Paediatric ARV Procurement Working Group **Progress Review at 31 December 2015**

Version 4 March 2015

Updated with complete 2015 data from version presented at the January 27 2016 PAPWG meeting





















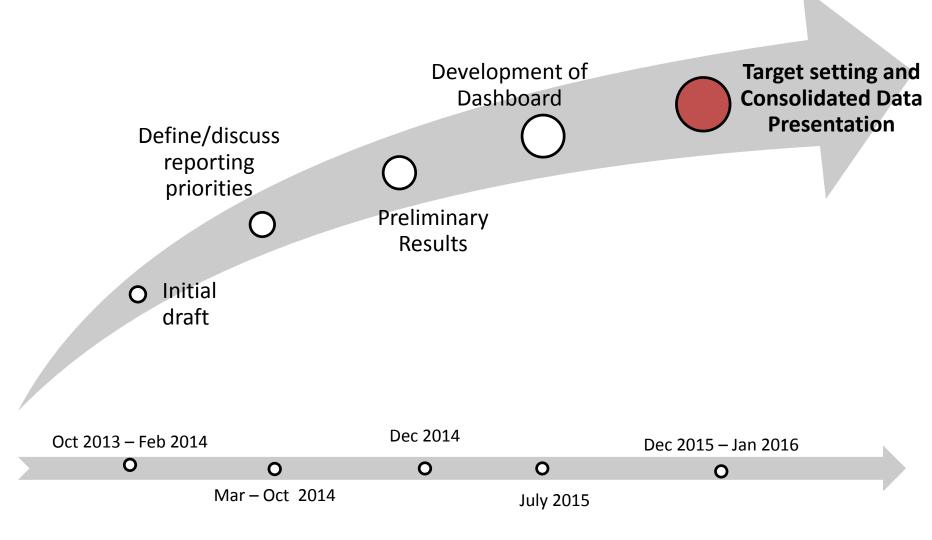




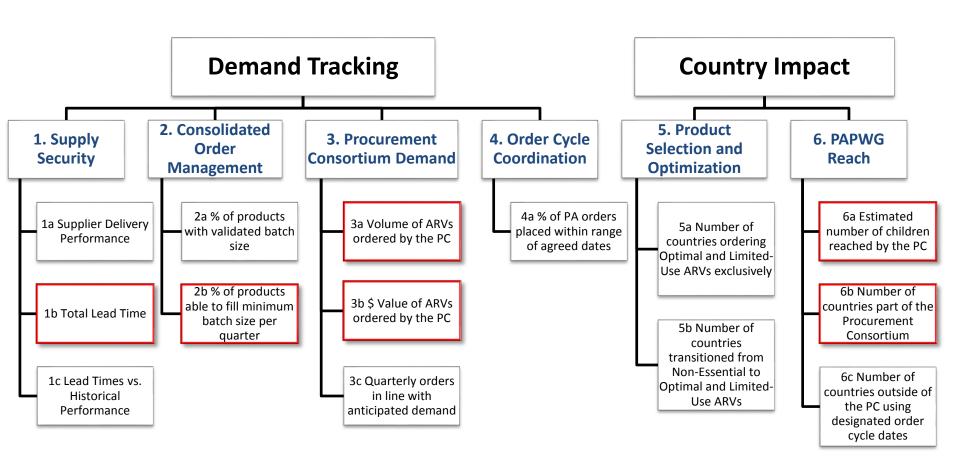




PAPWG Reporting Indicators Through Time



PAPWG Key Reporting Indicators

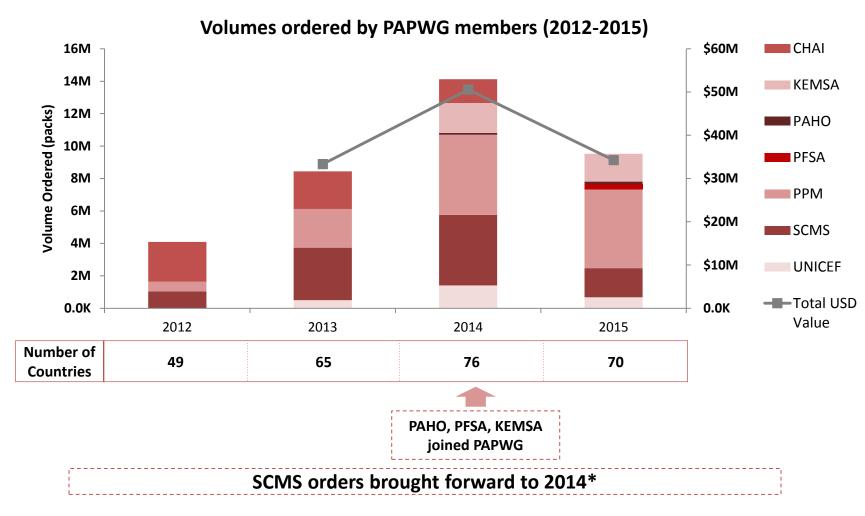


Highlighted indicators will be discussed in detail; others available in appendix

ARV Volume/Value:

Year-over-Year Volumes Shift with Member Order Planning

