovirals (ARVs). These options allow national treatment programs to better serve the needs of their patients, support significant treatment scale-up, reduce costs, and achieve public health goals. Use of the most optimal regimens and products offers many benefits to national HIV programs and people living with HIV (PLHIV), including:

- **Improving quality of patient care** and effectiveness of national treatment programs through improved clinical outcomes, reduced side effects, and improved patient convenience, tolerability and adherence;
- **Enabling the continued scale-up of treatment** despite funding constraints through less costly products, and ultimately;
- **Enhancing the sustainability** of overall public health programs by providing more efficacious and affordable regimens.

Accelerating the availability of new, optimal ARVs and expanding treatment coverage are major priorities for patients and governments in low- and middle-income countries (LMICs). Facilitating rapid access to these products will reduce patient morbidity and mortality while at the same time enhancing the long-term viability of public health programs in reaching the [90-90-90 targets](#) set by the Joint United Nations Programme on HIV/AIDS (UNAIDS). The process of adopting new ARV products requires significant strategic planning and coordination across national and international stakeholders.

The **HIV New Product Introduction Guide** outlines key considerations for introducing new ARV products. This guide provides a framework for ministries of health (MoHs) and partners to guide the product adoption, phase-in planning, and implementation process. The framework is not intended to be a “one size fits all” approach, but should provide approaches and tools that can be tailored to meet local needs and context. While this framework focuses on ARVs, it can also be applied to other health commodities.

With the World Health Organization’s (WHO) recent inclusion of dolutegravir (DTG) and lower-dose efavirenz (TLE400) as alternate first-line regimens, and availability of tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) as a fixed-dose combination (FDC), countries are moving towards large scale shifts in first-line products. Further, several optimal pediatric products are being rolled out across LMICs, with additional new products in the development pipeline for a small treatment population. Development, implementation and monitoring of detailed, systematic product introduction strategies is critical to ensuring smooth product transitions. The approaches and tools in this guide and the accompanying [HIV New Product Introduction Toolkit](#) are designed to help MoHs to direct and manage the transition process.

HOW TO USE THIS GUIDE

The HIV New Product Introduction Guide provides a framework and explanation of key approaches, available tools and best practices for new product introduction, and supplements the online [HIV New Product Introduction Toolkit](#), which features tools that can be leveraged when introducing a new product in-country. The guide and toolkit contain a wide range of information, tools, and resources spanning the entire chain of product introduction, including product adoption, forecasting, procurement, rollout, and supply planning and monitoring.

The guide is organized according to CHAI's New Product Introduction Framework. Although the steps in this process are illustrated sequentially, in practice many of these steps are best conducted in parallel and some, such as stakeholder engagement, should be ongoing throughout the entire introduction process.

Figure 1. CHAI's New Product Introduction Framework



Source: CHAI HIV Access Program, 2017.

Through the content in this guide, users should gain a high-level understanding of the key considerations when adopting and rolling out new HIV products and have access to resources to support implementation. As MoHs, CHAI, and partners continue to gather lessons learned from new in-country product introductions, the [HIV New Product Introduction Toolkit](#) will be continuously updated and we welcome partners to submit their resources for inclusion in the toolkit. For more information or to contribute resources and tools, please contact: HIVToolkit@clintonhealthaccess.org.

PRODUCT ADOPTION AND DECISION-MAKING



Supporting a Ministry of Health's decision to incorporate products into national guidelines

IN THIS CHAPTER

- 1.1 Product Adoption Considerations: The Five Lenses Approach
- 1.2 Building the Adoption Case
- 1.3 Ministry of Health and Stakeholder Engagement
- 1.4 National Guidelines Revision
- 1.5 Key Challenges and Mitigation Strategies
- 1.6 Resources and Tools for Product Adoption and Decision-Making

Programs should assess the clinical, programmatic and cost benefits and implications when making decisions about whether to adopt new products into national treatment programs and guidelines. To guide the adoption of new products, programs should work collaboratively with the Ministry of Health (MoH), partners, and groups representing the interests of people living with HIV (PLHIV).

PRODUCT ADOPTION AND DECISION-MAKING CHECKLIST

- ✓ Evaluate the **benefits and considerations** of new products using the **five lenses approach**
- ✓ **Gather key information** on the new product to **build a case** for its adoption and introduction
- ✓ Build consensus on product adoption priorities by engaging key **stakeholders and decision makers** utilizing existing forums such as technical working groups (TWGs)
- ✓ Conduct **guidelines analysis and costing evaluation**; e.g., using the CHAI WHO Guidelines Costing Tool
- ✓ Update **national treatment guidelines** based on new product decisions

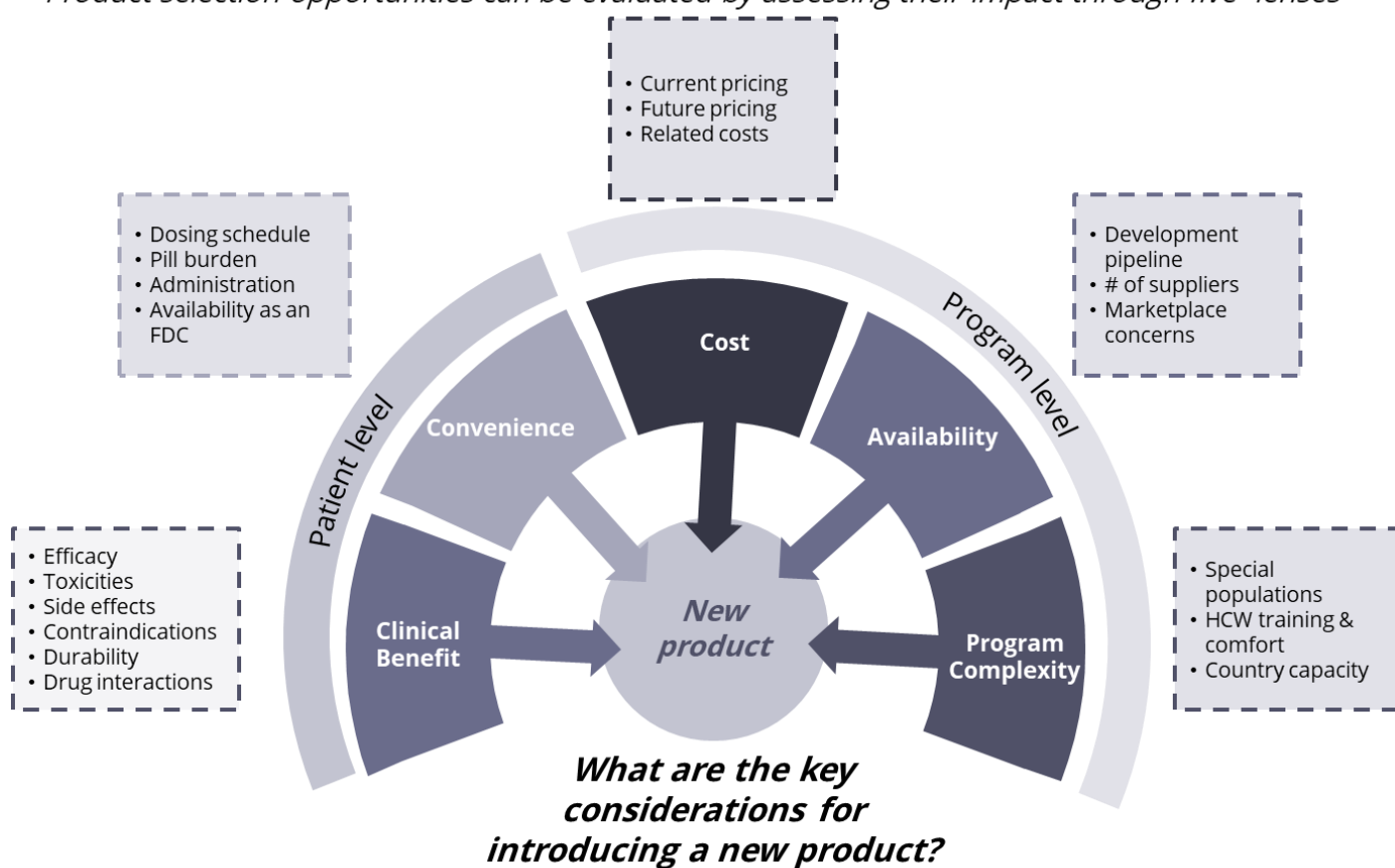
1.1 PRODUCT ADOPTION CONSIDERATIONS: THE FIVE LENSES APPROACH

In order to make decisions on a product, MoHs and partners need to weigh the relative benefits and phase-in considerations of the new product in comparison with continued use of existing regimens or formulations or other available alternatives. After identifying and weighing benefits such as improved efficacy, and considerations such as limited data on use in special populations, stakeholders can take a balanced view to reach consensus about whether or not to adopt a product in-country.

Product adoption decisions can be viewed through five lenses that relate to implications for individual patients and for the broader treatment program. The five lenses include: Clinical Benefits, Convenience, Cost, Availability, and Program Complexity. The impact of new products can be assessed according to each of these lenses, as outlined in the Five Lenses Approach chart in the following page.

Figure 1. New Product Evaluation – The Five Lenses Approach

Product selection opportunities can be evaluated by assessing their impact through five “lenses”



Source: CHAI HIV Access Program, 2017.

1.2 BUILDING THE ADOPTION CASE

Developing a comprehensive product adoption case that aligns with the five lenses approach and outlines all of the key clinical, programmatic, cost benefits and implications of adoption, as well as the latest market and availability data, can help stakeholders to conduct an informed discussion about the options available to treatment programs. Critical information that should be included in the product adoption case includes:

1 International guidance on new products, including treatment guidelines: The most widely applied recommendations for use of antiretrovirals (ARVs) are the World Health Organization (WHO) HIV Care and Treatment Guidelines, available [here](#). Other relevant information may include looking at guidelines in use in neighboring countries and national treatment guidelines in high income markets, where optimal products usually come to market more quickly than in low- and middle-income countries (LMICs).

2 Clinical Trials: Summaries on [clinical trials or studies](#) conducted on new ARV products, including full details of the studies, findings, and recommendations. Specific information from the studies could include clinical efficacy, pharmacokinetic (PK) studies, toxicity profiles, and adverse events. CHAI maintains a repository of relevant clinical studies for key new products, and summarizes key trials in product [clinical memos and regimens aides](#).

3 Comparative advantage of new products: Detailed analysis of the comparative advantages, as they relate to clinical efficacy, patient convenience, cost, availability, and simplicity for the national program (see table below), of the new product against those already available in country, or available alternatives.

4 Regulatory Status: Information on regulatory approvals [WHO Prequalification of Medicines Programmed \(WHO PQ\)](#), [United States Food and Drug Administration \(FDA\)](#), and the relevant [national drug regulatory authority \(NDRA\)](#). The [CHAI Stringent Regulatory Authority \(SRA\) Approvals Database](#) records approvals of HIV medicines by [WHO PQ and FDA tentative approval](#). National regulatory approvals may be available on local NDRA websites, through committee minutes or through direct request for approval status of priority products.



Photo Credit: Clinton Health Access Initiative, Inc.

5 Market Intelligence: Information on the latest developments and global outlook for the ARV marketplace and product pipeline, such as the [CHAI ARV Market Report](#), an annual report developed by CHAI's HIV Market Intelligence Team. In addition to a global report, the team also publishes regional-specific reports on the ARV marketplace in [Eastern Africa](#), [Southeast Asia](#), [West and Central Africa](#), and [Southern Africa](#).

6 Transition Scenarios: Leverage analytic tools, such as the [CHAI WHO Guidelines Costing Tool](#) (highlighted below), to evaluate uptake and budget scenarios. These scenarios can be based on a variety of strategies, including national scale-up targets, or targeting special populations for phase-in/phase-out. Learn more about the CHAI WHO Guidelines Costing Tool in the section below.

1.3 MINISTRY OF HEALTH AND STAKEHOLDER ENGAGEMENT

Engagement of all key stakeholders and decision makers is critical to building consensus around product adoption and introduction decisions. Mapping and understanding the key decision-makers and influencers is critical to ensuring all key audiences are included in the review and decision-making process. Often there is a dedicated TWG governing the HIV treatment program, which reviews and makes such decisions. Key stakeholders to include in the consultation or engagement process include:

- 1. MoH Program Leads:** Coordinate initial meetings with key program managers in the MoH HIV treatment program to introduce the new ARV product, share the full technical details of the new ARV product and get support for including discussion on the new product in TWGs or relevant committees.
- 2. Procurement and Implementing Partners:** Utilize opportunities at national forums where key implementing partners, the clinical community, and donor agencies meet to share information on the new ARV product.
- 3. Supply Chain Departments:** Schedule meetings with the logistics department or supply chain teams, national central medical stores, and regional warehouses to share information focusing on supply chain considerations.

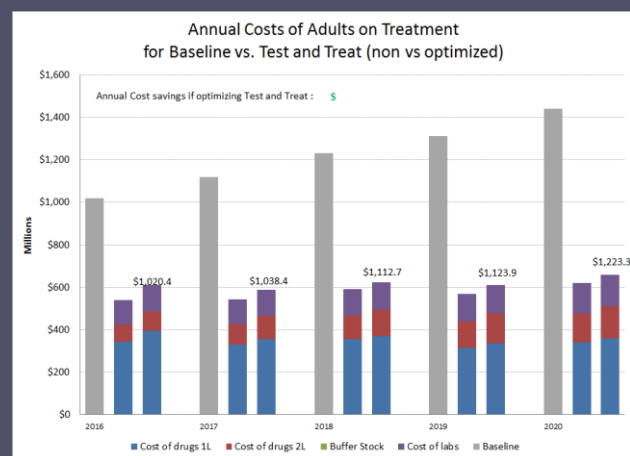
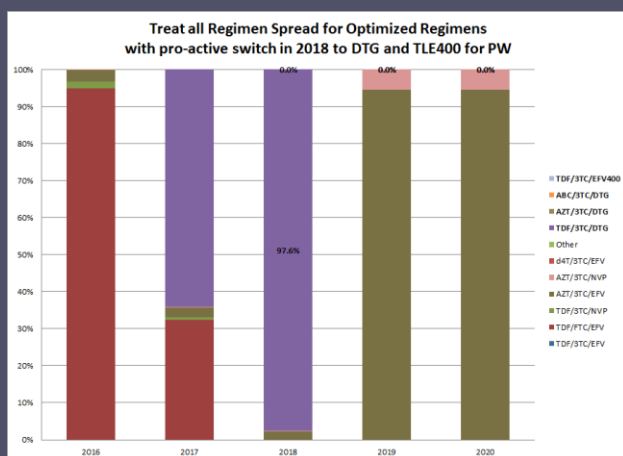
4. **Representatives of PLHIV:** Engage with representatives of PLHIV to understand the community's perspective and to get feedback on the new product.
5. **Clinicians and healthcare workers (HCWs):** Clinicians and healthcare workers should be involved throughout the decision-making process to provide insights on clinical practices, challenges, and opportunities. Involvement by prescribers from the early stages of information sharing can also promote uptake and usage of the product when it becomes available in country.
6. **Minister of Health:** Once decisions have been made by relevant guidelines committees, Ministers may need to be briefed or sign off on the guidelines committee's decision.



FEATURED TOOL: CHAI WHO Adult, Adolescent, Pediatrics Guidelines Costing Tool

To inform evidence-based policy decisions, developing a phase-in strategy and budgetary impact analysis for implementing a new product, and comparing costs of comparative product adoption and phase-in scenarios, can assist decision-making.

The **CHAI WHO Guidelines Costing Tool** helps programs make decisions about how to adopt WHO-recommended regimens and model different scale-up scenarios for patient scale-up and new product uptake. The use of the tool is facilitated by trained CHAI staff and allows program managers to assess and compare different scenarios to answer policy questions for adults, adolescent, and pediatric guidelines. Outputs of this tool include: Costs of ARV drugs, lab commodities, and required facility-level human resources under comparative scale-up scenarios. Below are two screenshots of outputs from the tool including annual costs of adults on treatment for baseline vs test and treat, and treat-all regimen spread for optimized regimens with proactive switch in 2018 to DTG and TLE400 for PW. To learn more about the CHAI WHO Guidelines Costing Tool, and for technical support to conduct this analysis, please reach out to HIVToolkit@clintonhealthaccess.org. Watch for an open access version of the tool, coming soon!



Output examples from the CHAI WHO Guidelines Costing Tool

1.4 NATIONAL GUIDELINES REVISION

Once product adoption decisions have been made by the relevant committees and decision makers, national guidelines or guidance should be updated to communicate to HCWs how the product can be used for treatment when available. Typically, this involves revision of the national treatment guidelines by a committee of technical experts. However, given that these are large documents and are updated every two to five years, many MoHs choose to issue circulars to healthcare workers to govern use of new products when they become available in between guideline updates.

Many countries also have Standard Treatment Guidelines (STGs) that define what products and services should be available at each level of the health system across all disease areas. Programs should work with the relevant committees to make sure changes in national HIV guidelines are reflected in the STGs.

1.5 KEY CHALLENGES AND MITIGATION STRATEGIES

The below table provides a high-level summary of the challenges in product adoption and decision-making, in addition to the various ways MoHs, partners, and suppliers can play a role in mitigating those challenges.

| Challenges | SUPPORT STRATEGIES | | |
|---|---|--|---|
| | MoH/Buyers | Partners | Suppliers |
| <p>Lack of information: Insufficient knowledge about clinical efficacy, pricing and availability or lack of clinical studies to support adoption.</p> <p>Delayed/Infrequent review of country guidelines</p> <p>Supply capacity: Lack of supplier capacity, causing supply security concerns.</p> <p>Notable downsides for the product: For example, pricing.</p> | <p>Timelines: Develop clear criteria, process, and timelines for new product adoption.</p> <p>Due diligence: Conduct sufficient research and analysis of information on new products to ensure enough evidence is available to support decision-making.</p> <p>Technical working groups: Assign a working group responsible for new product assessment and adoption decisions.</p> | <p>Partner coordination: Support advanced discussions with key opinion leaders.</p> <p>New product tools and aides: Summarize product benefits and risks.</p> <p>Information sharing: Improve visibility between MoH and suppliers.</p> | <p>Accessible data: Make product data easily accessible and communicate capacity and lead times transparently.</p> <p>Comprehensive product timelines: Provide enough clarity and information on product availability timelines and address supply capacity challenges.</p> |

Source: CHAI HIV Access Program, 2017



CLINICAL ACTION MEMOS AND INFORMATIONAL BRIEFS

[APWG ABC/3TC \(120/60 mg\) Tablet Informational Brief \(ENG, ESP, FRA\)](#)

This informational brief provides ART program managers, implementing partners, clinicians, procurement and supply chain managers, and other relevant stakeholders with key points to consider regarding the introduction of the scored, ABC/3TC 120/60mg tablet.

[CHAI Accelerating Access to Dolutegravir & Other Optimal ARVs - IAS 2017](#)

An overview on the importance of accelerating optimal ARVs, including dolutegravir (DTG), for scaling up effective treatment. The presentation also highlights practical steps for facilitating and introducing new ARVs in LMICs. This slidedeck was presented at the 2017 IAS Conference on HIV Science in Paris, France in July 2017.

[CHAI ATV/r Clinical Memo](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, phase-in strategies, and FAQs for ATV/r, including all clinical trial information.

[CHAI ATV/r vs LPV/r Product Memo](#)

This memo outlines the current state of knowledge for ATV/r and rationale for its selection as the preferred PI option for second-line therapy. This memo is also intended to educate decision-makers responsible for product selection by addressing common clinical and programmatic questions around the use of ATV/r.

[CHAI DRV/r Clinical Action Memo](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, phase-in strategies, and FAQs for DRV/r, including all clinical trial information.

[CHAI TLD and TLE400 Phase-In Decision-Making Tool](#)

A tool used to assist national programs to determine which products to rollout for specific patient populations.

[CHAI TLD Clinical Action Memo](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, phase-in strategies, and FAQs for TLD, including all clinical trial information.

[PEPFAR ARV Formulation Priorities](#)

A list of ARV formulation priorities for PEPFAR. This report could be used to communicate a message to assist pharmaceutical manufacturers in strategically targeting investments towards formulations that will be in high demand from PEPFAR-supported countries. Similarly, this report could be used in countries during discussions to determine modifications of national HIV treatment guidelines.

NORMATIVE GUIDANCE

[WHO Guidelines](#)

A comprehensive list of approved guidelines on HIV/AIDS.

[WHO Transition to new antiretrovirals in HIV programmes](#)

This policy brief provides advice on a phased approach to transitioning to new WHO-recommended HIV treatment regimens. The aim is to ensure a continuous supply of ARVs, safely, rapidly and efficiently implement the 2016 WHO guidelines and enable a smooth transition to optimized ARV

regimens. The target audience includes country HIV program managers, procurement agencies, implementing partners, and other relevant parties.

