

PAEDIATRIC ARV PROCUREMENT WORKING GROUP

Consolidated paediatric ARV planned for procurement by the Consortium, 2016-2017

Geneva, Switzerland

9th March 2016



PAEDIATRIC ARV PROCUREMENT WORKING GROUP MEMBERSHIP

Working Group Members

- Clinton Health Access Initiative
- Global Fund to Fight AIDS, TB and Malaria
- Organization of Eastern Caribbean States
- Partnership for Supply Chain Management
- UNICEF
- UNITAID
- PEPFAR
- PAHO
- KEMSA
- PFSA
- EVA

Working Group Observers

- Drugs for Neglected Diseases initiative
- International AIDS Society
- Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
- Médecins Sans Frontières
- World Health Organization

Procurement Consortium

- Global Fund Pooled Procurement Mechanism (PPM)
- UNICEF
- PFSCM – PEPFAR
- GHSC-PSM – PEPFAR
- CHAI
- OECS (observer)
- MSF (observer)
- PAHO
- KEMSA
- PFSA

PAEDIATRIC ARV PROCUREMENT AND SUPPLY SECURITY RISKS

Market Landscape

- Unattractive market: large number of countries with small orders and small tenders
- Large range of products; demand for some less than batch size, further fragmented by the use and procurement of duplicative and suboptimal formulations (e.g., syrups, non-dispersible ARVs)
- Lack of sufficient visibility, volumes, and/or capacities to individually coordinate sufficient orders and to aggregate demand
- Poor supply security with long and variable lead-times

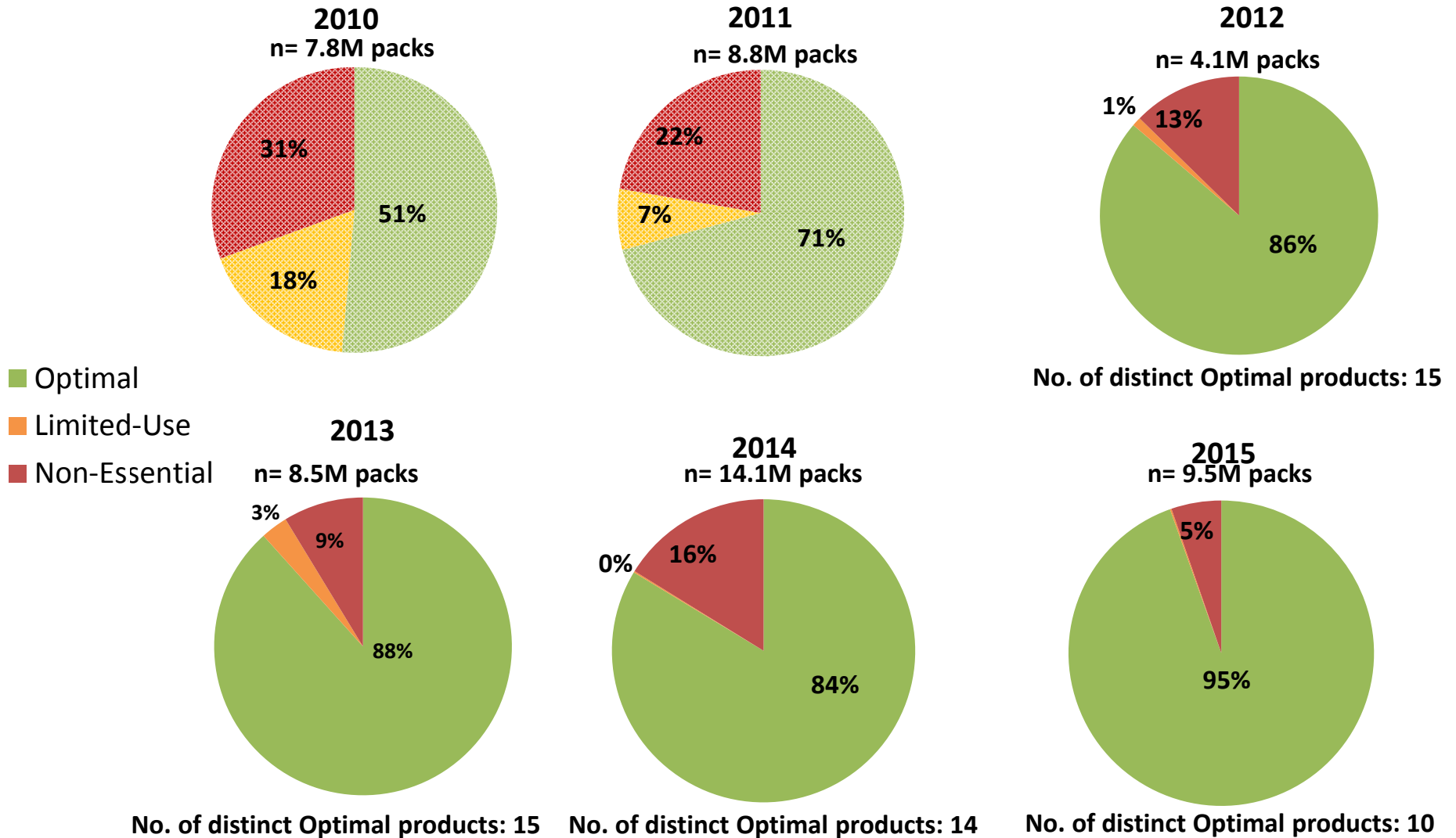
Objective: Reducing the risks of supply disruption to paediatric ARVs
(*improving the supply security*)