Global reach has remained consistent with 60+ countries since 2013



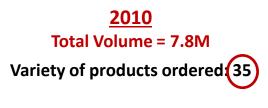
^{*}SCMS procured more product in 2014 due to the USAID contract transition and not due to an increase in underlying demand. Additional product was bought earlier to account for potential service gaps in the upcoming GHSC contract

Data source: Current PAPWG Member Data 2010-2015.

Data includes all known procurements based on when procurement agents joined the PAPWG

Product Consolidation:

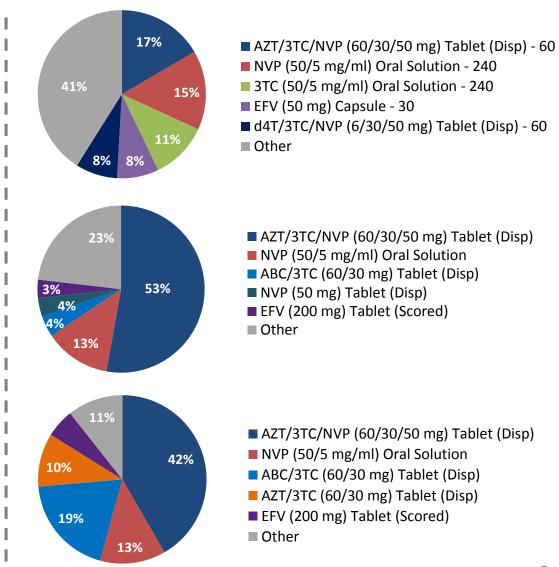
Successful Consolidation around Fewer Products