[WHO Guidelines on the public health response to pretreatment HIV drug resistance](#)

This publication provides guidance on the public health response to pretreatment HIV drug resistance to NNRTIs among people without prior ARV drug exposure or people with prior ARV exposure who are initiating or reinitiating first-line antiretroviral therapy (ART).

PRODUCT PROFILES

[CHAI ABC/3TC Product Profile](#)

Brief overview of the profile, implementation, and key benefits of ABC/3TC 120mg/60mg.

[CHAI ATV/r Product Profile](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, and phase-in strategies for ATV/r.

[CHAI DRV/r Product Profile](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, and phase-in strategies for DRV/r.

[CHAI LPV/r Oral Pellets Product Profile](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, phase-in strategies and FAQs for LPV/r regimen and oral pellets.

[CHAI TLD Product Profile](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, and phase-in strategies for TLD.

CLINICAL STUDIES

[ARV Clinical Studies](#)

A repository of clinical trials and studies on ARVs., including ABC/3TC, ATV/r LPV/r, DRV/r, DTG and TLD, LPV/r, TAF, and TLE400.

[CHAI Basics of ARV and ART Training Materials](#)

A training deck on basics of ART and overview of drug classes, treatment guidelines, and key products.

[HIV i-Base *Fit for purpose: antiretroviral treatment optimisation*](#)

This annual i-Base publication reviews and updates current and planned research for treatment optimization studies looking to get increased outcomes from reduced doses in low- and middle-income countries.

[HIV i-Base *Introduction to HIV pipeline*](#)

This annual publication provides a review of the new HIV drugs in development.

MARKET INTELLIGENCE: ARV MARKET REPORTS

[CHAI ARV Market Report](#)

CHAI's ARV Market Report provides a global perspective on the ARV marketplace in low- and middle-income countries.

[CHAI HIV Mid-Year Market Memo](#)

Highlights of the latest trends in HIV treatment, diagnostics, and prevention.

[CHAI East Africa ARV Regional Market Brief](#)

CHAI's regional ARV Market Report provides a regional perspective on the ARV marketplace in low- and middle-income countries. This document provides a regional overview of East Africa in 2016.

[CHAI Southeast Asia ARV Regional Market Brief](#)

CHAI's regional ARV Market Report provides a regional perspective on the ARV marketplace in low- and middle-income countries. This document provides a regional overview of South East Asia in 2016.

[CHAI Southern Africa \(ex-RSA\) ARV Regional Market Brief](#)

CHAI's regional ARV Market Report provides a regional perspective on the ARV marketplace in low- and middle-income countries. This document provides a regional overview of Southern Africa in 2016.

[CHAI West and Central Africa ARV Regional Market Brief](#)

CHAI's regional ARV Market Report provides a regional perspective on the ARV marketplace in low- and middle-income countries. This document provides a regional overview of West and Central Africa in 2016.

To see the most up-to-date resources, visit the [Resource Directory on the CHAI HIV New Product Introduction Toolkit](#).

CHAPTER 2 REGISTRATION



Ensuring all new products are registered for use in-country

IN THIS CHAPTER

- 2.1 Stringent Regulatory Authority
- 2.2 National Drug Regulatory Authorities (NDRAs)
- 2.3 Common Registration Bottlenecks
- 2.4 Generic Registration Steps and Timelines
- 2.5 Expert Review Panel
- 2.6 Key Challenges and Mitigation Strategies
- 2.7 Resources and Tools for Registration

In order for products to be used in national programs, they must comply with national and/or donor regulatory requirements. While suppliers take responsibility for submitting dossiers for product registration, processes can often be subject to bottlenecks that cause delays in access to new products. National treatment programs and partners may be able to assist with communication and addressing challenges in the regulatory process.

REGISTRATION CHECKLIST

- ✓ **Ensure suppliers have filed dossiers with National Drug Regulatory Authority (NDRA)** to register new antiretrovirals (ARVs)
- ✓ **Monitor registration status and progress** with NDRAs
- ✓ When appropriate, apply for a **registration waiver** or **expedited review process** while national registration is pending
- ✓ Ensure the new product is included in the country's **essential medicines list and standard treatment guidelines**, where applicable
- ✓ **MoH and NDRA collaboration** to communicate public health priority products and address **common registration bottlenecks**

2.1 STRINGENT REGULATORY AUTHORITY (SRA)

A Stringent Regulatory Authority (SRA) is a medicines regulatory authority that enforces and ensures medicines developed by manufacturers and suppliers comply with internationally agreed regulatory standards. SRAs are defined as regulatory authorities which are (a) Founding or Standing Regulatory Members of the [International Conference on Harmonisation](#), or b) Standing Observers.¹ In addition, countries with mutual recognition with one of the Founding Regulatory Members (e.g. European Medicines Agency has mutual recognition with Australia and New Zealand) are considered SRA. A full list of members can be found [here](#).

SRA approval, and sometimes specific United States Food and Drug Administration (FDA) tentative approval or World Health Organization Prequalification of Medicines Programme (WHO PQ), are often prerequisites for procurement in-country, and by specific donors. Typically, products need to be close

¹ **Founding or Standing Regulatory Members of the ICH include:** European Union member States (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, and United Kingdom); Japan; and the United State of America; **Observers** include the European Free Trade Association (EFTA) represented by Swiss Medic of Switzerland, and Health Canada (as may be updated from time to time); and **Associates through mutual recognition agreements**, including Australia, Norway, Iceland, and Liechtenstein.

to SRA approval or approved, or WHO PQ in order to be included in forecasts. Generally, a product cannot be procured by the largest funding agencies until it receives either SRA approval or WHO PQ. For example, procurement using U.S. government funding requires products to have approval from the FDA. Procurement using the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) funding requires products have WHO PQ and SRA approval. If the product does not have both approvals, or only has one approval, the product may be permitted for a time-limited procurement after review by the Expert Review Panel (ERP). More on the ERP below.

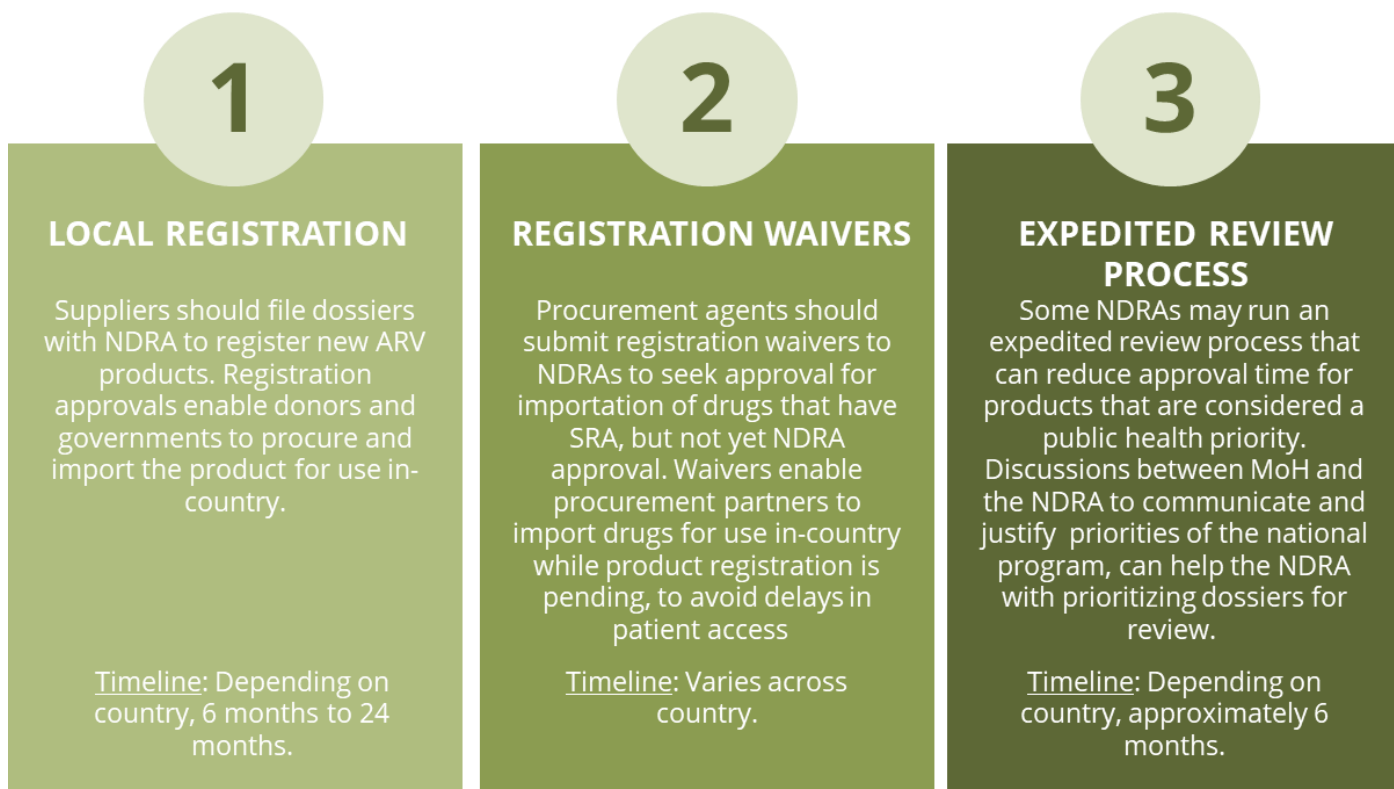


Photo Credit: Clinton Health Access Initiative, Inc.

Additionally, it is important to ensure that the drug is registered in-country through an NDRA. Import waivers (which often require FDA or WHO PQ approval before obtaining) can be sought when needed, but they are not a long-term solution. For example, if a product is FDA approved, it may be procured by United States President's Emergency Plan For AIDS Relief (PEPFAR). However, that product also requires in-country registration or an import waiver to be allowed into the country by the national program.

2.2 NATIONAL DRUG REGULATORY AUTHORITIES (NDRA)

NDRAs are typically mandated to ensure that all medicines and medical devices used in country are safe, effective, and of high quality. Below are some key considerations and possible actions to ensure that drugs comply with set regulatory procedures.



National Essential Medicines List

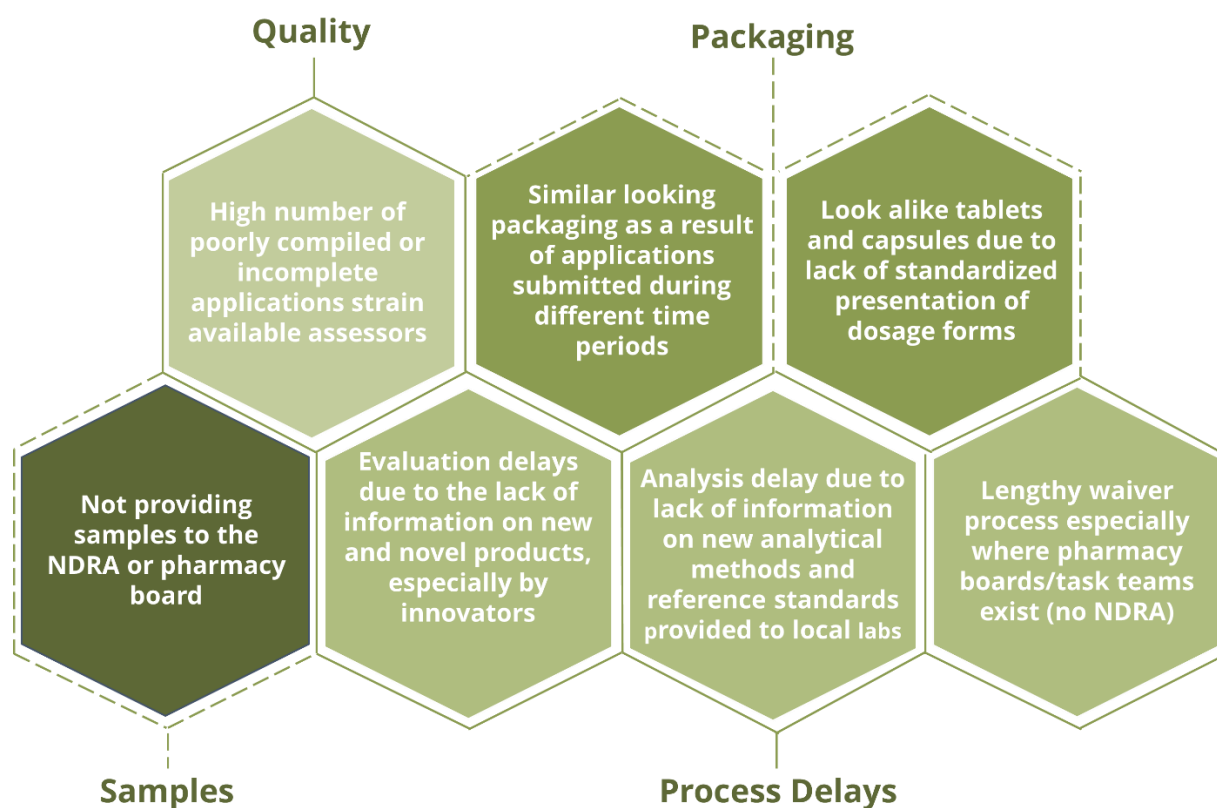
In addition to registering with the appropriate NDRA, program implementers should ensure that the product is included in the country's essential medicines list if it is required for use. In some countries, if

a product is registered with the NDRA but is not registered with the national essential medicines list, the product may not be eligible for tender or procurement. Registration with the relevant country essential medicines list is not required in all countries, but it is important to confirm before proceeding and work with the relevant committees in advance of product registration to complete the required processes for inclusion.

2.3 COMMON REGISTRATION BOTTLENECKS

When working to register new products, there are a number of bottlenecks that may occur. Program managers should be prepared for these challenges and troubleshoot as they arise. Developing clear communication channels with the NDRA will help with understanding product registration requirements, communicating public health priorities and identifying and collectively addressing challenges.

Figure 1. Common Registration Bottlenecks



Source: CHAI HIV Access Program, 2017.

2.4 GENERIC REGISTRATION STEPS AND TIMELINES

The registration timeline will vary country to country. Below are the key high-level steps and key considerations when building out the registration timeline:

- 1. Submission:** Suppliers should be encouraged to submit dossiers for key products to NDRAs at the same time as submission to SRAs, so that reviews can take place in parallel. This will help to reduce the time to product availability in countries where these products are most needed.
- 2. Review and approval:** Timelines can vary significantly across agencies, but an assumption of 12 months is the expected timeline; however, expedited reviews may be possible if a product is fast-tracked. For life-saving products that have not been approved for use by NDRA and are deemed a public health priority, MoHs and NDRAs should work to prioritize

products and set-up 'fast track' processes if possible in order to expedite the registration process.

- 3. Response to queries:** Re-evaluation timelines can be lengthy, so careful preparation and submission of high quality dossiers that meet the specific NDRA's requirements are critical, as are providing full and prompt responses to NDRA queries.
- 4. Board Approval:** Board approves or rejects submission. At this point, the product can be procured and imported into the country from the perspective of the NDRA. If a product is rejected, the national program should work to understand the grounds for rejection and suppliers should provide additional evidence to address concerns.

2.5 EXPERT REVIEW PANEL

The Expert Review Panel (ERP) is an independent body of technical experts hosted by the WHO's Quality and Safety of Medicines Department. Made up of pharmaceutical quality experts with extensive regulatory experience, the ERP assesses the quality risks of pharmaceutical products that have not yet received an SRA approval. The ERP is not a replacement for an SRA approval, rather a time-limited mechanism that allows procurement for a 12-month period for urgently needed health commodities while they undergo the SRA approval process. The Global Fund typically shares invitations to manufacturers to submit an expression of interest (EOI) for specific products required for public health purposes, and once eligible products have been submitted for review by the ERP, the panel advises whether or not a product is acceptable for procurement during the following 12 months. If a product has been approved by the ERP, this indicates to national programs and procurement agents that the product can be procured and used even while SRA approval or WHO PQ is pending.



Best Practices in Regional Product Registration Harmonization

The East African Community (EAC) launched a new program through the African Medicines Registration Harmonisation (AMRH) Programme to harmonize and coordinate national registration mechanisms across its member countries, including Burundi, Kenya, Rwanda, Tanzania, and Uganda. Implemented by the EAC Medicines and Food Safety Unit, the goal is to have:

- Quicker access to affordable, priority essential medicines of assured quality for patients;
- Improved public health outcomes;
- More effective medicines control by the strengthened NDRA's;
- Improved procurement practices for securing priority medicines; and
- Cost efficiency for governments.

The Southern African Development Community (SADC) created a similar registration harmonization body called the Zazibona Collaborative Registration Procedure. The initiative includes Botswana, Namibia, Zambia, and Zimbabwe. Learn more about the initiative [here](#).

Source: EAC Medicines and Food Safety Unit

2.6 KEY CHALLENGES AND MITIGATION STRATEGIES

The below table provides a high-level summary of the challenges in product registration, in addition to the various ways MoHs, implementing partners, and suppliers can play a role in mitigating those challenges.

| Challenges | SUPPORT STRATEGIES | | |
|---|--|---|---|
| | MoH/Buyers | Partners | Suppliers |
| <p>NDRA requirements: Complex and variable NDRA requirements.</p> <p>Submission delays: Delays in supplier submission and query responses, in addition to delays in NDRA review, and queries. Delays due to incomplete dossier submissions or data.</p> <p>Bureaucratic and complex review processes and systems: Contribute to delays in dossier reviews.</p> | <p>Clear timelines: Clarify and simplify processes and requirements and commit to set review timelines on priority dossiers.</p> <p>Communicate priorities: Clear communication of program needs and priority products to NDRA, as needed.</p> <p>Process frameworks: Develop frameworks for prioritizing assessments and ensure efficient review.</p> <p>Waiver flexibility: When applicable, allow for waivers for first shipment.</p> | <p>Registration visibility: Improve visibility into registration process.</p> <p>Process frameworks: Support with frameworks for prioritizing products.</p> | <p>Data collection: Align data collection processes and analytics for broad based registrations.</p> <p>Dossier submissions: Accelerate dossier submissions and query response.</p> |

Source: CHAI HIV Access Program, 2017





[Adult ARVs Indicative
SRA Filing Timelines](#)

This resource shows the latest understanding of targeted regulatory filings for key adult ARVs. Please note that these timelines are very dynamic and can change from month-to-month. This resource will be updated as information of timelines changes.

[Pediatric Pipeline
Products Indicative
Filing Timelines](#)

This resource shows the latest understanding of targeted regulatory filings for key pediatric ARVs. Please note that these timelines are very dynamic and can change from month-to-month. This resource will be updated as information of timelines changes.

[CHAI SRA Approvals
Database](#)

An easy reference resource compiled and regularly updated by CHAI which summarizes all currently SRA-approved ARVs, including FDA tentative approvals and WHO PQ. National Programs and procurement agents can access the database to check which products have SRA approval to inform procurement choices.

[FDA Approved and
Tentatively Approved
ARVs in Association
with PEPFAR](#)

List of products that have received FDA tentative approval, which is required for procurement through US government funds.

[Global Fund Sourcing
and Management of
Health Products
resources](#)

This section of the Global Fund website provides updates on [ARVs found to be quality assured, including by the Expert Review Panel](#), as well as updates on any quality assurance issues or changes to procurement guidance.

[WHO PQ List for API
and Finished Products](#)

These lists contain details of finished products and API sources which have received WHO Prequalification (WHO PQ) and found acceptable for procurement by UN agencies.

[WHO Expert Review
Panel \(WHO ERP\)](#)

The Expert Review Panel (ERP) is an independent body of technical experts hosted by the WHO's Quality and Safety of Medicines Department. This information note provides a high-level overview of the ERP, including the program's basic principles, eligibility criteria, and dossier review process.

[CHAI NDRA Registration
Waiver Process](#)

Guide to obtaining a registration waiver for accelerated access to health products without national drug regulatory authority (NDRA) registration

**To see the most up-to-date resources, visit the
[Resource Directory on the CHAI HIV New Product Introduction Toolkit.](#)**

NATIONAL-LEVEL PLANNING & BUDGETING



Transition and budgeting strategies for effective implementation and rollout of new products

IN THIS CHAPTER

- 3.1 National Ministry of Health Transition Planning
- 3.2 Key Considerations for National-Level Planning
- 3.3 Budgeting Considerations
- 3.4 Budget Processes
- 3.5 Reference Pricing
- 3.6 Donor Engagement
- 3.7 Key Challenges and Mitigation Strategies
- 3.8 Resources and Tools for National-Level Planning and Budgeting

Thorough national-level planning that includes consideration of phase-in strategies, existing stocks and procurement plans, national and donor budgetary cycles, and rollout implementation and monitoring requirements is key to building consensus and providing a roadmap for product introduction.