- ✓ Ensure sustained supply through coordinated procurement mechanism
- ✓ Strategically manage demand
- ✓ Reduce fragmentation through streamlined product selection
- ✓ Advocate for and transition countries to use the IATT formulary list of optimal and limited-use products

Optimal Formulations form 95% of 2015 PAPWG Procurement

Consolidation around optimal list, despite fewer products

PAPWG Volumes Distribution by IATT Status



2016 FORECAST OF THE PROCUREMENT CONSORTIUM

Methodology and Assumptions

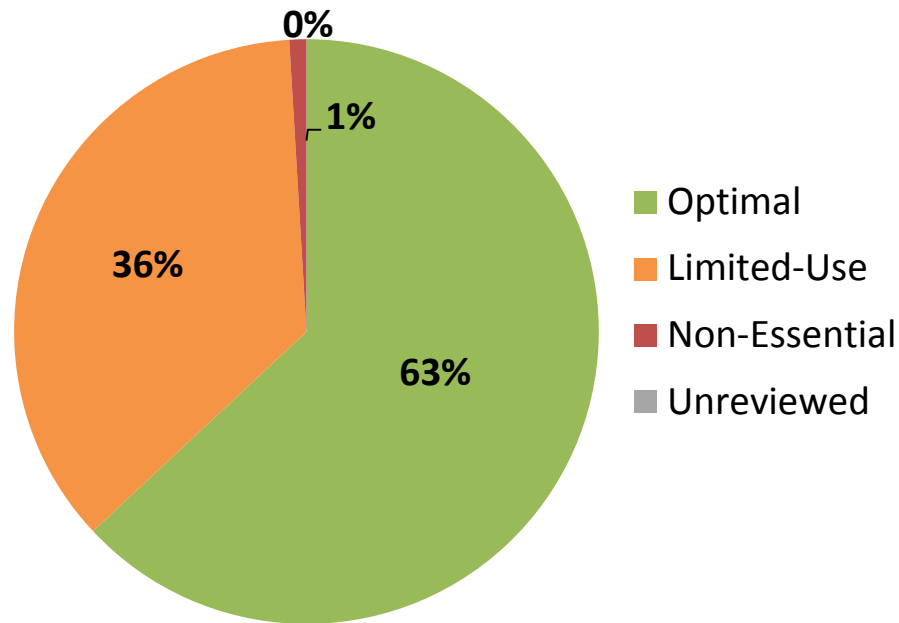
This Anticipated Demand Forecast represents the 2016 preliminary planned procurement orders for paediatric ARVs procured through the PAPWG Procurement Consortium. Countries receiving GFATM funding but procuring through their own procurement systems have not been included.

Source Data

- GF PSM: Preliminary planned volumes from the Global Fund PSM (Procurement and Supply Management) for orders procured through PPM only
- KEMSA: Anticipated 2016 annual forecast
- SCMS: Aggregated forecast data from SCMS procurement database for orders to be placed in 2016 where the procurement channel is SCMS, GHSC, or to be determined
- UNICEF: Anticipated paediatric ARV orders to be procured through UNICEF in 2016

Majority of Procurement in 2016 Expected to be Optimal, Limited-Use Volumes Driven by Triple FDC

2016 PAPWG Anticipated Demand
n= 11,875,179



Variety of Formulations Anticipated: 25

Product variety anticipated to be ordered has a net decline of 2 formulations (29 → 25)