NATIONAL-LEVEL PLANNING AND BUDGETING CHECKLIST

- ✓ Develop a **detailed rollout strategy**, including identification of **target patient populations, regions, or facilities**
- ✓ Consider **available financial and human resources** when developing a rollout strategy (i.e. nationwide versus targeted)
- ✓ If resources are limited, consider a **phased rollout strategy** until there are sufficient resources to facilitate national scale up (e.g. required trainings, mentorships etc.)
- ✓ **Inventory existing products** to be phased out
- ✓ Develop **phase-out strategy for existing products** that will be switched out
- ✓ **Consider budget cycles** for the funding source to align procurement with funding availability
- ✓ **Include new products** within national budgets and donor budget plans (e.g. PEPFAR Country Operational Plan for Global Fund PSM Plan)
- ✓ Earmark funding for key programmatic activities such as **training and mentorship**

3.1 NATIONAL MINISTRY OF HEALTH TRANSITION PLANNING

Countries should develop comprehensive product introduction plans that enable implementation of the national guidelines while taking account of the available resources, including finances and human resources. A number of different approaches can be employed, but two high-level rollout strategies for consideration include:

- **Nationwide Phase-In Strategy:** Introduce a new product on a national scale, making it available to all antiretroviral therapy (ART) facilities.
- **Selected target patient populations:** Some patient groups may be considered a priority to benefit from new products (e.g. pediatric patients unable to tolerate lopinavir/ritonavir (LPV/r) syrup would be a priority for pellets, adolescents with poor adherence would be a priority for

dolutegravir (DTG)). Rollout strategies can define and focus on priority patient groups before expanding access.

- **Geographically phased rollout strategy:** Rollout the product in a number of sites, monitor the challenges/feedback, and apply lessons learned before the rollout is nationwide, or focus on high-volume facilities or regions before cascading to lower level facilities or other regions.

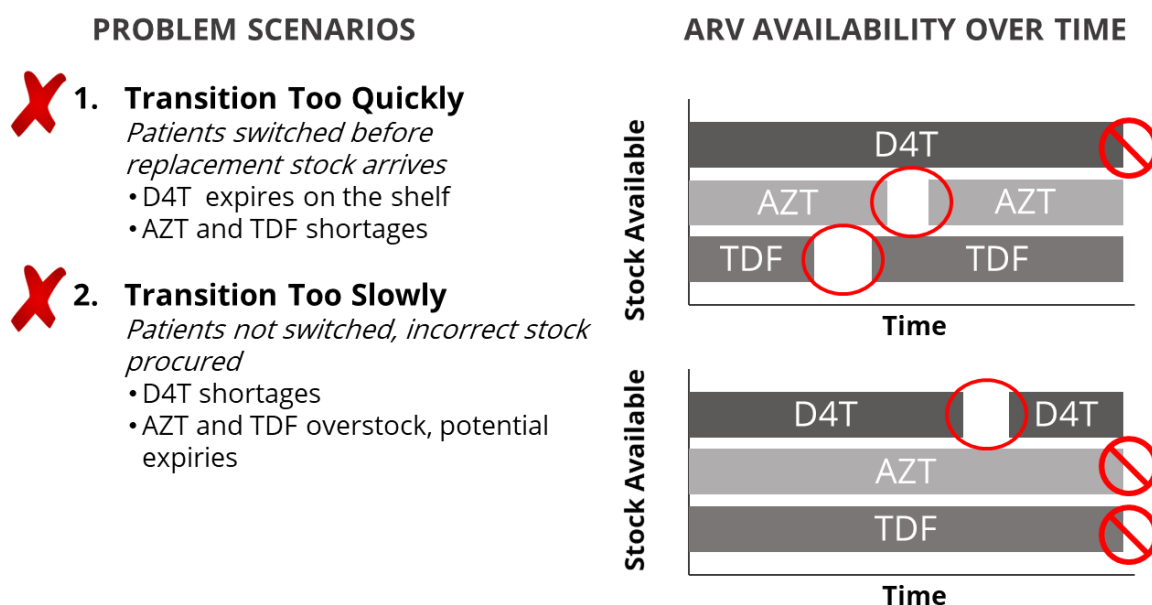
3.2 KEY CONSIDERATIONS FOR NATIONAL-LEVEL PLANNING

Some key considerations when developing a rollout strategy include:

INVENTORY OF EXISTING PRODUCTS THAT WILL EVENTUALLY BE PHASED OUT If introducing the new product results in a sudden and dramatic reduction in consumption of the existing product, the existing product may be at risk of expiring before being consumed, leading to significant funding wastage. Stocks of the product being phased out should therefore be taken into account in forecasting for new products, and a phase-out plan created that aligns to the phase-in plan of the new product. A phased transition can be considered in which only some sites or patient groups adopt the new product initially, or regions or sites can be given target patient numbers for transition on a monthly basis to optimize use of existing and new stocks. It is important to closely monitor stock during product transitions and flag when there is a risk of stock-out so that an appropriate solution can be found. The stock module of the [CHAI ARV Phase-In/Phase-Out Tool \(APIPO\)](#) can assist with planning.

Careful phase-in, with simultaneous phase-out planning, reduces risk of stock-outs, expired products, and emergency orders. Below is an illustrative example from the introduction of tenofovir disoproxil fumarate (TDF), showing some scenarios if a product is transitioned too quickly or too slowly.

Figure 1. Product Transition Scenarios



Source: CHAI HIV Access Program, 2011.

HUMAN AND FINANCIAL RESOURCES

Before deciding on a rollout strategy, an assessment of existing human and financial resources should be conducted. If there are limited human and financial resources in a specific region, countries may consider focusing initial rollout efforts in other areas of the country where there is more bandwidth to facilitate product switching. Furthermore, in instances where there are limited resources, countries may choose a phased rollout strategy until there are sufficient resources to facilitate national scale-up (e.g., required trainings, mentorships etc.).

PARTNER SUPPORT AVAILABLE FOR INTRODUCTION

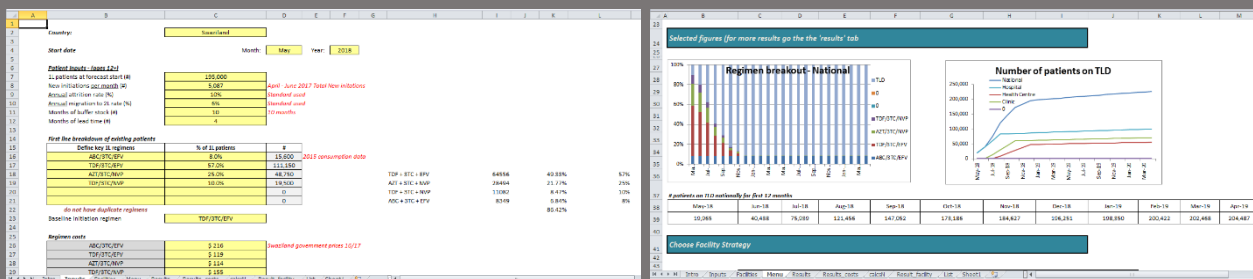
When introducing a new product, it is important to ensure there is coordination and buy-in from key partners. Partners play a critical role in providing the funding or human resources necessary to facilitate product uptake. Additionally, given that there are partners implementing at different levels of the health system, partner coordination is important for identifying and leveraging existing mechanisms for new product introduction.



TOOL HIGHLIGHT: CHAI ARV PHASE-IN/PHASE-OUT TOOL

As national programs phase-in new, generic ARVs, like Tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD), there is a need for planning of how and when the new product will be phased-in to ensure smooth and sustained adoption of optimal formulations. During the phase-in planning, Ministries of Health must decide 1) which patient groups will be eligible to initiate on the new product 2) when each patient group will start and 3) how the new product will be rolled out geographically (national, regional, facility, or pilot). This tool is designed to help national programs simulate scenarios for product phase-in and evaluate these criteria to develop a comprehensive phase-in strategy.

The [CHAI ARV Phase-in/Phase-out Tool](#) is a simple rollout planner for programs to evaluate phase-in strategies for DTG. The tool allows Ministries of Health to select various options that include which patient populations will be initiated, the time when each population will be initiated, and the type of phase-in program (national, regional, facility, or pilot).



Output examples from the CHAI ARV Phase-In/Phase-Out Tool

3.3 BUDGETING CONSIDERATIONS

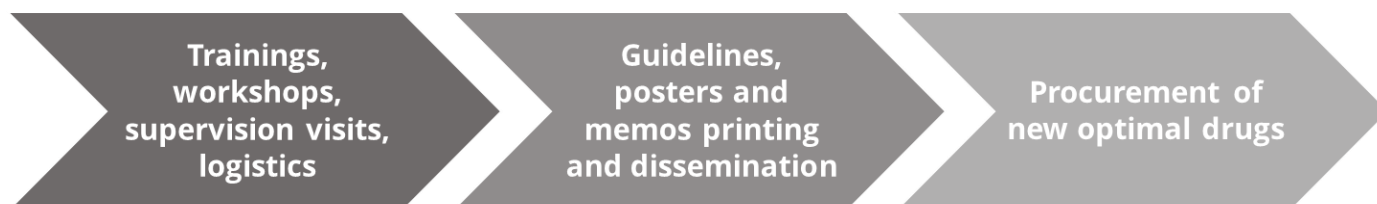
Budget availability is a key factor that will allow ease of adoption and rollout of the new optimal drugs. Countries should ensure there are enough funds to implement the new regimens, and that new products are included within national and donor budgeting processes. Many new, optimal products are cost saving or cost neutral, and may have a positive impact on budgets.

In addition to the commodity costs required for procurement of new products, rollout activities that will require funds should be identified and appropriately planned for. The budget should cover all expenses including training and/or workshop venues, printing of the new guidelines and dissemination, provision for training sessions and workshops, provision for supervision and mentorship and other expenses needed to support new product introduction.

Where additional funds are needed, collaboration to build a case for new product introduction, including assessment of the patient and programmatic benefits, can be helpful. Coordination across stakeholders and prioritization of activities can assist with both advocating for sufficient resources and ensuring optimal use of available resources.

An additional way of quantifying the impact of new product adoption to support advocacy efforts is through cost-benefit analysis, where costs associated with treatment beyond the commodity costs are assessed. This may include reduced costs to the health system from reduced side effects, patient visits and laboratory tests, for example. If countries are interested in support to conduct cost-benefit modeling, please contact HIVToolkit@clintonhealthaccess.org.

Figure 2. Budget planning: Example rollout activities



Source: CHAI HIV Access Program, 2017.

It is important to anticipate whether required resources will be made available on time. Planning well in advance for any funds requested can help ensure that approval and release of funds will not disrupt the timing or implementation of the rollout plan. In case opportunities for synergy with other program initiatives exist (e.g. joint supervision visits or trainings), existing activities or resources could be leveraged, or shared, to maximize efficiency, reduce costs associated with implementation and to reinforce messaging in multiple forums.

3.4 BUDGET PROCESSES

The following considerations should be taken into account when incorporating new products into national budgetary processes:

- **Countries with government funding:** For countries that have funding from their own governments, consider the budget cycle of the country to align procurement with funding availability.
- **Countries with donor agency support:** Countries that rely either partly or wholly on donor agencies should consider the budget cycle of the donor to align procurement with funding availability.

- Technical Working Groups (TWG) should advocate for or earmark funds for programmatic activities such as training and mentorship in conjunction with the adoption of new antiretrovirals (ARVs).
- As a consequence of the way public finances are managed, some countries have experienced challenges with budget availability due to funds initially budgeted for health commodity purchases being redirected elsewhere. One practice to safeguard resources for new ARVs is “budget ringfencing”, designating a dedicated fund reserved exclusively to procure critical commodities. This practice requires certain conditions:
 - Specific funding source or budget line established for this purpose with clear conditions for use.
 - Clarity and transparency over available budget and access to funding.
 - Regular monitoring of spending activities and run rate within ring-fenced budget.

Should countries be interested to learn more about budget ring-fencing, please contact HIVToolkit@clintonhealthaccess.org.

3.5 REFERENCE PRICING

There are several sources of reference pricing, including the [CHAI ARV Reference Price List](#) and the [Global Fund Pooled Procurement Mechanism \(PPM\) ARV Reference Pricing List](#), which can provide inputs for the budgeting process. Please note that countries should strive to achieve the best available prices through optimizing procurement practices (please see Chapter 6 on Procurement Planning) and rely on reference prices for guidance.

3.6 DONOR ENGAGEMENT

It is important to engage donors and procurers, such as the [Global Fund to Fight AIDS, Tuberculosis and Malaria \(the Global Fund\)](#) and [PEPFAR](#) in the national-level planning process given their role in providing funding to fulfill procurement cycles. Specifically, after deciding to adopt a new product in-country, Ministries of Health (MoHs) will conduct quantification and forecasting, and develop a supply plan. Once forecasting is done and a supply plan has been finalized, the MoH will share the proposed supply plan and engage with relevant donors to discuss procurement plans for that product. Donor engagement will be critical to ensuring that the budget and product rollout timelines are aligned, thereby contributing to a smooth product transition.

The primary mechanisms for funding through these two largest donors are the [Global Fund Concept Note process](#) and the [PEPFAR COP](#):

GLOBAL FUND CONCEPT NOTE

The Global Fund operates in a three-year funding cycle. At the beginning of each funding cycle (the current one is from 2017 to 2019) the Global Fund allocates funding envelopes to eligible countries so they can achieve greater impact in their fight against HIV, tuberculosis and malaria. Countries, through their respective Country Coordinating Mechanisms (CCMs), can apply for their allocated funding at any time during the three-year cycle.

PEPFAR COUNTRY OPERATIONAL PLAN (COP)

At the beginning of each fiscal year, all US Government PEPFAR agencies develop COPs to plan and facilitate programming for the following year. In order to complete the COP, U.S. Government (USG) agencies meet with partners and the host-country government to plan and budget activities. The COP is approved by the host-country government and the request is sent to the Office of the U.S. Global AIDS Coordinator

This allows them to align the funding request with their own national processes as well as with their national strategic plan for the diseases. Due to the long Global Fund funding cycles, procurement plans are often developed for the period of the funding cycle and will need to be updated when national programs choose to introduce new products. Changes should be communicated to the Global Fund grant manager and countries may request to include new products within the procurement plan, potentially substituting projected orders for products being replaced.

Eligibility and timeline: Eligibility for Global Fund support is based on a country's income level and disease burden. Applicants can apply at any time within the 3 year period. Funding requests should be based on the country's national strategic plan for the diseases.

Learn more about the Global Fund: [2017-2019 Funding Cycle Overview](#) | [Global Fund Applicant Handbook](#)

and Health Diplomacy (OGAC) for approval. The COP process includes a forecast for health commodity procurement during the COP cycle; new ARVs and phase-in plans should be reflected in that forecast.

Timeline: The COP Process is done annually and facilitated by the US Embassy in each relevant country. The initial release of COP guidance and tools typically takes place in January (or towards the end of the previous calendar year) and, depending on country, COPs are typically due between March and June. The funding cycle is October 1 to September 30 of each year per the U.S. federal budget cycle.

Learn more about PEPFAR: [PEPFAR](#) | [2017 Submission and Review Dates](#)

3.7 KEY CHALLENGES AND MITIGATION STRATEGIES

The below table provides a high-level summary of the challenges in national-level planning, in addition to the various ways MoHs and implementing partners can play a role in mitigating those challenges.

| CHALLENGES | SUPPORT STRATEGIES (MOH AND PARTNERS) |
|---|--|
| <p>Lack of planning flexibility: Product uptake must be an ongoing process. Even with advanced rollout planning, deviations occur. For example, sites may switch too many patients or too few.</p> <p>Lack of consensus across stakeholders: Lack of consensus among partners, donors and/or key opinion leaders on viable transition strategies often affect the planning process.</p> <p>Communications: Inconsistent and/or unclear communication from central level to facilities.</p> <p>Incomplete budgeting for key activities: During the planning phase, key activities may not be prioritized, and consequentially are not budgeted for. Often these activities are critical aspects in the transition and rollout phases, requiring additional budgeting and funding later in the process to ensure successful product transition.</p> | <p>Strategy: Ensure that there is a coordinated launch strategy in place for product rollout, <i>before</i> the first delivery arrives in country.</p> <p>Timing: Time procurement and deliveries of new product to ensure no wastage of phase-out product.</p> <p>Supply chain and distribution considerations: How many supply chains in country? Will certain regions or IPs be targeted first? Has product been added to necessary order forms?</p> <p>Phase-in programmatic plan: Develop and communicate clear criteria as to which patients will be eligible for the new product. Having up-to-date patient data is critical when determining a cohort phase-in plan for the new product.</p> <p>Budget Flexibility: Provide clear guidance on how procurement plans can be amended as</p> |

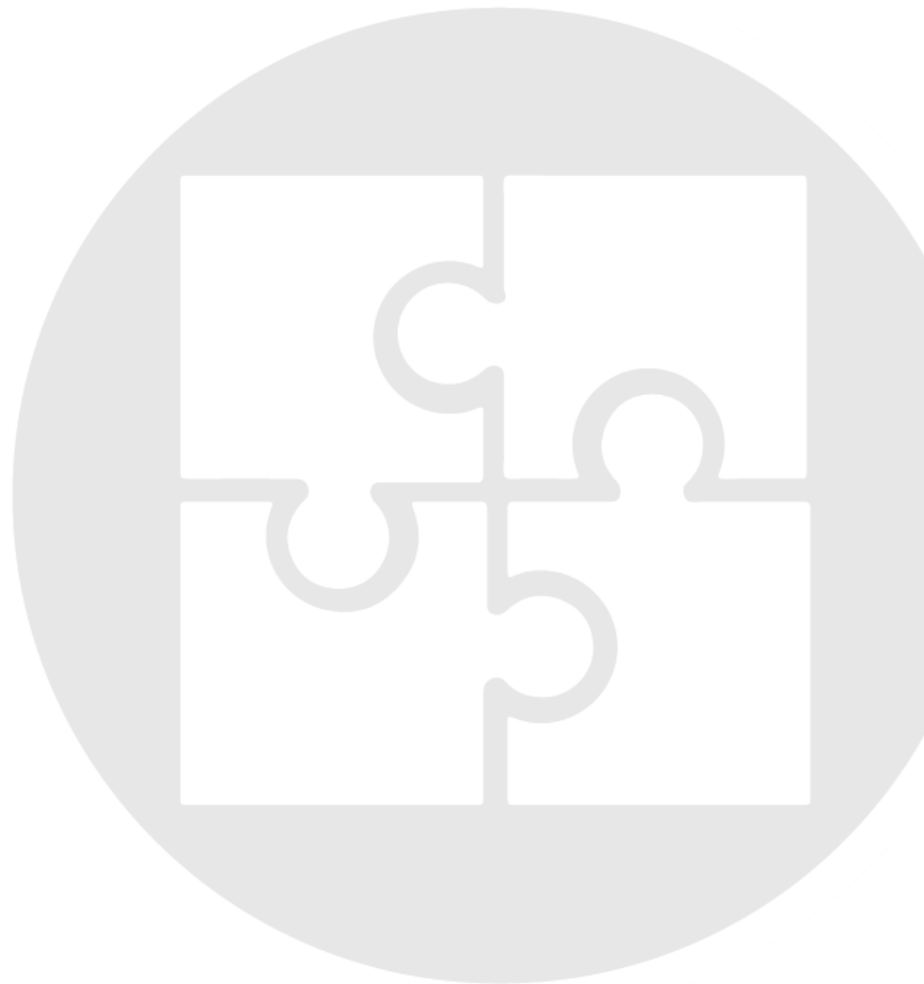
Delays in disbursement from government and/or donor funds: Delayed transitions due to the unavailability of funds even when funding has been confirmed. Accessing funds are often delayed due to bureaucratic processes. Confirmed funds, particularly government funds, are sometimes diverted and used for different purposes.

Lack of flexibility: Some funding mechanisms are inflexible when it comes to changing budgets and making any additions post approvals.

needed to facilitate product introduction within a budget cycle or volumes adjusted.

Budget Ringfencing: Within MoH funds, consider setting up a separate fund specifically for ARVs to avoid fund diversion if this is an issue.

Source: CHAI HIV Access Program, 2017.





NEW PRODUCT TRANSITION PLANNING RESOURCES

[CHAI ARV Phase-In/
Phase-Out Planning
Tool \(APIPO\)](#)

A simple rollout planner for programs to evaluate phase-in strategies for DTG. The tool allows Ministries of Health to assess various phase-in scenarios, including target patient populations to be initiated, the time when each population will be initiated, and the type of phase-in program (national, regional, facility, or pilot). The outputs of the tool can also inform target setting for rollout at each of these levels.

[CHAI ARV Transition
Planning Template](#)

The purpose of this document is to allow MoHs to document in summary form the decisions that have been made on product phase-in and phase-out and define key timelines for optimizing treatment regimens. The document is designed as a template to allow MoHs to input decisions based on current stock information to provide a clear summary of the considered decision-making process surrounding product phase-in and phase-out.