2016 Product Mix based on 2016 IATT List

FDCs

- ABC/3TC (60/30 mg) Tablet (Disp)
- AZT/3TC (60/30 mg) Tablet (Disp)
- LPV/r (80/20 mg/ml) Oral Solution
- LPV/r (100/25 mg) Tablet (HS)
- LPV/r (40/10 mg) Oral Pellet - HS
- AZT/3TC/NVP (60/30/50 mg) Tablet (Disp)

Singles

- EFV (200 mg) Tablet (Scored)
- NVP (50 mg) Tablet (Disp)
- RAL (100 mg) Tablet
- ABC (60 mg) Tablet (Disp)
- DRV (75 mg) Tablet
- AZT (100 mg) Capsule
- DRV (150 mg) Tablet
- EFV (200 mg) Capsule
- EFV (50 mg) Capsule
- ETV (100 mg) Tablet
- ETV (25 mg) Tablet
- ddI (250 mg) Capsule (EC)

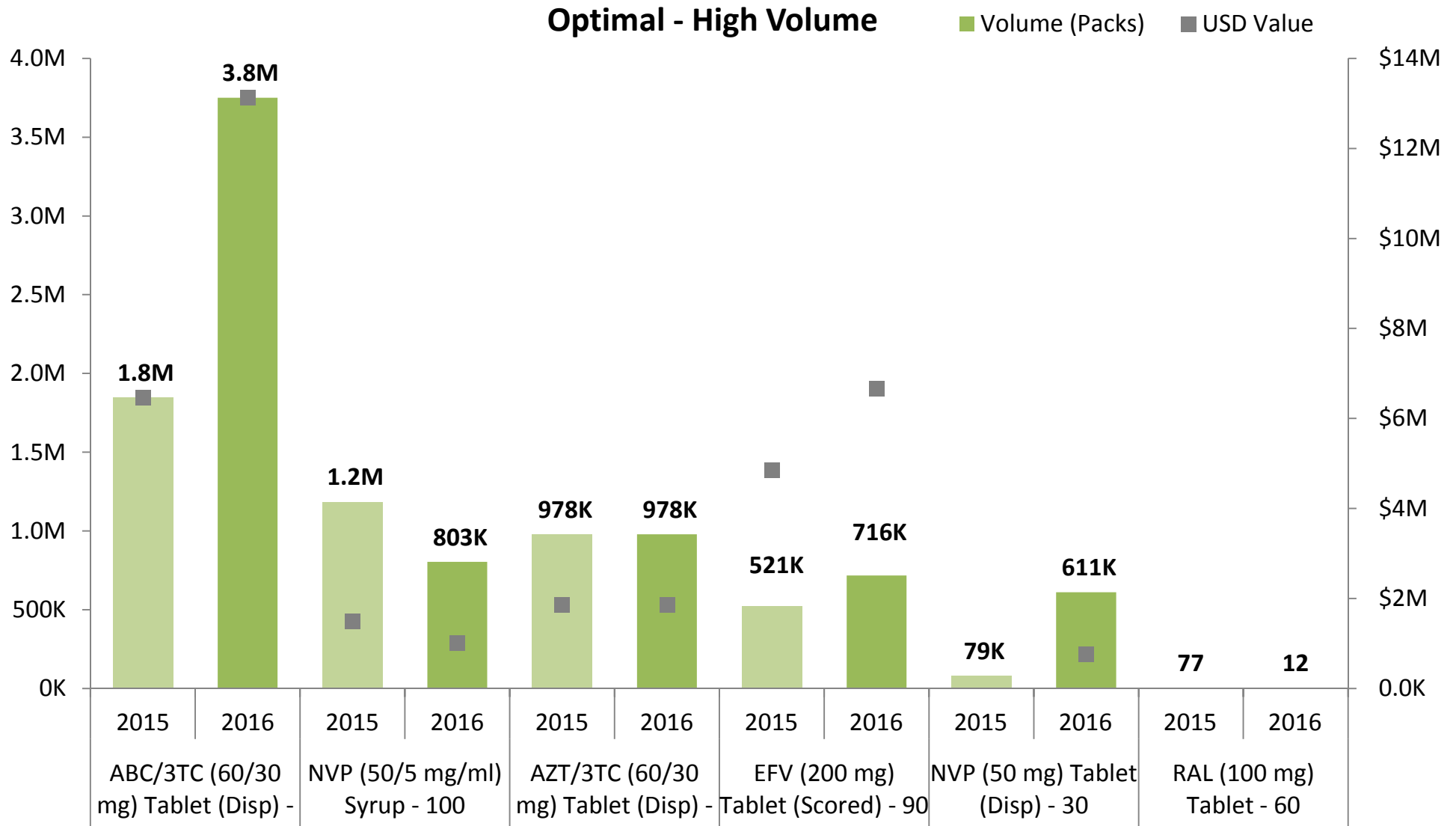
Oral Solutions

- NVP (50/5 mg/ml) Oral Solution - 100
- 3TC (50/5 mg/ml) Oral Solution - 100
- AZT (50/5 mg/ml) Oral Solution - 100
- r (80 mg/ml) Syrup
- ABC (20 mg/ml) Oral Solution