[CHAI Accelerating
Access to Dolutegravir
& Other Optimal ARVs –
IAS 2017](#)

An overview on the importance of accelerating optimal ARVs, including dolutegravir (DTG), for scaling up effective treatment. The presentation also highlights practical steps for facilitating and introducing new ARVs in LMICs. This slidedeck was presented at the 2017 IAS Conference on HIV Science in Paris, France in July 2017.

[CHAI Best Practices for
New Product
Introduction](#)

An overview presentation on the best practices for new product introduction. This presentation took place at the International AIDS Conference in Durban, South Africa in July 2016.

[CHAI Ministry Briefing
Note Template for New
Products](#)

The purpose of this template is to build a case for adopting a new product in-country. After compiling sufficient information on the new product, including international guidance, clinical trials, market intelligence, and regulatory filings, implementing partners can develop a summary brief to discuss new product opportunities with key stakeholders within the Ministry of Health. This document helps to concisely demonstrate opportunities and cost benefits for adopting a new product.

[CHAI Planning Product
Transitions in Country](#)

Best practices and lessons learned on planning product transitions in country. This slidedeck was presented at the Global Fund-PEPFAR ARV Manufacturers Engagement in Dubai, UAE in June 24, 2014.

[USAID HIV/AIDS
Commodity Security: A
Framework for Strategic
Planning](#)

This paper presents a framework for strategic planning that brings together a series of functions, programs, and activities necessary for the improvement of HIV/AIDS commodity security.

[USAID Tool to Assess
Site Readiness for
Initiating Antiretroviral
Therapy or Capacity for
Existing ART Sites](#)

This tool was designed to provide sites and programs with a set of criteria to assess a site's readiness to implement ART or the current capacity and needs of an existing program, and to identify key areas that need strengthening. This tool can provide a rapid baseline assessment for sites planning implementation of an HIV treatment program, or be used to assess needs for programs which have already started ART.

BUDGETING AND REFERENCE PRICING RESOURCES

[CHAI ARV Benchmark Price Comparison List](#) The CHAI ARV Benchmark Price Comparison list provides per pack or bottle prices for key adults and pediatric ARVs. Prices are Ex-Works (EXW) unless otherwise noted.

[CHAI ARV Reference Price List](#) The CHAI reference prices are those that the indicated manufacturers have committed to CHAI to offer the CHAI procurement consortium countries regardless of order volume. The prices are reflective of actual market prices across procurers rather than simply a maximum, as was the case with ceiling prices.

[CHAI Financial Interventions Resource](#) Several countries are finding new ways to improve financial security and management for critical commodities. This resource highlights budget ringfencing, process mapping and improved order tracking, and improved financial management practices.

[Global Fund PPM ARV Reference Pricing](#) The Global Fund has established Framework Agreements with manufacturers of antiretroviral medicines with the aim to achieve lower prices and also ensure the sustainable and reliable on-time supply of the full range of the needed ARVs. The Pooled Procurement Mechanism (PPM) aims to deliver the orders for the following ARVs at or below reference pricing. These prices should be used for budgeting purposes and used on all PPM Price Quotes.

[HIV i-Base Introduction to HIV pipeline](#) This annual publication provides a review of the new HIV drugs in development.

[MSF Untangling the Web of ARV Price Reductions](#) This annual report provides information regarding the changing product landscape, and updates on pricing and access to three critical medical interventions: optimal HIV therapy with dolutegravir; pediatric HIV therapy; and opportunities to improve treatment for two common opportunistic infections: cryptococcal meningitis and Kaposi's sarcoma.

[USAID Guide to Public Health Supply Chains Costing](#) This guide details the reasons for conducting a supply chain costing exercise, the USAID | DELIVER PROJECT's recommended supply chain costing methodology, and recommendations and considerations for conducting a supply chain costing activity

DONOR ENGAGEMENT

[PEPFAR COP Guidance](#) The 2017 PEPFAR Country/Regional Operational Plan Guidance provides guidance and outlines the process for countries submitting Country/Regional Operational Plans. Guidance for 2018 will be shared in January 2018.

[Global Fund Concept Note Guidance](#) Guidance for the Global Fund Concept Note Process.

To see the most up-to-date resources, visit the [Resource Directory on the CHAI HIV New Product Introduction Toolkit](#).



Coordinating key stakeholders to ensure smooth transition of new products

IN THIS CHAPTER

- 4.1 Key Partners
- 4.2 Community Engagement
- 4.3 Stakeholder Mapping
- 4.4 Media Engagement
- 4.5 Key Challenges and Mitigation Strategies
- 4.6 Resources and Tools for Stakeholder Engagement

The Ministry of Health (MoH) provides complete oversight of HIV programs in-country, including managing supply chains and procurement. The MoH also coordinates engagement across key partners through various Technical Working Groups (TWGs), such as HIV TWGs, procurement working groups, and other forums. In addition to collaboration within the MoH, it is important that key partners, community representatives, and other Ministries are engaged and work in close coordination to support the new product introduction process.

STAKEHOLDER ENGAGEMENT CHECKLIST

- ✓ **Engage key MoH decision makers, partners, and opinion leaders** to discuss and agree on product introduction priorities and phase-in strategies
- ✓ Convene key stakeholders through **national TWGs** to decide on national guidelines, priority populations, and rollout strategies
- ✓ Involve key stakeholders in the rollout planning process and **define clear roles and responsibilities** to leverage the skills, expertise, and resources of all involved
- ✓ Ensure clear communication between **program managers, procurement partners, and National Drug Regulatory Authorities (NDRAs)** on national product introduction plans to guide inclusion in national forecasts and NDRA priorities
- ✓ Coordinate with **procurement partners** to ensure smooth commodity procurement, consumption, and monitoring for supply continuity
- ✓ Leverage partners to conduct **clinical trainings, facilitate mentorship, and guide accurate product use**
- ✓ Develop **community engagement strategies** to support treatment literacy and demand for optimal products
- ✓ Ensure community groups are engaged throughout product introduction to help inform **the rollout process and communication strategies**
- ✓ Consider how **engagement with the media** could help to disseminate key messaging around new product availability and drive demand

4.1 KEY PARTNERS

The below table outlines key partners to engage in the new product introduction process.

| Category | Overview | In-Country Partner Examples |
|--|--|--|
| Global Partners and Donor Agencies | Provide funding and coordination for commodity procurement. | <ul style="list-style-type: none"> • The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) principal recipient; the in-country Global Fund procurement agent; Local Fund Agent (LFA) • World Health Organization representatives • United States President's Emergency Plan for AIDS Relief (PEPFAR) country representative and implementing partners • Global Fund Country Coordinating Mechanisms (CCMs) |
| Procurement Partners | Ensure coordination of procurement and supply chains, thereby promoting supply security for new and existing products, facilitating procurement and supply security monitoring, and ensuring product availability for countries to purchase new and existing products. | <ul style="list-style-type: none"> • PEPFAR procurement agents, such as those under the Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) umbrella, including Chemonics, etc. • Partnership for Supply Chain Management (PfSCM) for Global Fund's Pooled Procurement Mechanism (PPM) |
| Local Implementing Partners | Lead HIV treatment at the national and regional levels. Implementing partners also ensure coordination across clinical evidence, messaging, product prioritization, and new product adoption and rollout activities. | <ul style="list-style-type: none"> • Médecins Sans Frontières (MSF) • Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) • ICAP • Baylor • Partners in Health • WITS in South Africa • <i>And many others – varies considerably by country</i> |
| Civil Society and Community Representatives | Provide strategic direction and leadership to strengthen community engagement in product rollout, generate demand, and improve treatment literacy in their communities. | <ul style="list-style-type: none"> • National networks of People living with HIV (PLHIV) such as the National Empowerment Network of People living with HIV/AIDS in Kenya (NEPHAK) or RNP+ Senegal • Local community and civil society groups (e.g. Treatment Action Campaign in South Africa) • African Community Advisory Board (AfroCAB) • International Treatment Preparedness Coalition (ITPC) • CHAI Optimal ARV Community Advisory Board (CAB) • International Community of Women living with HIV (ICW) |

4.2 COMMUNITY ENGAGEMENT

As indicated in the above table, engaging with civil society organizations, community representatives, and national networks of PLHIV is critical in empowering people and expanding access to information on new antiretrovirals (ARVs). This in turn generates demand for optimal products by having a well-informed community. Furthermore, engaging communities in the initial stages of product introduction helps promote an effective implementation of new product rollout plans.

While *many* groups are involved in community engagement around treatment optimization, including those listed above, the efforts of three key groups – [AfroCAB](#), [HIV i-Base](#), and the Optimal ARV CAB – are described in more detail below.

AfroCAB is a network for HIV treatment advocates across Africa and is focused on providing a platform for African HIV advocates and PLHIV to engage on influencing new product development and sharing experiences on treatment optimization, product rollout, and scale-up. In addition to facilitating national treatment literacy and optimization meetings, AfroCAB recently launched an application to allow community members to easily report stock-outs and rapidly flag service delivery issues so that remedial action can be taken. See the AfroCAB website [here](#).

HIV i-Base is a treatment activist group committed to providing timely and up-to-date information about HIV treatment to community members and healthcare professionals. HIV i-Base produces informative patient resources, including information about new ARVs, the latest clinical trials, and treatment for special populations. These resources are available and can be adapted for use in local contexts. All resources are produced by and with the involvement of HIV positive individuals and are reviewed by a medical advisory group. See their resources [here](#).

The Optimal ARV CAB convenes community members from across countries most heavily affected by HIV to provide strategic guidance on the Unitaid-CHAI Optimal ARV project's global engagement with community groups, as well as facilitate national-level coordination on product introduction priorities across MoHs, community groups, and partners involved in developing and implementing product rollout strategies. For more information, please reach out to Kenly Sikwese who leads the Optimal ARV CAB. Email Kenly Sikwese [here](#).



Photo Credit: Kenly Sikwese, AfroCAB



4.3 STAKEHOLDER MAPPING

Stakeholder mapping can be an important exercise to understand the key influencers in product adoption and decision-making and to develop appropriate engagement strategies for each actor according to their level of criticality in the process. An approach to consider for stakeholder mapping includes identifying 1) key stakeholders, 2) their current level of engagement or role in treatment optimization, 3) the level of involvement that would be required of stakeholders for a product transition to be effective, and 4) the actions necessary to ensure effective collaboration with stakeholder. The [CHAI Stakeholder Mapping for Treatment Optimization](#) can be helpful in outlining the wide-range of stakeholders affected and engaged in new product adoption. This simple tool can be used to identify stakeholders to engage with directly and to leverage for broader engagement. For example, stakeholders with high levels of influence and support towards the new product can be leveraged to engage with stakeholders who are resistant or have reservations about the new product's introduction.

| [PRODUCT NAME] Treatment Optimization Stakeholder Mapping | | | | | |
|---|--------------------|--------------------|---------------|--|---|
| Instructions: The following sheet maps key stakeholders involved in product adoption and rollout. This tool can be used to identify stakeholders to engage with directly and to leverage for broader engagement. For example, stakeholders with high levels of influence and support toward the new product can be leveraged to engage with stakeholders who are resistant or have reservations about the new product's introduction. | | | | | |
| Stakeholder Mapping | | | | | |
| Stakeholder group 1: Policy-makers/MoH/government | | | | | |
| Group/individual | Level of awareness | Level of influence | Priority | Key issues/concerns | Key communication messages |
| Professor X, Head of National AIDS Control Program | Aware - resistant | High | High priority | Resistant to change - thinks EFV is a fine drug. Concerned about program costs. | Clinical benefits, cost and programmatic benefits |
| | | | | | |
| | | | | | |
| Stakeholder group 2: Clinicians and prescribers | | | | | |
| Group/individual | Level of awareness | Level of influence | Priority | Key issues/concerns | Key communication messages |
| | | | | | |
| | | | | | |
| | | | | | |
| Stakeholder group 3: Implementing Partners | | | | | |
| Group/individual | Level of awareness | Level of influence | Priority | Key issues/concerns | Key communication messages |
| | | | | | |
| | | | | | |
| | | | | | |
| Stakeholder group 4: Community groups/People living with HIV | | | | | |
| Group/individual | Level of awareness | Level of influence | Priority | Key issues/concerns | Key communication messages |
| | | | | | |
| | | | | | |
| | | | | | |

CHAI Stakeholder Mapping for Treatment Optimization

4.4 MEDIA ENGAGEMENT

Media can be a positive channel for disseminating key information when introducing a new product. However, clear communication with media partners is necessary to ensure messaging is accurate and to dispel any potential misconceptions about the product. Strategies for media engagement should be considered during rollout planning. Should national media misconceive the evidence or rationale for product transition, this could cause challenges for the effectiveness of rollout and delay patient use of more optimal products. Proactive communication to media outlets, most likely to report on new developments in the national treatment program, can foster collaboration on disseminating messaging of new products. At a minimum, preparing a response strategy for media misrepresentation of national transition plans should be a part of risk mitigation in national rollout plans.

Some examples of successful media engagement to disseminate information about new product rollout include recent media coverage from Kenya and Tanzania on the use of generic dolutegravir (DTG) in-country. The media, including the Reuters played an influential role in demonstrating, through user interviews, the [benefits of this new, optimal ARV in Kenya](#). The article was widely disseminated and picked up by other news agencies, including the British Broadcasting Corporation News (BBC New). Following the initial launch in Kenya, other media agencies followed suit, with [The East African highlighting how DTG will soon be launched in Tanzania](#). This instance is indicative of how influential the media can be in disseminating information and driving demand in-country.

4.5 KEY CHALLENGES AND MITIGATION STRATEGIES

The below table provides a high-level summary of the challenges in stakeholder engagement, in addition to the various ways MoHs and partners can play a role in mitigating those challenges.

| CHALLENGES | SUPPORT STRATEGIES (MOH AND PARTNERS) |
|---|--|
| <p>Lack of coordination: During the planning phase, a lack of coordination can result in duplicated efforts and funds.</p> <p>Misalignment in communication: A lack of coordination across key stakeholders can result in misconceptions or misalignment in prioritization of new products.</p> | <p>Partner Coordination: Ensure implementing partners and donors are coordinated by setting up working groups and budget committees.</p> <p>Communication and Messaging: Engage key partners including the MoH, implementing partners, clinicians, communities, and donors throughout the entire process to ensure consistent messaging and communication.</p> |

Source: CHAI HIV Access Program, 2017



STAKEHOLDER ENGAGEMENT[African Community Advisory Board \(AfroCAB\)](#)

AfroCAB is a network for HIV treatment advocates across Africa and is focused on providing a platform for African HIV advocates and PLHIV to engage on key issues affecting PLHIV. In addition to facilitating national treatment literacy and optimization meetings, AfroCAB recently launched an application to allow community members to easily report stock-outs and rapidly flag service delivery issues so that remedial action can be taken. Android users can download the app [here](#). Individuals using Apple products can download the "AfroCAB" app in the app store.

[CHAI Stakeholder Mapping for Treatment Optimization](#)

This template maps key stakeholders involved in product adoption and rollout. This tool can be used to identify stakeholders to engage with directly and to leverage for broader engagement.

[ITPC Advocacy for Community Treatment \(ACT\) Toolkit](#)

The ACT Toolkit supports communities to realize their rights to optimal HIV treatment and includes information on the science of HIV, the relationship between human rights and HIV treatment, financing for health, opportunities and barriers to scaling up treatment, and practical guidance on how to mobilize communities to increase access to treatment.

[HIV i-Base Resources](#)

HIV i-Base is a treatment activist group committed to providing timely and up-to-date information about HIV treatment to community members and healthcare professionals. HIV i-Base produces informative patient resources, including information about new ARVs, the latest clinical trials, and treatment for special populations.

[HIV i-Base Introduction to HIV pipeline](#)

This annual publication provides a review of the new HIV drugs in development.

[HIV i-Base Fit for purpose: antiretroviral treatment optimisation](#)

This annual i-Base publication reviews and updates current and planned research for treatment optimization studies looking to get increased outcomes from reduced doses in low- and middle-income countries.

[Optimal ARV Community Advisory Board \(CAB\) Terms of Reference](#)

The Optimal ARV CAB serves to foster engagement with civil society groups to co-develop product adoption and rollout strategies and to improve understanding of and demand for new medicines. This document outlines the CAB's Terms of Reference and can be leveraged for other partners looking to engage with communities.

[USAID Center for Accelerating Innovation and Impact: Idea and Impact](#)

The center's Idea to Impact is a guide to the introduction and scale of global health solutions. The guide describes priority areas and includes case studies and practical tools to help global health practitioners accelerate impact through coordination and planning.

[USAID OPTIMIZE](#)

Supported by USAID, OPTIMIZE is a consortium led by WITS RHI in South Africa and aims to accelerate access to optimal ARVs. The consortium brings together a diverse set of partners from research, manufacturing, market access, program implementation and community and advocacy engagement. Members include ICAP at Columbia University, Mylan

Laboratories, the University of Liverpool, and the Medicines Patent Pool. View an overview of the group [here](#).

MEDIA ENGAGEMENT

[Dolutegravir: A milestone in the fight against HIV in Kenya \(Unitaid\)](#) To accelerate access to better antiretroviral (ARV) drugs, on 28 June 2017 the Government of Kenya and Unitaid announced the introduction of a new first-line drug for people living with HIV, making Kenya the first African country to introduce the generic version of this new drug for routine use. Unitaid highlights this achievement in a video (YouTube).

[Kenyans are first in Africa to get generic of latest AIDS drug \(Thomas Reuters\)](#) Thomas Reuters highlights the introduction of dolutegravir (DTG) in Kenya in June 2017.

[Tanzania set to introduce new HIV drug \(The East African\)](#) *The East African* highlights the government of Tanzania's plans to include a new generic version of DTG in the national HIV/Aids treatment protocols.

To see the most up-to-date resources, visit the [Resource Directory on the CHAI HIV New Product Introduction Toolkit](#).

QUANTIFICATION & FORECASTING



Forecasting to ensure a continuous supply of essential medicines

IN THIS CHAPTER

- 5.1 Quantification and Forecast Planning
- 5.2 Quantification Methodologies
- 5.3 Key Challenges and Mitigation Strategies
- 5.4 Resources and Tools for Quantification and Forecasting

The quantification process is a critical supply chain activity that translates national-level program policies into practical plans for procuring appropriate quantities of products to fulfill the rollout plan and inform decision-making on the financing and procurement of commodities.

QUANTIFICATION AND FORECASTING CHECKLIST

- ✓ Constitute a **national team of experts** in a Technical Working Group (TWG) to run the quantification process, facilitated through a national quantification committee
- ✓ **Gather key inputs and ensure data is sufficient and of high-quality** in order to build out a forecast
- ✓ Develop a national forecast for the new product using the appropriate **quantification methodology**
- ✓ **Develop a supply plan** based on the forecasting exercise
- ✓ **Review and adjust supply plan regularly**, based on uptake and consumption trends [this is covered in detail in the [Monitoring and Uptake chapter](#)]

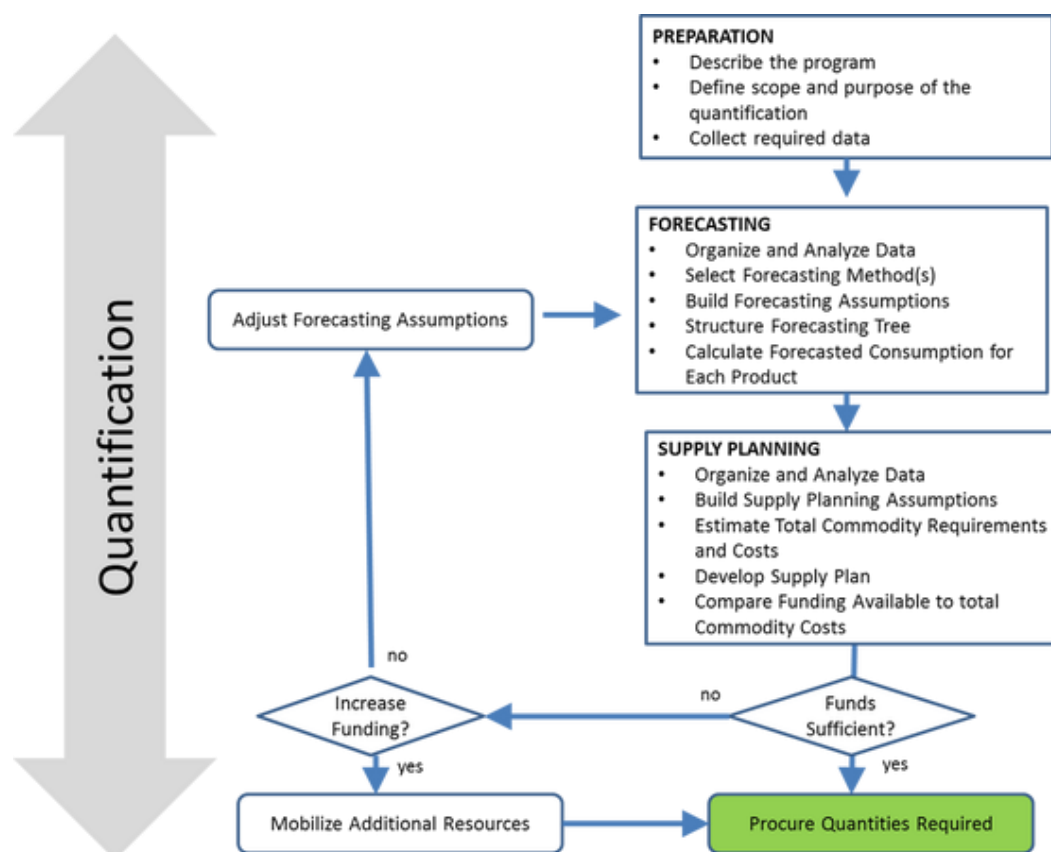
Quantification and supply planning is an ongoing exercise which should be conducted by a team of stakeholders and key personnel. These personnel include program managers, logistics officers, technical experts, procurement officers, policy makers and service providers who are involved in the entire process, from data collection and analysis to presentation and validation of forecasts with key stakeholders. Several software tools and databases are used for quantification and forecasting, such as:

- [CHAI Simple Tool](#), forecasting tool developed by CHAI's HIV Access Program that allows for the quantification of ARV needs for a three year period in a HIV/AIDS treatment program.
- [Quantimed](#), a tool developed by Management Sciences for Health that calculates the forecast quantities and costs of medicines and medical supplies needed for health programs.
- [PipeLine](#), a desktop software tool that helps program managers plan optimal procurement and delivery schedules for health commodities, and it monitors their orders throughout the supply chain.

Accurate forecasting for new product introduction is critical to ensuring uninterrupted commodity availability for patients. If a country fails to produce and update an accurate forecast, there can be serious repercussions for patients, for national antiretroviral (ARV) programs, and for the global ARV marketplace.

Four key steps are part of the quantification process: preparation, forecasting, supply planning, and funding considerations. Outlined in the [USAID Quantification of Health Commodities \(2009\)](#) resource guide, the diagram below depicts the flow in which these steps are utilized through the quantification process.

Figure 1. Quantification Process Steps



Source: USAID Quantification for Health Commodities Guide, 2009.

5.1 QUANTIFICATION AND FORECAST PLANNING

The development of a robust supply plan begins with an assessment of the inventory levels of ARV products at all levels of the supply chain, as well as any orders currently in the pipeline. Based on the rollout strategy agreed upon during the strategic planning phase, it is critical to ensure that the existing stock of products to be replaced is being steadily drawn down in the months preceding the rollout, minimizing wasted resources. The following should be considered when introducing new ARV products:

1. **Advanced planning:** Significant advanced planning is required, as countries often hold 6 to 9 months or more of buffer stock, and need to account for supplier lead times for delivery of orders.
2. **Forecast methodology:** New ARVs should be a part of the national consumption forecasts. In the initial stages of a new product rollout, consumption patterns can be unpredictable and erratic. In order to ensure adequate supply (and minimal wastage) of both the new and substitute products, it is critical to generate informed forecasts to drive procurement planning. Additionally, it is important to consider which forecasting methodology would be appropriate between the consumption and morbidity-based methods. Below is a brief description of the two methodologies.

5.2 QUANTIFICATION METHODOLOGIES

| METHODOLOGY | CONSUMPTION-BASED | MORBIDITY-BASED |
|-----------------------|---|---|
| Approach | Uses historic consumption patterns to predict future needs | Estimation of needs based on prevalence of a disease or patient populations |
| Starting Point | Quantities of products historically consumed | Number of patients |
| Requirements | Robust data on the quantities of drugs actually dispensed to patients at the service delivery points; high data reporting rates | Robust data on patient numbers and antiretroviral therapy (ART) regimens, understanding of how trends will change over time |
| Dangers | If there were stock-outs, historic consumption data will not reflect true demand, difficult to account for changing trends | Treatment protocols or scale-up targets may not reflect the true trends on the ground |

Countries should select the most appropriate methodology based on their needs, programmatic targets, and data available. For example, a morbidity-based methodology may be more preferable where a country is trying to scale-up to a specific coverage rate as it is more reflective of the evolving trends and nature of HIV disease. In other cases, the consumption-based method may be preferable where the program has complete and high quality data on past consumption that may be a good predictor of future consumption. However, in all cases of new product introduction, countries will have to make assumptions on uptake rates, as products are phased in to replace alternatives already in use. Thus, it's very important to keep in mind that when a product is being phased in, it is by nature volatile and forecasts need to account for consumption deviating from what is planned and what has been seen historically for existing products. Morbidity- and consumption-based approaches need not be mutually exclusive, and in fact, the consumption approach can be used to validate the morbidity approach.

Additionally, assumptions for the forecast should be developed based on the strategic decisions made on:

- **Rate of uptake:** The rate of uptake of the new product.
- **Policy decisions:** Forecasts should be informed by policy decisions regarding how the product will be used and timing for introduction, for example starting with specific target patient groups or geographies. They should also reflect input from clinicians in order to realistically assess how rapidly prescription patterns will change. The timeline of training and communication to health facilities will also determine the rate of uptake.
- **Placed orders:** Forecasting for new products should also make assumptions about how uptake will displace the use of older products being replaced, and adjust future order quantities accordingly. Where existing orders for new products are placed or planned, they must be considered in the forecast. Efforts should focus on “managing out” use of old substitute products by ensuring those products are reduced significantly and eliminated over time. In the absence of proactively managing down orders for older substitute products, orders for these products will typically continue at the same historic level and therefore stymie efforts to drive uptake of new ARV products, or result in wastage. Successful introduction is inherently dependent on actively managing down stocks of the replaced product. This can be achieved in several ways, through clear and direct communication about product replacement across the supply chain,

5.3 KEY CHALLENGES AND MITIGATION STRATEGIES

The below table provides a high-level summary of the challenges in quantification and forecasting, in addition to the various ways MoHs and partners can play a role in mitigating those challenges.

| Challenges | Support Strategies | |
|---|---|--|
| <p>Inaccurate forecasting: Stock emergencies leading to waste in time and funding (via increased rush deliveries).</p> | <p>Data: Strengthen data management systems to collect accurate data.</p> | <p>Working group: Form a working group to coordinate activities across offices, departments, and facilities involved.</p> |
| <p>Data: Lack of or inaccurate data inputs can drastically impact forecasting results. For example, inaccurate stock levels can lead to over-procurement and expiries.</p> | <p>Timing: Plan ahead. Accurate quantification takes time and allow extra time for consultation and cross-checking calculations.</p> | <p>Training: Ensure team members are trained in the quantification method and in data collection and analysis.</p> |
| <p>Training: Lack of data analytics and data collection skills can lead to inaccurate forecasting.</p> | <p>Planning: Designate the official or office that will manage the quantification process.</p> | |
| <p>Planning: Lack of planning can delay the quantification process, and ultimately, rollout of products.</p> | | |
| <p>Timing: Accurate estimate of the time required to undertake the quantification process.</p> | | |

Source: CHAI HIV Access Program, 2017





QUANTIFICATION AND FORECASTING

[CHAI Simple Tool \(ENG, FRA\)](#) The CHAI Simple Tool is a forecasting tool that allows for the quantification of ARV needs for a period of three years for a HIV/AIDS treatment program. The tool is available in English and French. This folder contains tools for Adult/Adolescents, in addition to pediatrics.

[CHAI Pediatric ARV Cost Comparator Tool](#) The Pediatric ARV Cost Comparator Tool is designed to demonstrate the potential cost savings realized by using fixed-dose combinations (FDCs) instead of single tablets, oral solutions, or pellets when considering regimen optimization. The tool can also be used to calculate the difference in price for the latest LPV/r formulations as part of a program's evaluation

[JSI PipeLine](#) A desktop software tool that helps program managers plan optimal procurement and delivery schedules for health commodities, and it monitors their orders throughout the supply chain.

[MSH Quantimed](#) A tool developed by Management Sciences for Health that calculates the forecast quantities and costs of medicines and medical supplies needed for health programs.

[USAID Quantification of Health Commodities](#) Developed by USAID, this toolkit is a guide to forecasting and supply planning for procurement.

To see the most up-to-date resources, visit the [Resource Directory on the CHAI HIV New Product Introduction Toolkit](#).



Ensuring a stable supply of new antiretrovirals (ARVs) for uninterrupted patient access to treatment

IN THIS CHAPTER

- 6.1 Understanding Donor Procurement Requirements, Mechanisms and Cycles
- 6.2 Key Considerations for Developing a Procurement Supply Plan
- 6.3 Procurement Channels and Processes
- 6.4 Key Procurement Planning Questions
- 6.5 Freight Considerations
- 6.6 Tendering
- 6.7 Key Challenges and Mitigation Strategies
- 6.8 Resources and Tools for Procurement Planning

During product phase-in and phase-out, coordination across stakeholders, forward planning, and monitoring can help ensure a steady supply of new optimal ARVs and uninterrupted patient access. A robust supply plan that provides a forward summary of confirmed orders, expected future purchases, and estimated lead times should be developed to provide full visibility of the product pipeline across procurement channels and to identify any potential issues or shortfalls.

PROCUREMENT PLANNING CHECKLIST

- ✓ Use the national forecast to develop a **procurement supply plan**, factoring in key considerations described in detail below
- ✓ Understand **key procurement procedures, including donor and government procurement**, and ensure procurement plans align with the associated requirements and timelines (e.g. Stringent Regulatory Authority (SRA) or National Drug Regulatory Authority (NDRA) approvals)
- ✓ **Ensure new products are included within the supply plan**, and assess whether planned orders should be reduced for the products that are being replaced
- ✓ **Obtain appropriate reviews and sign-offs for donor-funded procurement plans** from local or central procurement offices, as required
- ✓ **Communicate procurement plans to donors and suppliers** to help with forward demand visibility globally
- ✓ For countries using a **tender process**, reference the key considerations listed in the toolkit below to ensure a fair, transparent and competitive process
- ✓ Benchmark procurement prices against reference pricing to ensure prices offered are, at a minimum, **within ceiling prices**
- ✓ Factor clearance, shipping and distribution costs, including relevant **international commercial terms (incoterms)** into procurement costs
- ✓ **Place orders with suppliers**, either directly or through local or global procurement partner
- ✓ Confirm **scheduled delivery date** for order

- ✓ **Monitor order deliveries** to ensure an on time in full delivery
- ✓ Should delays occur, **request clear communication from procurement partners and suppliers** on updated delivery timelines and seek remedial action if delays risk stock-outs

6.1 UNDERSTANDING DONOR PROCUREMENT REQUIREMENTS, MECHANISMS, AND CYCLES

The procurement of HIV commodities is a complex process that, done well, ensures the timely, cost-effective supply of high-quality products in the right quantities. To conduct an effective procurement process that fulfills the needs of national treatment programs, countries need to be aware of the antiretroviral (ARV) market dynamics, the various options for procurement in terms of funding route and applicable conditions (e.g., through national government or through donors), and different options for procurement (e.g., direct single order procurement from supplier, releasing a tender, or using donor pooled procurement mechanisms).



Photo Credit: Clinton Health Access Initiative, Inc.

Understanding the current funding sources for procurement in-country, and the procedures in place (e.g., does the country issue a tender for ARVs? Do all procurements go through a donor procurement mechanism?) will inform your strategy as you develop your supply plan. Ensuring the procurement plan aligns with existing systems and requirements is key to accelerating the initial procurement of new products.

There may be options available to countries to improve their procurement systems, which could yield better value for money in procurement and other benefits such as pooling volumes for lower volume products across countries to improve sustainability and reduce prices. This guide and documents such as CHAI's white paper on [Best Practices in Strengthening National Procurement and Tendering](#) should provoke some ideas on how systems can be improved. For any specific questions or advice on how to implement changes, please contact HIVToolkit@clintonhealthaccess.org.

6.2 KEY CONSIDERATIONS FOR DEVELOPING A PROCUREMENT SUPPLY PLAN

The following specifics should be considered when developing the **procurement supply plan**:

1 Completeness and Flexibility: The plan should provide the most up-to-date view of the pipeline, across all procurement from the Ministry of Health (MoH) and partners. The plan should include stock-on-hand, monthly consumption, any expected changes in consumption patterns over time, and pipeline orders to give a complete view of all available stock, stock deliveries, and how this tracks against the actual and anticipated consumption. Supply planning must be a continuous exercise that is updated as the situation on the procurement and uptake side changes. Supply plans must be regularly reviewed and adjusted, ideally every three months.

2 Pipeline orders for existing products and transition planning: Forecasting often considers orders to be placed months or years in advance, based on the current regimen usage and phase-in plans. However, regimen usage, data, and consumption changes quickly, and both MoH and donors are working hard to ensure planning is sufficiently flexible to accommodate changing conditions and circumstances. Pipeline orders should be included in the supply plan; however, orders that have not been placed can be substituted for optimal products.

3 Budgeting: The supply plan must align with *the available budget*. The supply plan should be timed to align with and inform all steps throughout the entire transition and rollout process. For example, procurement and expected delivery timelines should align with training schedules on new products.

4 Procurement Mechanism: A procurement mechanism refers to the route through which a product is procured; either through national procurement systems, through donor funds, or through donor procurement systems. The procurement plan should specify the funding source and procurement route for each order.

5 Customs, storage and distribution funds: Account for funds required for customs clearance, storage, distribution, and handling.

6 Lead Times: Factor in lead times which account for production time, transport, clearance, and onward transportation to the warehouse. Monitor global market updates, such as CHAI's [HIV Mid-Year Market Memo](#) or information from the ARV Procurement Working Group (APWG), for any products where longer lead times should be accounted for (e.g., due to low product demand, meaning volumes must be pooled for a batch to be manufactured). Lead times for deliveries can be requested from suppliers, and should be accounted for in their scheduled delivery dates. Lead times and delivery date estimates should be included in the supply plan and adjusted as new information becomes available to ensure existing stocks are sufficient to buffer against any delays.

7 Buffer stocks: When introducing a new product, a larger initial order may be required to create sufficient buffer stocks in line with national policy. An estimate of monthly consumption developed during the supply planning process should be used to determine the quantity and timing of initial buffer stocks orders to enable rollout of new products at the desired time. Most countries aim for six to nine months of buffer stock, but national policies vary and may also vary by product. The [CHAI ARV Phase-In/Phase-Out Planning Tool](#) can assist in determining timing and quantities for buffer stock.

8 Demand Visibility: Forecasts for uptake of new products should be developed as part of the [national quantification process](#). Procurement plans should be based on these uptake forecasts and appropriate buffer stocks procured, as outlined above. However, countries should ensure regular consumption monitoring as part of the ongoing supply planning process to adjust order quantities in line with consumption trends. Sharing updated forecasts and supply plans regularly with global procurement partners and suppliers can assist efforts to ensure alignment of supply and demand at the global level to avoid any capacity constraints for new products.

6.3 PROCUREMENT CHANNELS AND PROCESSES

There are several channels through which HIV commodity procurement is commonly undertaken in countries:

| Procurement Mechanism | Overview |
|--|--|
| I. Tendering | Competitive tendering is the formal process by which countries invite bids from suppliers and award supply contracts based on clear assessment criteria of technical fit and competitiveness. This process ensures transparency in the selection of suppliers and widens the pool of potential suppliers by openly tendering to the whole marketplace. |
| II. Donor Procurement | Countries benefiting from the advantages of linkage to large procurement pools can leverage donor procurement. Options include the Global Fund Pooled Procurement Mechanism (PPM) or Global Health Supply Chain Program-Procurement and Supply Management Public-Private Partnerships (GHSC-PSM PPP) . |
| III. Own Pooled Procurement Mechanism | Countries may also elect to collaborate with other countries to build their own pooled procurement mechanism to improve supply security and reduce prices. |
| IV. National Direct Procurement | The MoH procures directly from suppliers without doing a competitive tender, either through spot-buying or entering into a long-term agreement. |

Many countries procure ARVs through a donor procurement agent, such as GHSC-PSM which is used for United States President's Emergency Plan for AIDS Relief (PEPFAR)-funded procurement and commodity management. Procurement activities are carried out on behalf of countries, with the donor directly contracting for services, including tendering, order placement, warehousing, clearing, and other related activities, across multiple countries. Orders and deliveries are carried out in accordance with national quantification and supply management plans.

Through this process, procurement agents manage orders for multiple countries and have the ability to aggregate orders to achieve certain supply and price benefits. For example, integrated procurement models may include global or regional warehousing of pre-purchased ARVs, which can be used as a buffer for emergency orders and to open additional methods of shipping to reduce costs. A further benefit of this procurement route for countries may be access to better pricing through the pooled demand and increased volumes which allows global procurement agents to leverage better pricing than countries could do individually.

Several countries now manage their own national ARV procurement processes either using funding managed by the national treatment programs or donor funding. For example, in Kenya, the Kenya Medical Supplies Authority (KEMSA) manages all procurement centrally, though orders are funded by the United States Agency for International Development (USAID), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), and domestic funds. Procurement functions are carried out by specialized agents or relevant government departments, such as the central medical stores, which perform all functions from tendering, order placement, warehousing, and inventory management to delivery throughout the country. Through this process, countries carry out their own procurement and supply chain management independent of other countries, making national monitoring of market intelligence key to ensure uninterrupted commodity access. For example, some countries with small populations on a given drug, such as pediatric ARVs, can only order in small volumes that are well below a production batch size. These orders should be synced with global orders for the same product to enable production. For this reason, countries are [encouraged to place orders for pediatric products at the same time on a quarterly cycle](#).

6.4 KEY PROCUREMENT PLANNING QUESTIONS

Regardless of which procurement route a country chooses, the following key questions should be addressed and well understood before procurement decisions are made:

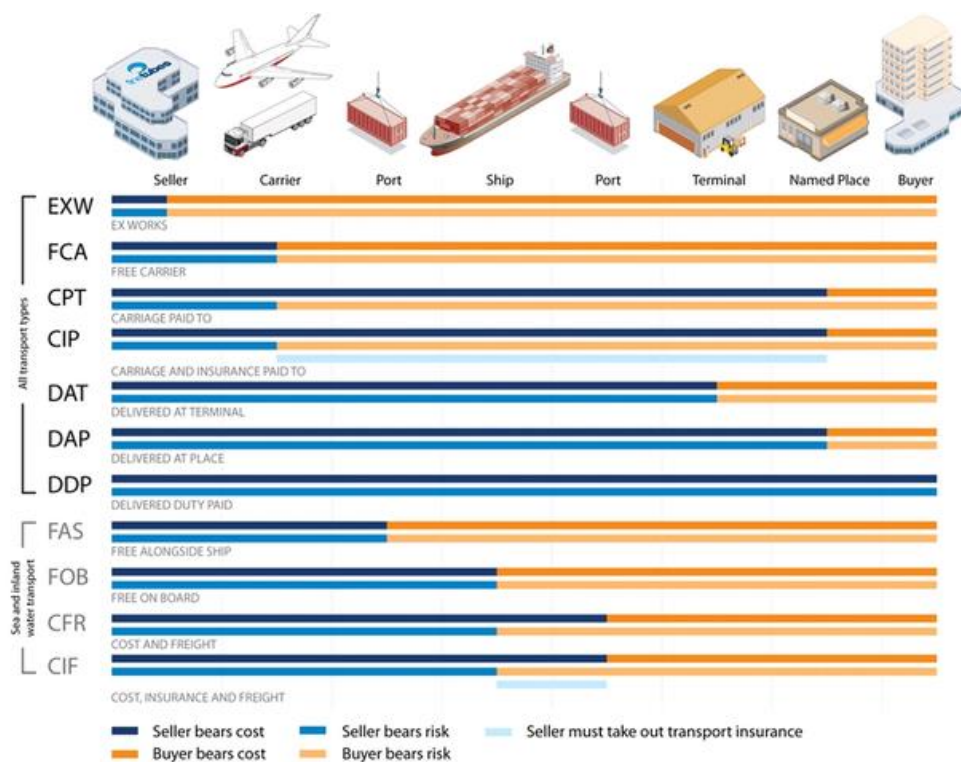
- Have the appropriate approvals been granted for the new product?
 - If PEPFAR is providing funding, United States Food and Drug Administration (FDA) approval is necessary, as well as NDRA approval or waiver in countries where an NDRA exists.
 - If the Global Fund is providing funding, FDA or WHO Prequalification of Medicines Programme (WHO PQ) is necessary, as well as NDRA approval or waiver in countries where an NDRA exists.
 - If only a national government is providing funds and an NDRA exists, NDRA approval or waiver is necessary.
 - If only a national government is providing funds and *no* NDRA exists, review country-specific policy guidance (e.g., some countries that do not have an NDRA may require WHO PQ approval for ARVs).
 - Review the [registration page](#) for additional information about SRA, WHO PQ, NDRA, and local registration.
- Does the NDRA require product registration before importation?
- What are the different procurement channels (e.g., PEPFAR procurement agents, Global Fund local fund agents, central medical stores, PEPFAR country representatives) used in the country?
- Does the order for procurement need to be pooled or ordered before a particular deadline to meet minimum batch sizes? For example, many pediatric product orders from an individual country will not meet a minimum batch size on their own. Therefore, ordering around a coordinated quarterly order date through the APWG could help to ensure shorter lead times.