- AZT (50/5 mg/ml) Oral Solution - 240
- NVP (50/5 mg/ml) Oral Solution - 240
- 3TC (50/5 mg/ml) Oral Solution - 240
- EFV (30 mg/ml) Oral Solution
- AZT (50/5 mg/ml) Injection

2016 FORECAST – OPTIMAL PRODUCTS

Optimal Product List	
ABC/3TC (60/30 mg) Tablet (Disp) - 60	3,750,457
AZT/3TC (60/30 mg) Tablet (Disp) - 60	977,938
NVP (50/5 mg/ml) Syrup - 100	803,154
EFV (200 mg) Tablet (Scored) - 90	716,481
NVP (50 mg) Tablet (Disp) - 30	611,022
LPV/r (100/25 mg) Tablet (HS) - 60	412,811
LPV/r (80/20 mg/ml) Syrup - 60	87,585
LPV/r (80/20 mg/ml) Syrup - 300	84,251
LPV/r (40/10 mg/ml) Pellets - 120	33,062
LPV/r (80/20 mg/ml) Syrup - 160	6,102
LPV/r (100/25 mg) Tablet (HS) - 120	2,250
RAL (100 mg) Tablet - 60	12

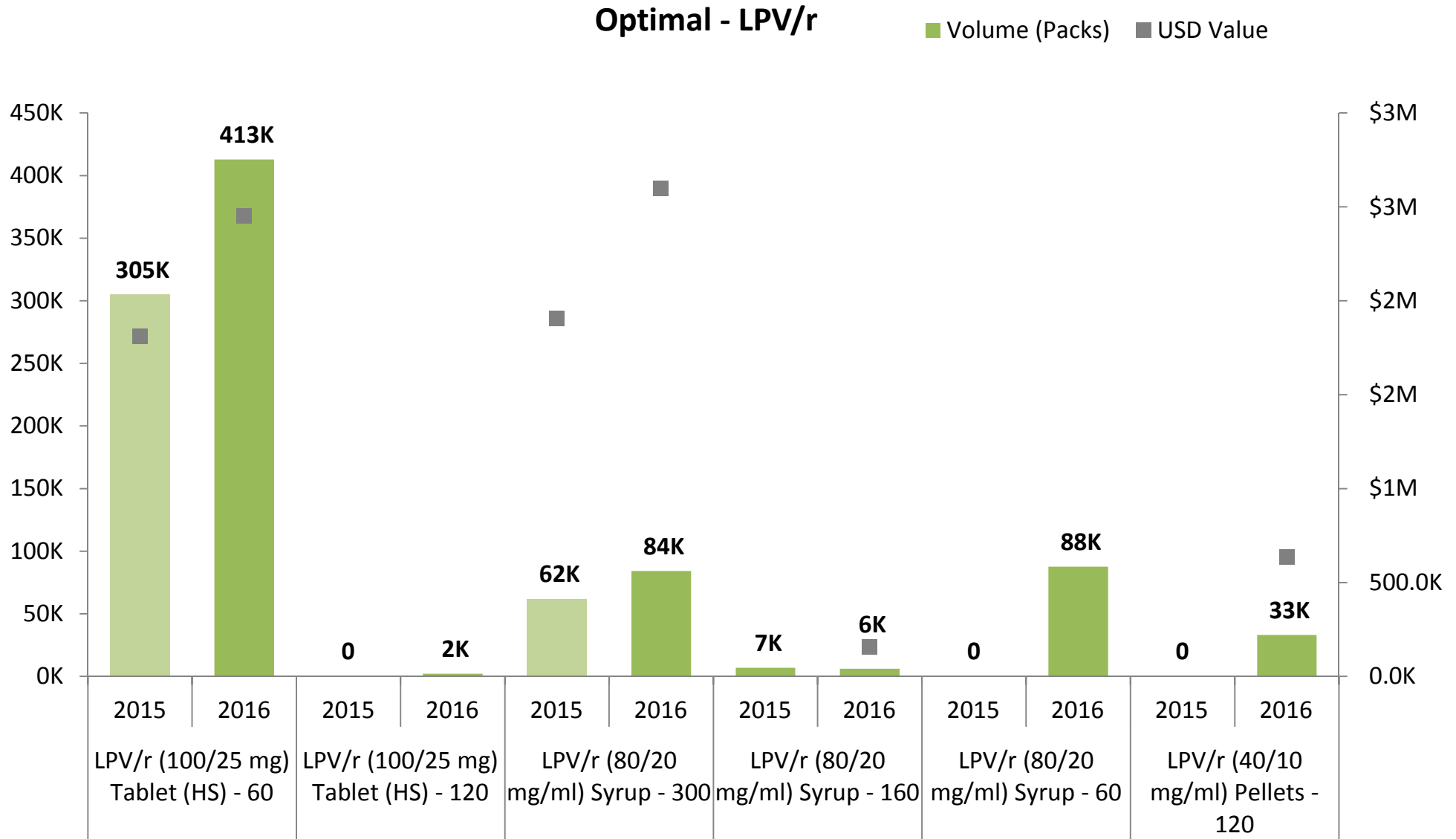
2016 Anticipated Optimal Procurement Remains High