6.5 FREIGHT CONSIDERATIONS

For international orders, it is important that countries gain an understanding of the transportation mechanisms and the incoterms that will be applied by suppliers when delivering these new products, as these will impact the overall cost of the products' delivery in-country. Incoterms define which party in a transaction, either the supplier or buyer, is responsible for the obligations, costs and risks throughout the delivery process. For example, Delivered Duty Paid (DDP) means that the supplier assumes all of the responsibility, cost, and risk of getting products from their warehouse to the buyers' required destination, which includes all transport, clearance, and fees.

Incoterms are an important consideration when reviewing various international price benchmarks and price quotes. Most reference prices are quoted ex-works (EXW), meaning the price represents the cost of the commodity only direct from the factory, without any delivery costs included. However, the costs of clearance, shipping and distribution (CSD) can vary greatly according to which incoterms are required of the supplier. Countries should look at historical pricing across products to estimate what level of CSD costs seems fair according to their incoterms. This will enable countries to benchmark prices against EXW reference prices. The graphic below shows and explains some of the most common incoterms that countries should be aware of:

Figure 1. Common incoterms



Source: Medmar Logistics, 2010.

6.6 TENDERING

Competitive tendering is the formal process by which countries invite bids from multiple suppliers and award supply contracts. Implementing a competitive bidding process can be an important instrument to access better pricing and may be particularly important when making procurement decisions for new products, given that suppliers typically introduce new products at a relatively higher price point. The tendering process ensures transparency in the selection of suppliers, widens the pool of potential suppliers, and ensures a competitive process, thereby ensuring best prices and facilitating supply security. If the country is using a tendering system, it is important to ensure that:

- New ARV products are included in national tender documents. Product list should clearly specify the correct pack size, dosage, and formulation (e.g., specify “scored” or “dispersible” where required).
- Indicative volumes are included to assist suppliers in planning production and offer more competitive pricing. Providing a guaranteed volume increases the incentive for suppliers to offer competitive pricing, but there is risk involved as there must be certainty that any guaranteed volume will be required by the country. By including indicative rather than committed volumes in the tender, countries reserve flexibility to account for unexpected variances from planned uptake of products. Using indicative and not guaranteed volumes is highly recommended for new products.
- Tenders should specify minimum shelf life. Current practice tends to be a minimum of 18 months for ARVs. Countries should avoid requiring a % commitment of remaining shelf life (e.g., 75%) as this may mean products with a longer shelf life cannot be procured, despite their exceeding the 18-month remaining shelf life (for example, a product with a 36-month shelf life could not be procured despite having 27 months remaining shelf life, since this would be on the 75% threshold). This can lead to wasted product, which increases prices overall, and lead to

longer lead times for countries as they must wait for new stocks to be produced, when suitable products are immediately available in inventory stocks. [See CHAI's memo on shelf life here.](#)

- Inclusion of international benchmark prices can be a useful tool in ensuring competitive bids. Consider developing a reference price list using CHAI ceiling prices along with other available sources of benchmarking prices for new products, and include it within tender documents. A reference price list can be found in [CHAI's Annual ARV Market Report](#). Prices being offered by suppliers in response to the request for proposal can then be compared to ensure they are reasonable. Also, make sure the benchmark prices are based on the same delivery terms as bid prices (e.g. EXW, DDP; this may require assumptions about delivery costs).

Sample Tender Checklist: Best Practices

- ✓ **Product list:** List of required products that includes indicative volumes, product specifications, and shelf life expectations assist suppliers to plan production and offer more competitive pricing.
- ✓ **International Price Benchmarking:** Including [CHAI's ARV Reference Price List](#) which contains (on the second page) price benchmarks from [Global Fund PPM Reference Pricing](#), South Africa, CHAI reference price, and others. Use of a reference price list can help to ensure competitive bids.
- ✓ **Split volumes:** Split volumes for higher-volume products across multiple suppliers to 1) decrease risk of supply disruptions, 2) encourage entry of new suppliers and avoid dependence on a sole supplier, and 3) sustain multiple suppliers in the market in the long run. Splitting volumes can be critical to sustaining affordable access to essential products.
- ✓ **Non-Price Factors:** Inclusion of non-price factors (such as supplier performance and registration coverage) can elicit desirable supplier behavior and outcomes.
- ✓ **Length of tender:** A longer tender (more than a year) can encourage better pricing as it offers suppliers surety of volumes over time; however, it can mean that purchasing new products outside of the tender as they become available can be more complicated. If products reduce in price these benefits may be missed, so including a clause that allows for price renegotiation in multi-year tenders is one option to mitigate this risk.
- ✓ **Stringent quality standards:** Include language that will ensure that products meet stringent quality requirements and consider allowing for inclusion of suppliers with pending NDRA registration.
- ✓ **Transparency and clarity in the language and structure of the document:** A clear, organized sample tender document will help make requirements clear for suppliers and lead to higher quality dossier submissions.
- ✓ **Previous Supplier Performance:** When developing tender evaluation criteria, consider including an assessment of the supplier's previous performance to ensure that the tender is awarded to a supplier who has the capacity to deliver new products in-country.



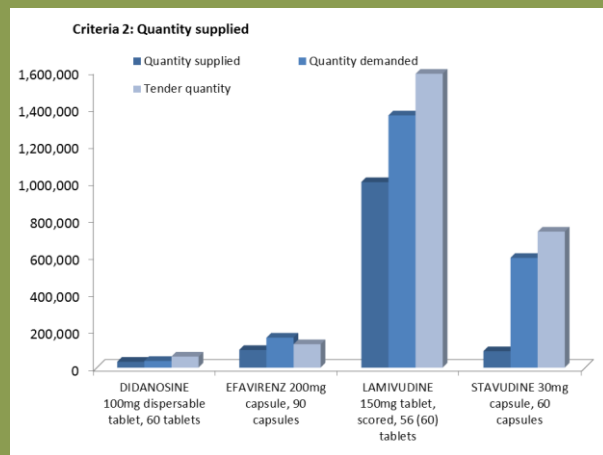
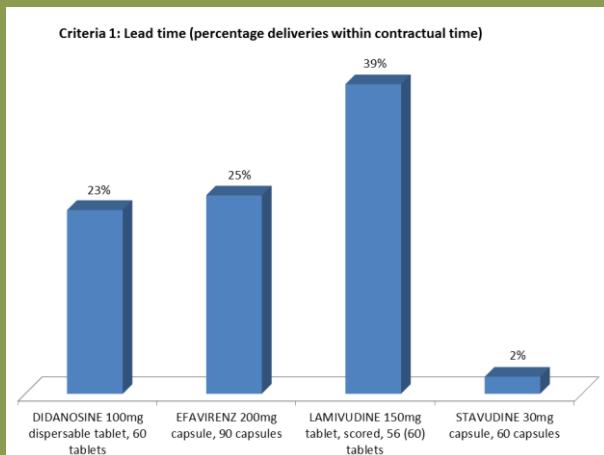
COUNTRY HIGHLIGHT: SUPPLIER PERFORMANCE TRACKING IN SOUTH AFRICA

Supplier performance can be a critical non-price factor to consider in a tender. The **South African National Department of Health (NDOH)** recently revamped its process of tracking supplier performance. The manual process of collecting performance data through Excel spreadsheets has been transferred to an online database where suppliers can directly enter data in real-time. Suppliers are scored on the following criteria:

1. Percent of deliveries (per product) that were delivered within contractual lead times
2. Quantities supplied compared to quantities demanded by facilities and quantities listed in the tender
3. Percent of complete deliveries made the first time (as opposed to multiple partial deliveries made to complete a single order)
4. Compliance with reporting requirements (delivery data submitted on time, attendance at quarterly meetings)

Below are sample graphs used to visualize supplier performance, which NDOH shares with suppliers during quarterly meetings. Revised forecasts are also shared with suppliers during these quarterly meetings. Data from supplier performance monitoring can inform the evaluation criteria for procurement decision-making to ensure contracts are awarded to the most reliable performers.

Read more best practices in procurement and tendering [here](#).



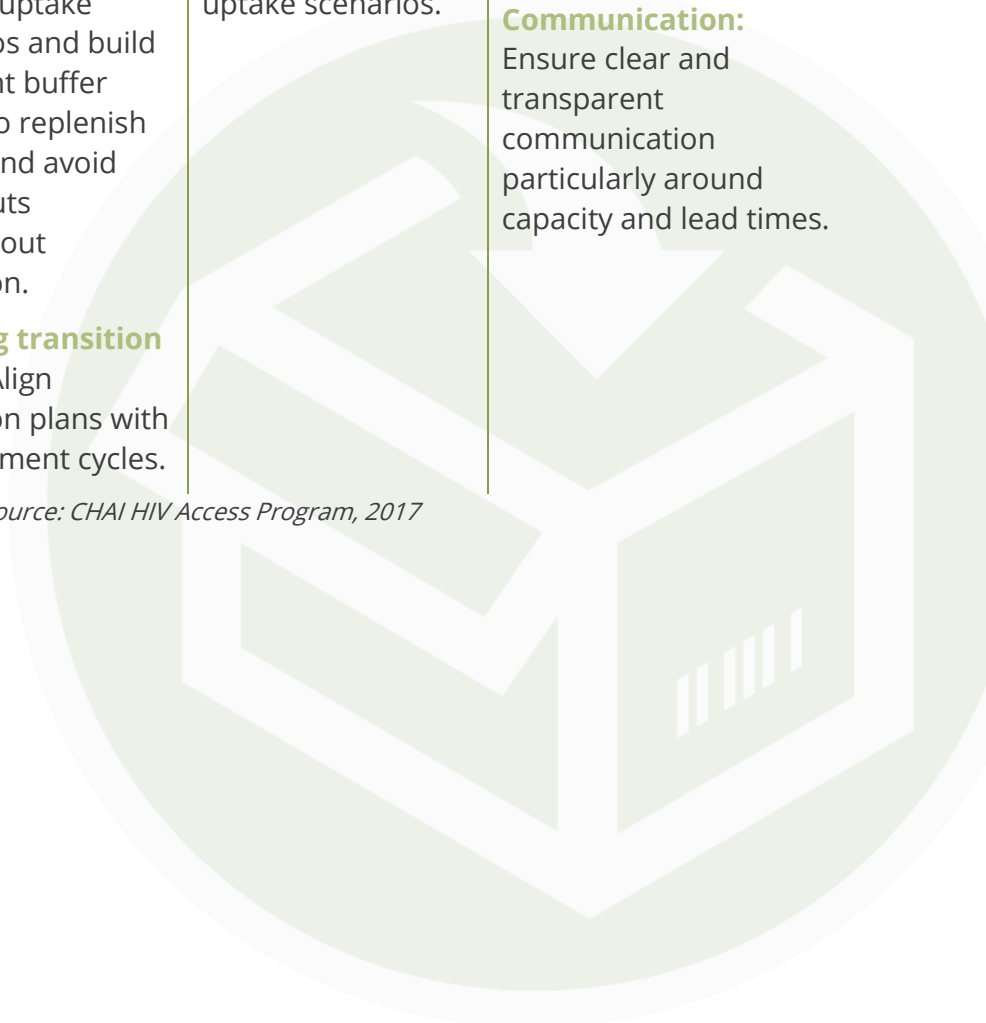
Sample Outputs from South Africa's Tool for Tracking Supplier Performance

6.7 KEY CHALLENGES AND MITIGATION STRATEGIES

The below table provides a high-level summary of the challenges in procurement planning, in addition to the various ways MoHs, implementing partners, and suppliers can play a role in mitigating those challenges.

| Challenges | Support Strategies | | |
|--|--|--|---|
| | MoH/Buyers | Partners | Suppliers |
| <p>Funding: Ensuring new products are included within national or donor budgets to avoid delays in uptake.</p> <p>Lack of Demand Visibility: Predicting uptake for new products can make accurate quantification challenging.</p> <p>Timing misalignment: Lack of alignment between product rollout timing and the procurement cycles particularly when it comes to donor funded commodities.</p> | <p>Procurement Coordination: Provide clear guidance on how to include or substitute new products into budgets and procurement plans.</p> <p>Contingency Planning: Develop various uptake scenarios and build sufficient buffer stocks to replenish stocks and avoid stock-outs throughout transition.</p> <p>Aligning transition plans: Align transition plans with procurement cycles.</p> | <p>Procurement Support: Support design and or alignment of coordinated procurement.</p> <p>Tool Development: Build forecasting and SCM tools for uptake scenarios.</p> | <p>Pricing: Offer pricing that can catalyze market growth.</p> <p>Risk Management: Expect some order volatility early in product introduction and design production to mitigate.</p> <p>Transparent Communication: Ensure clear and transparent communication particularly around capacity and lead times.</p> |

Source: CHAI HIV Access Program, 2017





PROCUREMENT OPTIMIZATION RESOURCES

[CHAI Best Practices in Strengthening National Procurement and Tendering](#)

Lessons learned and best practices for health commodity procurement and tendering.

[CHAI Shrink Wrap Packing Memo](#)

The memo recommends Ministries of Health and country programs to consider shrink plastic wrapping when procuring ARVs from generic suppliers. Enabling cost savings and other supply chain efficiencies, the shrink wrapping is an innovation worth inquiring about during tendering and order placement processes.

[CHAI Memo on Redefining the Shelf Life Threshold for Importing ARVs](#)

The memo recommends using a fixed number of months of remaining shelf life rather than a percentage of total shelf life, when importing ARVs, in order to reduce waste and prevent stock-outs.

PROCUREMENT PLANNING AND IMPLEMENTATION TOOLS

[APWG Memorandum: Available Supply of Paediatric LPV/r formulations and guidance for country procurement](#)

Due to increasing uptake of pediatric LPV/r formulations, the ARV Procurement Working Group (APWG) developed this memorandum to provide up-to-date information and guidance to country programmes planning to procure LPV/r oral pellets or LPV/r oral liquid. This memorandum was last updated in April 2017.

[CHAI Pediatric HIV Commodities - HIV Product Uptake Memo](#)

The Pediatric HIV Product Uptake Memo provides updates on pediatric commodity procurement key issues, approvals, and reference pricing.

[Global Fund Procurement Planning Tool](#)

When developing a proposal for the PSM plan, this tool can be used to develop a clear and detailed procurement plan for the quantities and costs of pharmaceuticals and health products needed for HIV.

[USAID Procurement Indicators Dashboard](#)

This guide describes suggested key indicators that can be helpful in tracking the performance of various aspects of a procurement system.

[WHO Checklist for Drug Receipts](#)

A part of the *WHO's Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies*, this resource is a checklist for what to look for in a shipment.

[WHO Guidance for Importation and Export of Pharmaceuticals](#)

A resource in the *WHO Expert Committee on Specifications for Pharmaceutical Preparations - WHO Technical Report Series, No. 863 - Thirty-fourth Report*, this section provides guidelines on import procedures for pharmaceutical products.

DONOR PROCUREMENT

| | |
|---|--|
| PEPFAR COP Guidance | The 2017 PEPFAR Country/Regional Operational Plan Guidance provides guidance and outlines the process for countries submitting Country/Regional Operational Plans. Guidance for 2018 will be shared in January 2018. |
| Global Fund Procurement Guide | A guide to the Global Fund's policies on procurement and supply management of health products. |
| Global Fund Sourcing of Health Products Strategy Review | A presentation on improving supplier performance management to drive value for patients. |
| USAID GHSC-PSM Procurement Webpage and Resources | The USAID GHSC-PSM Procurement Webpage provides high-level information on the project, as well as featured news and highlights. |

MARKET INTELLIGENCE: INTERNATIONAL BENCHMARK PRICING

| | |
|--|--|
| CHAI ARV Benchmark Price Comparison List | A consolidated list of published prices from suppliers for key adult and pediatric ARVs. Pricing information includes: CHAI reference prices, Médecins Sans Frontières (MSF) pricing, and the Global Fund Pooled Procurement Mechanism (PPM) reference pricing. This document is updated quarterly. |
| CHAI ARV Reference Price List | A published list of ceiling prices from suppliers for key adult and pediatric ARVs. The CHAI reference prices are those committed to CHAI to offer the CHAI procurement countries optimal pricing regardless of order volume. |
| CHAI ARV Market Report | CHAI's ARV Market Report provides a global perspective on the ARV marketplace in low- and middle-income countries. |
| Global Fund Pooled Procurement Mechanism ARV Reference Pricing | The Global Fund establishes Framework Agreements with manufacturers of ARVs with the aim to achieve lower prices and ensure the sustainable and reliable on-time supply of the full range of necessary ARVs. The Pooled Procurement Mechanism (PPM) aims to deliver orders for ARVs at or below the reference pricing on this document. |
| MSF Untangling the Web of ARV Price Reductions | This annual report provides information regarding the changing ARV landscape and updates on pricing and access to three critical medical interventions: optimal HIV therapy with dolutegravir; pediatric HIV therapy; and opportunities to improve treatment for two common opportunistic infections: cryptococcal meningitis and Kaposi's sarcoma. |
| WHO Access to AIDS medicines and diagnostics | Convened by the WHO, the AIDS Medicines and Diagnostics Service (AMDS) is a network of technical partners providing support and guidance to countries in procurement and supply management of HIV commodities. The main output of the AMDS is to develop strategic information on HIV drugs and diagnostics by publishing an annual forecast on global demand for ARVs and supporting capacity building activities for health supply chains. |

To see the most up-to-date resources, visit the [Resource Directory on the CHAI HIV New Product Introduction Toolkit](#).

FACILITY-LEVEL IMPLEMENTATION



Strategies to facilitate smooth product rollout and transition

IN THIS CHAPTER

- 7.1 Catalyzing Product Use
- 7.2 Training
- 7.3 Training Models
- 7.4 Community Training
- 7.5 Key Challenges and Mitigation Strategies
- 7.6 Resources and Tools for Facility-Level Implementation

Smooth product rollout and transition requires programs to plan ahead and develop tools and mechanisms, such as product memos that describe the key features of products and how they should be used, job aides, such as wall chart algorithms to decide if a patient is eligible for a new product, and trainings, to ensure effective uptake of new products. It is also critical that new products are integrated into patient information systems and existing systems for ordering and reporting.

FACILITY-LEVEL IMPLEMENTATION CHECKLIST

- ✓ Develop **national rollout plans** that **define activities** for phase-in and monitoring of product introduction, with **clear timelines**, and **roles and responsibilities** across Ministry of Health (MoH) and partners
- ✓ Develop and implement [product introduction tools](#), including **product memos, job aides, patient information guides**
- ✓ **Update stock monitoring tools** (e.g. [CHAI National ARV Stock Status Dashboard](#)), **ordering forms and patient management systems** to include new products
- ✓ **Develop a comprehensive rollout plan** (e.g. [CHAI Product Rollout Planning Template](#)) that clearly defines targets, timelines and roles and responsibilities across stakeholders
- ✓ **Disseminate and implement the rollout plan** working with key stakeholders at the national, regional, and facility levels
- ✓ **Educate health care providers**, patients, and civil society about the benefits and characteristics of new products so that they can better understand their treatment
- ✓ Incorporate supervision of **appropriate prescribing** and use of the new product within [ongoing training and mentorship](#) activities at facilities

7.1 CATALYZING PRODUCT USE

The following are some suggestions on how to generate understanding of, and demand for, use of better products among prescribers and patients:

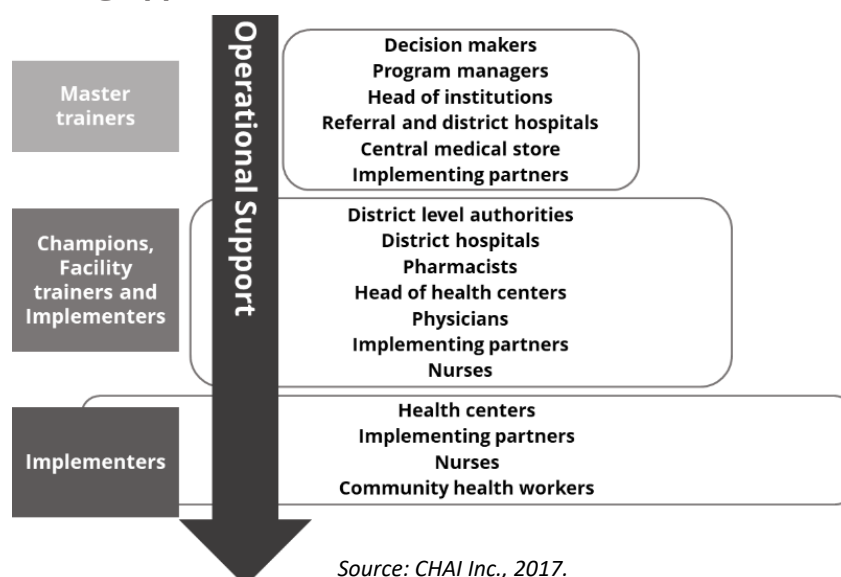
- **Clearly defining eligible patient groups:** To catalyze initial use, work with facilities to review patient files and identify eligible patients who may benefit from new products.
- **Implementing a so-called ‘informed push’** of stock down to facilities, since facilities may not order stock of a product where they are not currently using that product, particularly when they place orders based on past consumption.

- **Revising, updating, and distributing new order forms:** Revising antiretroviral (ARV) commodities report and requisition forms by removing sub-optimal formulations, adding optimal formulations, and re-arranging formulations such that more optimal formulations are prioritized and on top of the list.
- **Setting facility level uptake targets:** The [CHAI ARV Phase-in/Phase-Out Tool \(APIPO\)](#) can be used to plan a transition to new products and calculate the number of patients on a new product by facility or region over time. These target numbers and their justification can be shared with facilities or regions so they understand their role in the phase-in plan. Progress against targets can be monitored and an intervention can be made where a facility or region is significantly deviating from the plan.
- **Supporting clinical mentorship:** Clinical mentoring can be done by senior clinicians or trained peers to train and support staff to prescribe new medications. Mentorship can be timed to coincide with patient visits so that clinicians can provide mentorship as staff initiate patients on the new ARV.
- **Community engagement:** Keeping community groups regularly updated and informed about developments in treatment optimization and ensuring community involvement in product rollout can support understanding of and demand for optimal products.

7.2 TRAINING

Training personnel on the rollout of new drugs is vital. An optimal approach is to adopt a cascade training approach, training personnel from the central level and master trainers in the first phase, and moving on to lower level health staff in subsequent phases. This can involve a training of trainers model, where trained staff at each level are able to train peers at lower-level facilities. Training should be timed in advance of the product being available to prescribe at the facility (to avoid incorrect prescription before training), but not so far in advance that knowledge of the product is forgotten. Personnel to train include policy makers, physicians, nurses, pharmacists/logisticians, laboratory technicians, social workers, community health workers, expert patients, and opinion leaders and community leaders. The last are particularly important to ensure end users of products are fully informed about available treatment options, and communities can share information and play a key central role in product uptake.

Figure 1. Cascade Training Approach



TRAINING OBJECTIVES

- **Disseminate the latest information** on national guideline revisions, including full information on new products, such as how they can be prescribed, contraindications, benefits, drug-drug interactions, and side effects and how to manage them.
- Ensure **knowledge is accurately understood and retained**.
- **Build health-care worker capacity** and confidence to accurately prescribe new products and manage patients.
- Provide a forum to **ask questions**.
- **Correct** any already-existing **irregular practices** at facilities, which could include irrational prescribing not in line with existing national guidelines.
- Conduct trainings as **efficiently and cost-effectively** as possible to train as many people as possible, while ensuring that quality of training is maintained. This may include integrating training on new products into existing forums, training across topics, rather than just a specific product, and leveraging partners effectively to extend the reach of training and mentorship.

7.3 TRAINING MODELS

There are various approaches that can be taken to conduct training – several models are outlined below. Whichever model is chosen, training should include reinforcement mechanisms, such as leave-behind training materials and job aides for the facility that will allow healthcare workers (HCWs) to reference information. Pre- and post-training assessments can help with assessing baseline knowledge and checking that information has been understood accurately and retained. Follow-up supervision and mentorship visits can also assist with ensuring appropriate application of knowledge after initial training.

| MODEL | PROS | CONS |
|---|---|--|
| Model 1- Direct to providers in national or regional trainings | <ul style="list-style-type: none"> • Fastest way to get the information about new products directly to prescribers without relying on trickle-down approach of train the trainers model. • No or limited dilution of information. | <ul style="list-style-type: none"> • People invited for training are often not the facility-level implementers so the information does not trickle down to facilities. One way to resolve this is to address invitations to trainings to the specific facility-level HIV program managers tasked with rolling out the product. • Central level trainings can also be very expensive (per diems, fuel costs, etc.). |
| Model 2- Training of Trainers | <ul style="list-style-type: none"> • Cost effective. • Strengthens supervisory role of national and district/provincial MoH officials. | <ul style="list-style-type: none"> • Information may get lost in translation; requires follow-up and mentorship to ensure consistent messaging. |

| | | |
|---|---|---|
| | <ul style="list-style-type: none"> • Many more people are trained. • More sustainable than partner-led central trainings. | |
| Model 2 Format 1 – Classroom Training | <ul style="list-style-type: none"> • Focused learning without the distractions of on-site training. | <ul style="list-style-type: none"> • Expensive. • Not all the people who are involved in the program area can be invited. • Might be too theoretical and far removed from realities of work setting. |
| Model 2 Format 2- Mentorship at Facility Level | <ul style="list-style-type: none"> • More people can be trained. • Not as expensive as the classroom format. • Allows HCWs to ask questions in a real-life working context and apply theory to practice. | <ul style="list-style-type: none"> • Attention distracted by patients at facilities. • May take HCWs away from attending to patients. |

Additionally, timing of the training should also be considered:

| TIMING OF TRAINING | PROS | CONS |
|---|---|--|
| Training just before, just after or simultaneously with product availability | <ul style="list-style-type: none"> • Facilities are able to order the product with full knowledge about the product. | <ul style="list-style-type: none"> • No product to practice with for HCW trainings • If training is timed too far in advance, HCWs may forget how to use the product with time. The optimal timing for trainings is shortly before product availability. |
| Training after product availability | <ul style="list-style-type: none"> • Product is available during training/mentorship. | <ul style="list-style-type: none"> • HCW is not prepared to disburse products when products are available. This may lead to a delayed timeline for introduction or incorrect prescribing. |

The below considerations should be taken into account in developing and implementing a training plan:

- **Select a training strategy that will maximize coverage and embed new product into existing training modules:** The format of the training will depend on available resources, the landscape of treatment partners and existing training forums. In some cases, it may be possible to reach most healthcare providers directly during a national or regional-level training. In other

cases, it may be more effective to divide training responsibilities between implementing partners that provide clinical support to sites. Consider integrating information on treatment optimization and new products into existing training curricula.

- **Make the training practical:** The most successful training includes hands-on exercises that enable participants to work with and practice dosing new formulations. A combination of didactic methods, which provide important background, and participatory exercises, will



Photo Credit: Clinton Health Access Initiative, Inc.

ultimately leave participants feeling most comfortable with the new ARV products.

- **Focus training on those who prescribe AND dispense:** These are the people who will ultimately drive demand. The value of having those who prescribe is obvious, but including both facility-based and central-level dispensers is critical as they will be the ones responsible for issuing the drugs to patients, answering patient questions and ensuring that the new ARV products are ordered and stocked.

- **Incorporate reporting into training:** Sites should be trained on any new reporting requirements or tools,

including order forms and consumption/inventory records. It is critical for national-level decision-makers to have confidence in the data they receive from sites to ensure proper planning and forecasting.

- **Pharmacovigilance:** Ensure training covers possible side effects and how best to manage them, and that HCWs understand relevant pharmacovigilance and reporting procedures, and have access to the relevant forms or resources to do this appropriately. Training to health workers should also cover how to diagnose, manage, and prevent adverse drug reactions (ADR), including how to grade adverse events (mild, moderate, severe, and life threatening).
- **Monitor success:** In order to ensure that information is effectively being communicated to training participants, it is important to objectively evaluate the training. Various methods may be employed, including pre- or post-training tests of participants' knowledge and qualitative feedback forms asking participants to comment on effective aspects of the training, as well as potential improvements. Follow-up mentorship activities can ensure training has been effective and the products are being used appropriately.
- **Training Schedules:** Training schedules should be correlated with order forms or consumption patterns to track facility-level demand for products to determine which facilities may be over- or under-ordering in relation to expected uptake and require intervention.
- **Training Materials:** Contents of the training materials should be updated and in line with local treatment guidelines.

7.4 COMMUNITY TRAINING

Networks of people living with HIV (PLHIV) should be included in training. These networks are able to generate demand within their membership and dispel misinformation where necessary. Programs should collaborate with community leaders, for example members of the CHAI Community Advisory Board (CAB) and the African Community Advisory Board (AfroCAB), to co-develop appropriate communication materials tailored to the needs of the community in each country. HIV i-Base maintains a very useful [repository of materials](#) that can be adapted for local use.



Photo Credit: Clinton Health Access Initiative, Inc.



FEATURED TOOL: CHAI PRODUCT ROLLOUT PLANNING TEMPLATE

The [CHAI Product Rollout Planning Template](#) is designed to provide a template for MoHs and implementing partners to map out and document the key activities, milestones, and timelines required to implement product introduction plans. The tool is designed as a template for MoHs to add the relevant activities and milestones for their context; however, some key steps and milestones are included for consideration.

| Color Key | | Timeline | | | | | | | | | | | | Notes (e.g. required inputs/dependencies) | | |
|---|--------------------------|--------------|-----|-----|-----|-----|-----|------|-----|-----|-----|-----|-----|---|-----|------|
| Preparation process | | 2017 | | | | | | 2018 | | | | | | | | |
| Implementation | | Timeline | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | June |
| Product Adoption | | | | | | | | | | | | | | | | |
| Decision making around adopting new product in national guidelines | | | | | | | | | | | | | | | | |
| Constitute guideline revision committee | MoH Program Manager/CHAI | May '17 | | | | | | | | | | | | | | |
| Develop new product information package to inform guideline revision committee's decision making (refer to CHAI HIV New Product Introduction Guide and Toolkit) | | Jun '17 | | | | | | | | | | | | | | |
| Conduct guidelines analysis and costing evaluation to present to guideline revision committee (refer to CHAI HIV New Product Introduction Guide and Toolkit) | | Jun '17 | | | | | | | | | | | | | | |
| Guideline revision committee reviews compiled information packet and analysis on new products, including options for use in special populations | | July '17 | | | | | | | | | | | | | | |
| Guideline revision committee agrees and signs off on product adoption decisions | | July-Aug '17 | | | | | | | | | | | | | | |
| National guidelines updated with new product and distributed | | | | | | | | | | | | | | | | |
| Sub-group of guideline revision committee updates national guidelines with guidance on new products OR develops national circular on use of new products | | Aug '17 | | | | | | | | | | | | | | |
| Guideline revision committee reviews updated national guidelines and/or national circular and signs off | | Aug '17 | | | | | | | | | | | | | | |
| If required, Minister of Health reviews and approves updated national guidelines and/or national circular | | Aug '17 | | | | | | | | | | | | | | |
| Print and distribute updated guidelines and/or national circular | | Sept-Oct '17 | | | | | | | | | | | | | | |
| Registration | | | | | | | | | | | | | | | | |
| Register new product with local NDRA | | | | | | | | | | | | | | | | |
| Confirm suppliers have filed dossier with the NDRA to register new product | | | | | | | | | | | | | | | | |
| Monitor registration status and progress with NDRA | | | | | | | | | | | | | | | | |
| Secure import waiver or expedited review process, if needed to avoid delays in access | | | | | | | | | | | | | | | | |
| Include new product in essential medicines list | | | | | | | | | | | | | | | | |
| National-Level Planning and Budgeting | | | | | | | | | | | | | | | | |
| Develop phase-in strategy for new product | | | | | | | | | | | | | | | | |
| Define roll-out strategy and phase-in plan, including identification of target populations, regions or facilities and considerations of available financial and human resources (refer to CHAI HIV Phase-in/Phase-out Tool on New Product Introduction Toolkit) | | | | | | | | | | | | | | | | |
| Develop national mentorship and training plans | | | | | | | | | | | | | | | | |
| Translate uptake targets into procurement volumes | | | | | | | | | | | | | | | | |
| Inventory existing products to be phased out | | | | | | | | | | | | | | | | |
| Develop product introduction tools, product primers, job aides, training materials, product substitution algorithms | | | | | | | | | | | | | | | | |
| Develop phase-out strategy for existing products that will be switched out | | | | | | | | | | | | | | | | |
| Communicate phase-in and phase-out plans to donors | | | | | | | | | | | | | | | | |
| Develop communication strategy aligned with guideline implementation plan | | | | | | | | | | | | | | | | |
| Include new product and product phase-in activities in national and donor budgets | | | | | | | | | | | | | | | | |
| Include new products within national budgets and donor budget plans (e.g. PEPFAR Country Operational Plan for Global Fund FSM Plan) | | | | | | | | | | | | | | | | |
| earmark funding for key programmatic phase-in activities, such as training and mentorship | | | | | | | | | | | | | | | | |
| Quantification and Forecasting | | | | | | | | | | | | | | | | |
| Conduct quantification exercise to develop national forecasts for new product | | | | | | | | | | | | | | | | |
| Constitute a national team of experts in a TWG to run the quantification process, facilitated through national quantification committee | | | | | | | | | | | | | | | | |

Sample CHAI Product Rollout Planning Template

7.5 KEY CHALLENGES AND MITIGATION STRATEGIES

The below table provides a high-level summary of the challenges in product rollout, in addition to the various ways MoHs and implementing partners can play a role in mitigating those challenges.

| Challenges | Support Strategies (MoH and Partners) |
|---|--|
| <p>Product Availability: New products are not sufficiently available to enable smooth transitions, particularly when transition happens too fast (stock-outs) or too slow (wastage).</p> <p>Training: Training challenges include the cost of training hundreds (or thousands) of ARV sites; timing, which should take place close to product availability, not 6-12 months before product arrival; inappropriate personnel being trained; and lack of mentorship for those who miss trainings.</p> <p>Inconsistencies: Differences between sites, depending on size, region, implementing partner, etc. It is not possible to have a one-size-fits-all approach.</p> <p>Infrastructure: Availability of infrastructure to support product transition. Depending on the phase-in plans, smaller facilities sometimes end up with storage space constraints, etc.</p> <p>Data Management Systems: Failure to manage information on use and uptake of products which often impacts on the transition to new products.</p> <p>Communications: Information regarding timelines, approaches, and who to target for transition to new products many be incorrect.</p> | <p>Trainings: Provide supportive supervision and planning on job trainings and ensure the right personnel, those working in the pharmacy and dispensaries and in the HIV Units at clinics and hospitals, are trained. Training can be done in phases starting with high-volume sites or early adopters.</p> <p>Data Management Systems: Ensure all data management systems, including data forms and registers, are up-to-date and personnel are trained to update these systems with new information.</p> <p>Uptake at Sites: Facilitate product uptake to ensure rational medicines use for both old and new drugs, vetting orders and ensuring the ordering is in line with agreed phase-in plans.</p> <p>Partner presence: Leveraging partners is critical when capacity is limited. Whenever possible, it is important to harmonize the training materials among partners to ensure consistent messaging is communicated</p> <p>Ongoing Training and Mentorship: Plan for additional trainings and ongoing mentorship following the introductory phase, including developing job aides for all training sites.</p> |

Suppliers: Clearly communicate capacity and scale-up plans and meet those commitments. Implement early warning systems about capacity challenges and collaborate with buyers and partners to rapidly address them. Ensure there is always enough stock for emergency orders.

Source: CHAI HIV Access Program, 2017.



RESOURCES & TOOLS

FACILITY-LEVEL IMPLEMENTATION

FEATURED TOOL

[CHAI Product Rollout Planning Template](#)

The goal of the CHAI Product Rollout Planning Template is to support Ministries of Health (MoHs) and implementing partners in mapping out an implementation plan and timeline for new product introduction. This timeline includes key milestones and outputs to consider at the both facility and national levels.

TRAINING MATERIALS

[CHAI Basics of ARV and ART Training Materials](#)

A training deck on basics of ART and overview of drug classes, treatment guidelines, and key products.

[CHAI LPV/r Training of Trainers Resource](#)

A resource for Training of Trainers for LPV/r oral pellets.

[CHAI ARV Order Quality Tool Training Exercise - Uganda](#)

Originally developed by CHAI but now fully taken over by MoH, this free online survey tool monitors facility level training on new product guidelines and informs comparison with facility ordering at the central warehouse level.

RESOURCES FOR DOLUTEGRAVIR (DTG) ROLLOUT

[CHAI Acceptability of DTG-based Regimens for 1L ART](#)

A tool for training prescribers and counselors on implementing dolutegravir (DTG).

[CHAI DTG Rollout Algorithm](#)

A tool used to assist national programs when rolling out DTG to specific patient populations.

[CHAI TLD and TLE400 Phase-In Decision-Making Tool](#)

A tool used to assist national programs to determine which products to rollout for specific patient populations.

[CHAI TLD Clinical Action Memo](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, phase-in strategies, and FAQs for TLD, including all clinical trial information.

[CHAI TLD Product Profile](#)

Overview of clinical and programmatic benefits and considerations of product adoption, market factors, and phase-in strategies for TLD.

PEDIATRIC AND LPV/R ORAL PELLETS JOB AIDES

[APWG Memorandum: Available Supply of Paediatric LPV/r formulations and guidance for country procurement](#)

Due to increasing uptake of pediatric LPV/r formulations, the ARV Procurement Working Group (APWG) developed this memorandum to provide up-to-date information and guidance to country programmes planning to procure LPV/r oral pellets or LPV/r oral liquid. This memorandum was last updated in April 2017.

| | |
|--|---|
| CHAI LPV/r Oral Pellets Product Profile | Overview of clinical and programmatic benefits and considerations of product adoption, market factors, phase-in strategies and FAQs for LPV/r regimen and oral pellets. |
| CHAI LPV/r Oral Pellet Training Modules - Zimbabwe | Three training modules on rolling out LPV/r oral pellets in Zimbabwe. Modules cover an introduction of the LPV/r oral pellet, how to administer LPV/r oral pellets, and an overview of a pilot of the LPV/r pellet. |
| CHAI Pediatric Dosing Tool | The CHAI Pediatric Dosing Tool assists prescribers with accurate dosing for pediatric ARV regimens. |
| CHAI Pediatric Dosing Wheel (ENG, FRA) | Job aide to assist prescribers with accurate dosing for pediatric ARV regimens. |
| DNDi LPV/r demo video (Short, Long) | A demonstration video of LPV/r pellet administration. |
| DNDi How to use LPV/r pellets training materials (ENG, FRA) | Job aide for training explaining LPV/r pellets and administration. |
| DNDi LPV/r Oral Pellets - How to use pellets - Narrated Version (ENG, FRA) | A narrated job aide for training explaining LPV/r pellets and administration. |
| DNDi LPV/r Oral Pellets Poster | A job aide for use in facilities explaining pellet administration. |
| IAS 2016 Satellite Session: Scale Up HIV Treatment for Children | Presentations on LPV/r pellet use and findings from the LIVING study, as well as product introduction framework. |
| IATT LPV/r Fact Sheet (ENG, FRA) | An LPV/r fact sheet for MoH decision-making. |
| IATT LPV/r Pellet Supply Planning Brief (ENG, FRA) | A brief detailing supply planning considerations of LPV/r oral pellet rollout. |

RESOURCES FOR ABACAVIR/LAMIVUDINE (ABC/3TC) 120/60 MG

| | |
|---|---|
| APWG ABC/3TC (120/60 mg) Tablet Informational Brief (ENG, ESP, FRA) | This informational brief provides antiretroviral therapy (ART) program managers, implementing partners, clinicians, procurement and supply chain managers, and other relevant stakeholders with key points to consider regarding the introduction of the scored, ABC/3TC 120/60mg tablet. |
| CHAI ABC/3TC Product Profile | Brief overview of the profile, implementation, and key benefits of ABC/3TC 120mg/60mg. |

RESOURCES FOR ATAZANAVIR/RITONAVIR (ATV/R) ROLLOUT

[CHAI ATV/r Clinical Memo](#) Overview of clinical and programmatic benefits and considerations of product adoption, market factors, phase-in strategies, and FAQs for ATV/r, including all clinical trial information.

[CHAI ATV/r Job Aide](#) Job aide to support prescribers in administering ATV/r. The aide includes a guide on switching adult patients from LPV/r to ATV/r, a clinical update comparing LPV/r and ATV/r, and notes for patient counseling.

[CHAI ATV/r vs LPV/r Product Memo](#) This memo outlines the current state of knowledge for ATV/r and rationale for its selection as the preferred PI option for second-line therapy. This memo is also intended to educate decision-makers responsible for product selection by addressing common clinical and programmatic questions around the use of ATV/r.

[CHAI ATV/r Product Profile](#) Overview of clinical and programmatic benefits and considerations of product adoption, market factors, and phase-in strategies for ATV/r.

[CHAI Case Study: Improving HIV treatment outcomes for patients on second-line therapy through optimal regimen uptake](#) Access to better tolerated, more convenient regimens for HIV treatment promotes adherence and leads to better patient outcomes. CHAI is working to ensure affordable pricing and to address demand-side barriers to access. Increased uptake of optimal second-line regimens in Uganda and Nigeria has improved HIV treatment and will deliver \$6.5M in savings by 2018.