Data Source: 2015 PAPWG Preliminary procurement data. PAPWG 2016 Anticipated Demand Forecast, Jan 2016. Includes data from GF PSM plans, SCMS, KEMSA, and UNICEF. Q1 2016 PPM Reference Prices used. No orders of ABC/3TC (120/60 mg) currently available for forecast

2016 Anticipated Optimal Procurement Remains High

ABC/3TC (120/60 mg) currently not anticipated for procurement

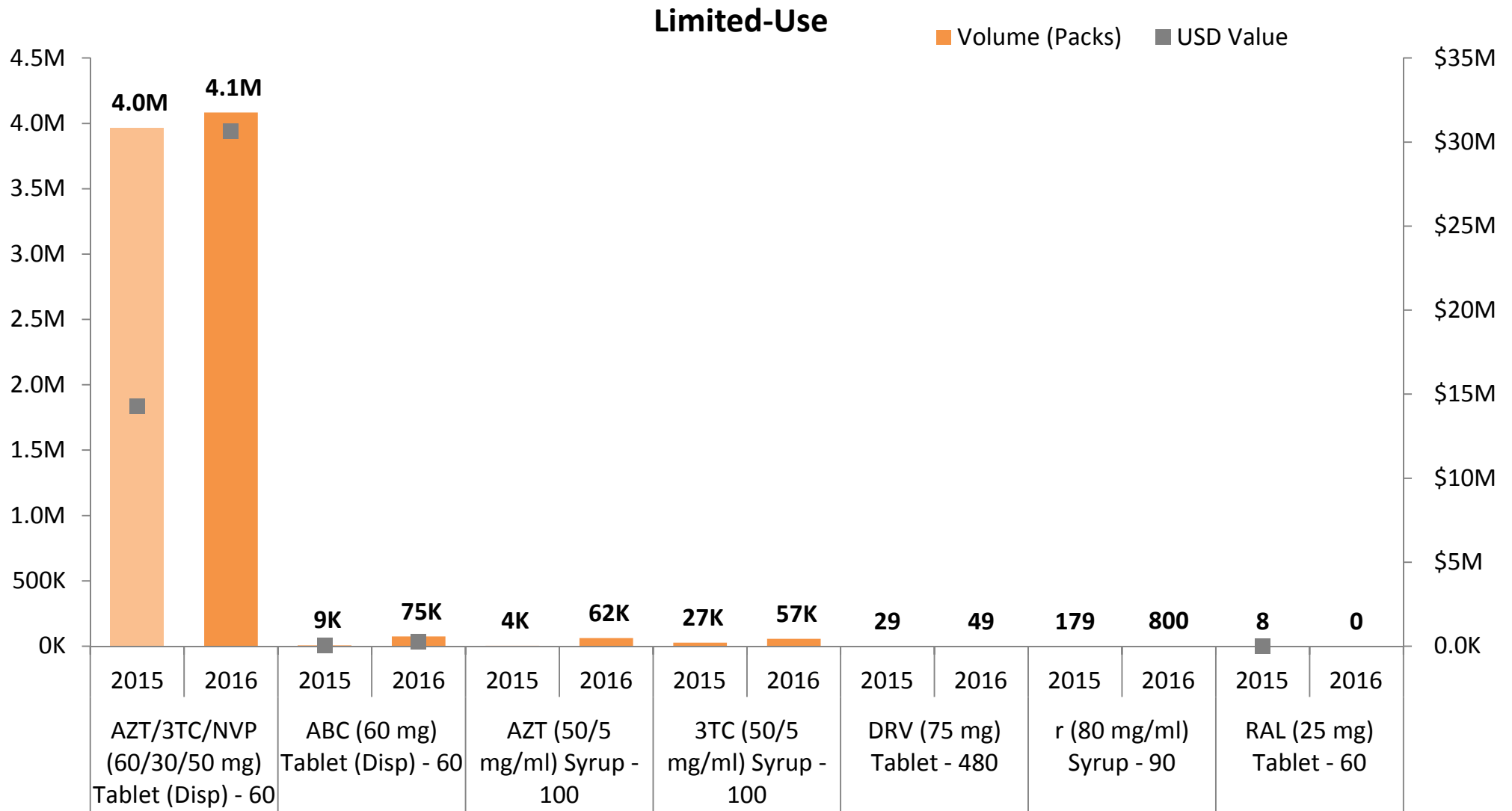


2016 FORECAST – LIMITED USE

Limited-Use Product List	
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	4,083,404
ABC (60 mg) Tablet (Disp) - 60	75,351
AZT (50/5 mg/ml) Syrup - 100	61,867
3TC (50/5 mg/ml) Syrup - 100	56,532
r (80 mg/ml) Syrup - 90	800
DRV (75 mg) Tablet - 480	49

Limited-Use Anticipated Demand

Limited-Use list will be revised by the IATT



Data Source: 2015 PAPWG Preliminary procurement data. PAPWG 2016 Anticipated Demand Forecast, Jan 2016. Includes data from GF PSM plans, SCMS, KEMSA, and UNICEF. Q1 2016 PPM Reference Prices used. Products excluded due to no procurement in 2015/2016: AZT (60 mg) Tablet (Disp), ATV 100 mg Capsule, r (25 mg) Tablet

ROAD AHEAD: IMPROVED ENGAGEMENT

- Active engagement with countries and partners to adopt/transition to the prescribed IATT formulary
- Periodic review of forecasts to communicate to Manufacturers/Suppliers
- Ongoing monitoring of market challenges and development of solutions as a group (e.g., registration/WHO PQ/FDA approvals, sub-batch orders, lead-times)
- Implement and monitor KPIs to track and validate progress made
- Work with countries not part of the procurement consortium to provide information on ordering cycle dates to enable them to align
- Continue to engage with suppliers individually and collectively
- Expansion of PAPWG to additional products

COORDINATED PROCUREMENT OF LOW VOLUME AND NEW OPTIMAL PRODUCTS (1/2)

- Procurement and Supply of most optimal paediatric ARVs mainstreamed
- Building on the paediatric ARV Procurement Working Group (PAPWG)
- Some adolescent and adult ARVs can also be challenging to procure
- Expanding scope to:
 - Supporting the uptake of optimal products for adults and children recommended by WHO
 - Coordinating the procurement of low volume and new adult ARVs (entry and exit)
- Expansion to other disease areas later if needed – e.g. low volume antimalarial medicines

COORDINATED PROCUREMENT OF LOW VOLUME AND NEW OPTIMAL PRODUCTS (2/2)

- Activities
 - Collating demand intelligence
 - Monitoring market challenges and developments
 - Supporting the uptake of optimal products
- Provisional list of products

Coordinated procurement (18)	Adults	· ABC 300mg	· DTG 50mg
		· ATV 300mg	· EFV 400mg & FDCs RTV 100mg
		· AZT 300mg	· TDF 300mg
		· DRV 600mg	· 3TC 150mg
	Paed	· ABC/3TC 120/60 mg dispersible	· AZT 50mg/5ml solution (100ml)
		· LPV/r 80/20 mg/ml solution	· AZT 60 mg dispersible
		· NVP 50 mg dispersible	· LPV/r oral pellets
		· ABC 60 mg dispersible	· 3TC 50mg/5ml solution (100ml)
Consolidated demand forecast only (4)	Adults	· ATV 100mg;150mg	· RTV 25 mg
		· RAL 400mg	
	Paed	· DRV 75 mg or 150mg	
		· RAL 25 mg; 100 mg	