HIV i-BASE RESOURCES

[HIV i-Base Resources](#) HIV i-Base produces informative patient resources, including information about new ARVs, the latest clinical trials, and treatment for special populations. These resources are available and can be adapted for use in local contexts. All resources are produced by and with the involvement of HIV positive individuals and are reviewed by a medical advisory group.

[HIV i-Base *Fit for purpose: antiretroviral treatment optimisation*](#) This annual i-Base publication reviews and updates current and planned research for treatment optimization studies looking to get increased outcomes from reduced doses in low- and middle-income countries.

To see the most up-to-date resources, visit the [Resource Directory on the CHAI HIV New Product Introduction Toolkit](#).



Robust monitoring to ensure uninterrupted access to optimal products for patients

IN THIS CHAPTER

- 8.1 Tracking Consumption Trends
- 8.2 Supply Monitoring
- 8.3 Increasing Uptake at Sites
- 8.4 Pharmacovigilance
- 8.5 ARV Procurement Working Group (APWG)
- 8.6 Key Challenges and Mitigation Strategies
- 8.7 Resources and Tools for Monitoring and Uptake

Monitoring uptake is critical as there are often disconnects between procurement and consumption. If uptake occurs at a different pace than planned, it could lead to either wastage or stock-outs. Therefore, early detection and risk mitigation is important to avert stock imbalances and ensure successful product transitions.

MONITORING AND UPTAKE CHECKLIST

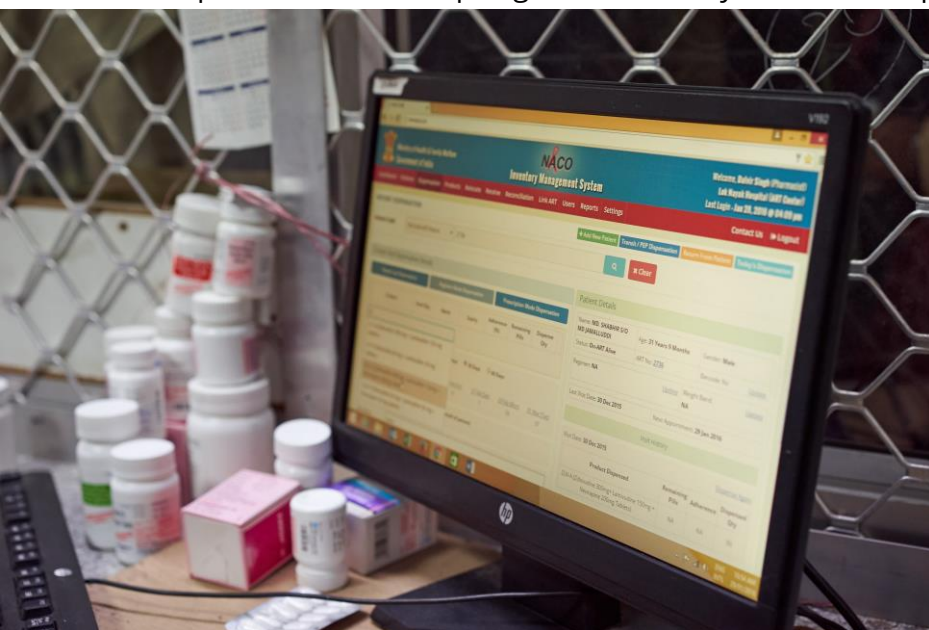
- ✓ **Develop a comprehensive monitoring plan** factoring in the number of patients, facilities dispensing product, and stock availability
- ✓ Consider using a **tool to track uptake trends** on a more frequent basis than regular reporting in the early stages of rollout to monitor uptake against planned usage and available supply
- ✓ **Monitor consumption patterns** and support adjustment of supply plan accordingly (closely monitor high-volume facilities as these greatly impact stock availability) (e.g. [CHAI Rapid Consumption Monitoring Tool](#))
- ✓ In the event of slower uptake than planned, **consider strategies listed in the guide below to drive uptake and avoid expiries and waste**
- ✓ **Monitor supplier performance** to ensure suppliers are delivering according to their contractual obligations
- ✓ Implement a robust **pharmacovigilance system** to monitor adverse drug reactions, drug resistance, toxicities, and treatment failure, in line with World Health Organization (WHO) guidance

8.1 TRACKING CONSUMPTION TRENDS

During the initial rollout period, to ensure that product uptake is well monitored and relevant data is collected, both electronic and paper-based tools used to collect essential supply chain logistics and patient information should be updated during the [National-Level Planning and Budgeting](#) phase to incorporate new products. These tools include facility ordering forms, stock cards, pharmacy registers, dispensing registers, warehouse registers, inventory management systems, and patient registers, which track which regimens each patient is prescribed.

Monitoring consumption trends when products are phasing in or phasing out should be a standing agenda item for the logistics technical working group (TWG). Overconsumption or underconsumption

could result in local or national stock-outs, or conversely, overstocking, wastage, and expiries. During this meeting, actual consumption should be reviewed against what was projected, or “uptake targets”. Uptake targets can be set at the national level, through the national forecasting process where assumptions of uptake rates of new products must be made to quantify the amount of packs required to fulfill demand. However, tools such as the [CHAI Antiretroviral \(ARV\) Phase-In/Phase-Out tool \(APIPO\)](#) can help countries develop regional or facility level rollout plans and define uptake targets at those



levels so that progress can be monitored and supported at facilities not meeting uptake targets.

Some countries may be subject to significant time-lags in data collection and collation in their supply chain and patient reporting systems, with data being reported quarterly and, in some cases, being delayed several additional months. In the early stages of uptake when consumption trends are hard to predict, countries may consider implementing a system for more frequent monitoring in a subset of facilities to estimate uptake trends and adjust plans if uptake seems to exceed or does not meet projections, risking

stock-outs. The [CHAI Rapid Consumption Monitoring Tool](#) allows users to input uptake targets from a subset of facilities and provides an easy-to-use tool to enable rapid monitoring of consumption trends in the early stages of product rollout.

Uptake is driven in part by training; therefore, it is important to monitor training against projected scale-up. For example, as soon as certain high-volume facilities are trained, uptake can be expected to increase significantly. Similarly, if a region is trained or a round of mentorship takes place, the supply chain should be prepared for a corresponding increase in product consumption.

Where possible, health facility orders should also be reviewed. Facilities not adhering to standard treatment guidelines should have targeted mentorship. The ratios in which facilities are ordering new versus old formulations should be analyzed and compared with the national quantification, as any deviations will lead to overstock of new ARVs and premature stock-out of the old formulations. An [Order Validation Tool](#), a tool meant to guide supervisors on facilities having challenges with ARV ordering including adhering to national product uptake targets, has been used successfully in Uganda and other countries to highlight irrational ordering.

8.2 SUPPLY MONITORING

- Monitor *patient numbers* on new product and *facilities dispensing product* – health management information system forms should be reviewed to track patient numbers. Where numbers are not explicit or are doubted, consumption (# of packs consumed) converted into patient numbers can be used as a proxy.

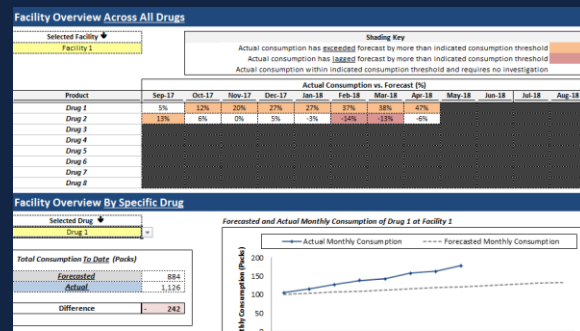
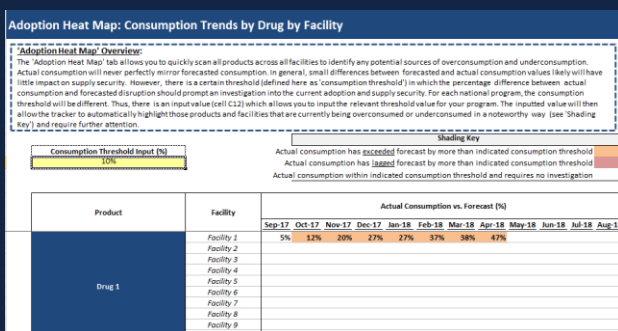
- Monitor **stock availability** at both national and facility levels. Create a stock monitoring tool to flag stock-outs before they happen. (e.g., [CHAI National ARV Stock Status Dashboard](#)).
- Consumption, stock status, and quantities ordered from **high-volume facilities** must be critically reviewed as these highly impact stock availability at the central level.
- **Revise forecasts** on a quarterly basis to reflect more recent uptake trends. Share revised forecasts with suppliers and revise procurement plans according to the updated forecast.
- **Supplier performance** should be monitored to ensure suppliers are delivering on their contractual obligations and meeting the required lead times to ensure stock levels remain stable. This should also be a standing agenda item during rollout TWG discussions.



FEATURED TOOL: CHAI RAPID CONSUMPTION MONITORING TOOL

As national programs continue to rollout new generic ARVs, there is a need for routine, careful monitoring of product uptake to ensure the smooth and sustained adoption of optimal formulations. During new product initiation in country, there are two common issues that may arise: overconsumption (i.e., actual demand exceeds anticipated demand) and underconsumption. (i.e., actual demand lags anticipated demand).

The [CHAI Rapid Consumption Monitoring Tool](#) is a simple tool for programs that have begun to rollout new ARVs to compare the actual consumption of new product at the facility level against forecasted adoption in the hopes of identifying any potential issues of under consumption or overconsumption. Below are two outputs of the tool: 1) consumption trends by drug by facility and 2) a facility overview across all drugs.



Output examples from the CHAI Rapid Consumption Monitoring Tool

8.3 INCREASING UPTAKE AT SITES

In the event that there is slower than planned product uptake, there are a number of strategies to drive uptake to avoid expiries and waste.

- **Shifting Stock:** Review product expiries in areas where there is low uptake and shift stocks to areas where consumption is higher.
- **Targeting Facilities:** Target key facilities and ensure they prioritize the new product.
- **Training:** Hold additional continuing medical education (CME) training sessions to train healthcare workers on appropriate regimens. Goals should include increasing health care

worker knowledge and confidence to prescribe the new product, and removing any remaining biases clinicians have about the new product. Clinical memos and job aides should be available at these training sessions.

- **Facility-level Clinical Mentorship:** Often targeted mentorship that takes place in the facility where prescribers can be coached while managing patients can be more effective than classroom based training.
- **Chart Reviews:** Supporting healthcare workers to review patient charts to identify eligible patients who may benefit from new products to be counseled and switched at their next visit
- **Partner and Community Engagement:** Engage with partners, civil society, and community groups to encourage uptake.

8.4 PHARMACOVIGILANCE

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. PV is not only relevant for the active pharmaceutical ingredient (API) but is also vital to detect drug interactions and determine the contribution of excipients or inactive ingredients.

In most countries, these activities are conducted by a central committee or the different hospital PV groups; these groups must be engaged as part of rollout planning.



Photo Credit: Clinton Health Access Initiative, Inc.

Considerations for pharmacovigilance:

- Existence of an active or functional **PV committee** at the national drug regulatory authority (NDRA).
- Inclusion of a member of the PV committee of the NDRA on the **rollout TWG**.
- Re-activate **regional/provincial, district, or hospital PV committees** or focal persons where these are inactive.
- Members of the NDRA should be included in **training curricula development** for new guidelines. Content on **adverse events** must be included in the guidelines, training materials, and job aides. These can be obtained from dossiers that are gathered and submitted to the NDRA during [product registration](#). Specific training tools include the [CHAI LPV/r Training of Trainers resource](#), [CHAI Basics of ARV and ART Training](#), and the [CHAI ARV Order Quality Training Tool](#). Training tool templates can be found in the [Facility-Level Implementation chapter](#).
- Develop or revise **materials/tools** needed to document and follow up **patients experiencing adverse events**. (e.g. [CHAI Adverse Event Reporting Tool](#))
- Where possible, set up a **toll-free hotline** for health facilities to report cases. This should be communicated during the training sessions.
- [Monitor adverse drug reactions](#), drug resistance, toxicity, treatment failure, etc., and share example **surveillance systems**. Countries should understand the surveillance mechanisms and reporting systems in-country. Surveillance mechanisms should be **active** and countries should have a **plan of action** to handle adverse events when reported.

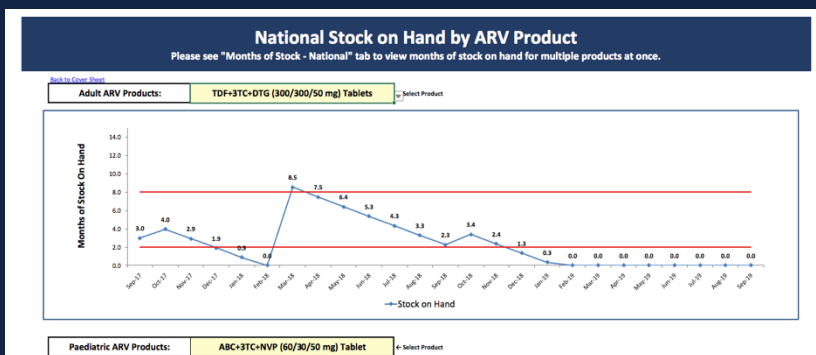
- Ensure effective **communication and collaboration** between key stakeholders in pharmacovigilance.



FEATURED TOOL: CHAI NATIONAL ARV STOCK STATUS DASHBOARD

Keeping an adequate stock of ARVs on hand is important for multiple reasons. Too much stock, and programs run the risk of products expiring before they can be used. Too little stock, and programs run the risk of a stock-out and patients going without vital medicines. Monitoring the stock on hand (SOH) of ARVs is an exercise that programs should conduct on an ongoing basis to ensure that resources are being used wisely.

The [CHAI National ARV Stock Status Dashboard](#) is a simple tool designed for programs to monitor the SOH of ARVs at the national level. The tool shows, over a two year period, when stocks are likely to exceed maximum stock levels (i.e., potential wastage) and when stocks will dip below minimum required levels (i.e., an impending stock-out), based on user-inputted current SOH, expected deliveries, and average monthly consumption (AMC).



Output example from the CHAI National ARV Stock Status Dashboard

8.5 ARV PROCUREMENT WORKING GROUP

Since 2011, the Pediatric ARV Procurement Working Group (PAPWG), whose members include the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), Unitaid, the United States Agency for International Development (USAID), the Partnership for Supply Chain Management (PfSCM), and CHAI, among others, made significant gains in stabilizing the pediatric ARV market by aligning demand and supply sides of the market.

In 2016, the PAPWG expanded its scope to include adult ARVs facing similar market conditions and was renamed the ARV Procurement Working Group (APWG) to reflect the expanded scope and mission. The group's original objectives and operating principles continue to guide the work and ensure increased market stability. Engagement within this forum is essential to support coordinated uptake of new products.

Since March 2017, the APWG has been publishing a quarterly rolling forecast for all ARVs (outside of non-essential pediatric formulations) based on anticipated procurement plans of member

organizations. This forecast is valuable for suppliers and procurers alike. By sharing forward-looking plans on projected orders and scale-up plans across countries, suppliers have better information on which orders to scale-up capacity. This helps to ensure supply keeps up with demand. During previous transitions to new ARVs, suppliers only saw orders once they were placed, and not pipeline orders, so they may have experienced capacity issues as orders spiked in line with demand. The new process is designed to mitigate these challenges which impacts both suppliers and buyers. The forecast will also make it possible to see on a quarterly basis which products may be vulnerable to long lead times due to 1) not having a critical mass of orders or 2) capacity challenges. This visibility allows appropriate conversations and actions to be carried out in response. When introducing new ARVs, country programs are encouraged to liaise with the APWG members, such as CHAI or the Global Fund, to communicate scale-up plans and to contribute efforts towards promoting global supply security during new product transitions.

8.6 KEY CHALLENGES AND MITIGATION STRATEGIES

The below table provides a high-level summary of the challenges in monitoring uptake, in addition to the various ways MoHs, implementing partners, and suppliers can play a role in mitigating those challenges.

| CHALLENGES | SUPPORT STRATEGIES | | |
|--|--|--|--|
| | MOH/BUYERS | PARTNERS | SUPPLIERS |
| <p>Uptake Frequency: Product uptake at a different pace than planned.</p> <p>Lack of Consumption Data Visibility: Lags in facility-level data collection and reporting means consumption trends are often not visible for months, leaving little time to adjust forward planning if trends are different than predicted.</p> <p>Pharmacovigilance: When a product is introduced at a large scale, new adverse effects that were not identified in the clinical trial may arise and robust pharmacovigilance systems are required.</p> | <p>Monitoring Uptake: Monitor degree of uptake by facility and consider rapid assessment of uptake in key facilities if there are lags with existing data systems.</p> <p>Monitoring Supply Chains: Monitor known pain points in supply chain.</p> <p>Pharmacovigilance: MoH to ensure they have functional pharmacovigilance support systems in place and health care workers are trained to report.</p> | <p>Tool Development: Support with monitoring tools and frameworks.</p> <p>Warning Systems: Develop early warning systems for potential stock-out situations.</p> | <p>Risk Management: Expect some order volatility early in product introduction and design production to mitigate.</p> |

Source: CHAI HIV Access Program, 2017.



FEATURED TOOLS

[CHAI National ARV Stock Status Dashboard](#)

A simple tool designed for programs to monitor the stock of ARVs on hand at the national level. The tool shows, over a two year period, when stocks are likely to exceed maximum stock levels (i.e., potential wastage), and when stocks will dip below minimum required levels (i.e., an implementing stock-out), based on user-inputted current stock on hand (SOH), expected deliveries, and average monthly consumption (AMC).

[CHAI Rapid Consumption Monitoring Tool](#)

A simple tool for programs that have begun to rollout new ARVs to compare the actual consumption of a new product at the facility level against forecasted adoption in the hopes of identifying any potential issues of underconsumption or overconsumption.

ADVERSE EVENTS AND MONITORING TOOLS

[CHAI DTG Adverse Drug Reaction among Pregnant Women Monitoring Tool](#)

A tool monitoring adverse drug reactions among pregnant women using dolutegravir (DTG).

[CHAI Adverse Event Reporting Tool](#)

A template for countries to monitor AEs of new or existing ARVs. The template should be adapted to meet the countries need and align with the country context. This form should be integrated within the country's reporting mechanism as appropriate.

IMPROVING PHARMACY PRACTICES

[CHAI ARV Order Quality Tool Overview- Uganda](#)

A tool meant to guide supervisors on facilities having challenges with ARV ordering including adhering to national product uptake targets.

[Pharmacy mentoring manual - Ethiopia](#)

A system-wide intervention aimed at building the capacity of front line health care workers in good end-to-end supply chain practices for commodities including new products.

CHAI CASE STUDIES

[CHAI Case Study - Improving service delivery to HIV patients in India by introducing an integrated online patient and inventory management system](#)

CHAI and the National AIDS Control Organization (NACO) in India improved delivery of HIV services by developing a web-based, integrated inventory and patient management system that compiles and consolidates patient-level treatment information to improve the quality of services provided. Evidence demonstrates that the system has improved the quality of reported data, drug availability, patient tracking throughout the treatment cascade, and increased the quality of overall national program monitoring to result in \$17 million in savings over six months from improved supply planning.

[CHAI Case Study - Improving patient access to medicines in South Africa by strengthening pharmaceutical supply systems](#) The National Department of Health in South Africa and CHAI increased patient access to medicines across disease areas by developing a pharmaceutical database tool that incentivizes improved supplier performance while optimizing tendering, forecasting, and tracking. More than 70% of South Africa's pharmaceutical suppliers now use the tool to centrally share pipeline data and benchmark performance, with cumulative data showing a trend of increased delivery efficiency.

ARV PROCUREMENT WORKING GROUP (APWG)

[APWG Anticipated Demand Forecast](#) Summary of the expected orders over the coming 12-18 months that are visible to APWG members. To keep the forecast current, the Procurement Consortium will share an updated anticipated demand forecast on a quarterly basis. Please note that the information provided is the best available at the time of publication, and is subject to change. This forecast was last updated on July 7, 2017.

[APWG Memorandum: Available Supply of Paediatric LPV/r formulations and guidance for country procurement](#) Due to increasing uptake of paediatric LPV/r formulations, the ARV Procurement Working Group (APWG) developed this memorandum to provide up-to-date information and guidance to country programmes planning to procure LPV/r oral pellets or LPV/r oral liquid. This memo was last updated in April 2017.

[Case Study - Sustaining Paediatric ARV Supply Security with the Paediatric ARV Procurement Working Group](#) The Paediatric ARV Procurement Working Group (PAPWG) was created to lead global collaboration and coordination amongst key partners including through procurement promoting optimal products and regimens. Learnings from this working group can be applied to other commodities with similar market conditions.

To see the most up-to-date resources, visit the [Resource Directory on the CHAI HIV New Product Introduction Toolkit](#).