2013
Total Volume = 8.5M
Total Value: US\$33.4M

Variety of products ordered: 32

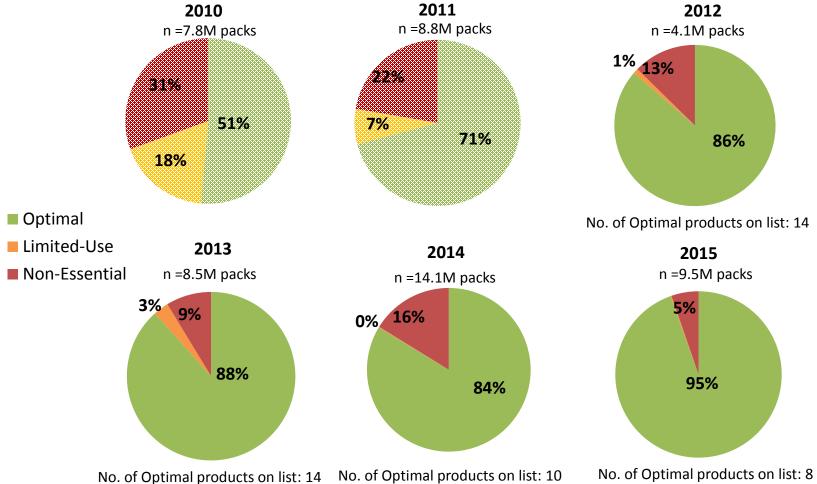




Optimal Formulations form 95% of 2015 PAPWG Procurement

Consolidation around optimal list, despite fewer products listed over time

PAPWG Volumes Distribution by IATT Status



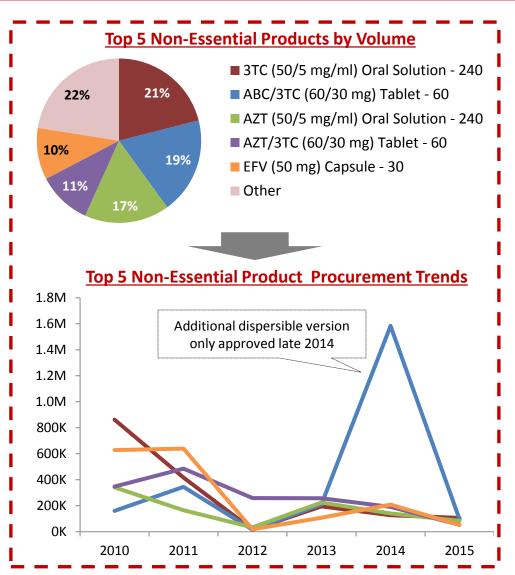
IATT Optimization:

Non-Essential Product Procurement Generally Declining

Products accounted for 5% of 2015 total volume

Non-Essential Formulations Procured in 2015 by Volume

1	3TC (50/5 mg/ml) Oral Solution - 240	105,74
2	ABC/3TC (60/30 mg) Tablet - 60	95,514
3	AZT (50/5 mg/ml) Oral Solution - 240	84,155
4	AZT/3TC (60/30 mg) Tablet - 60	53,160
5	EFV (50 mg) Capsule - 30	51,151
6	EFV (200 mg) Capsule - 90	27,166
7	3TC (50/5 mg/ml) Oral Solution - 100	26,793
8	AZT (100 mg) Capsule - 100	24,496
9	NVP (50/5 mg/ml) Oral Solution - 240	16,390
10	ABC (20 mg/ml) Oral Solution - 240	14,646
11	ATV (200 mg) Capsule - 60	1,546
12	FTC (10 mg/ml) Oral Solution - 170	1,093
13	EFV (30 mg/ml) Oral Solution - 180	744
14	AZT (100 mg) Tablet - 60	184
15	TDF (40mg) Oral Powder, scoop	79
16	DRV (150 mg) Tablet - 240	27
17	RAL (25 mg) Tablet - 60	8



Product Phase-Out/Phase-in:

Rapid and Complete Phase-Out of Non-Recommended Formulations Amongst PAPWG Orders

Formulation	Volume (Packs)				
	2010		2014		2015
d4T/3TC/NVP (6/30/50 mg) Tablet (Disp) - 60	626,723		2,000		0
d4T/3TC/NVP (12/60/100 mg) Tablet (Disp) - 60	616,859		207		0
d4T/3TC (6/30 mg) Tablet (Disp) - 60	120,340		13,887		0
d4T/3TC (12/60 mg) Tablet (Disp) - 60	89,250		0		0
d4T (20 mg) Capsule - 60	73,995		0		0
d4T (1 mg/ml) Powder - 200	61,921		0		0
ddl (125 mg) Capsule (EC) - 30	32,117		0		0
ddI (200 mg) Tablet (disp) - 60	20,712		0		0
ddl (200 mg) Capsule (EC) - 30	20,051		2,200		0
ddI (25 mg) Tablet (Disp) - 60	14,507		4,935		0
ddI (50 mg) Tablet (Disp) - 60	13,757		0		0
d4T (15 mg) Capsule - 60	9,946		0		0
ddI (100 mg) Tablet (Disp) - 60	8,204		0		0
ddl (250 mg) Capsule (EC) - 30	2,428		0		0
d4T/3TC (6/30 mg) Tablet (Disp) - 14	2,000		0		0
ddl (10 mg/ml) Oral Solution - 200	810		186		0
EFV (100 mg) Tablet - 30	11,576		0		0

Product Phase-Out/Phase-in:

Further Five Non-Essential Formulations in Rapid Decline

Possibility of Further Optimization Opportunities at the Country Level

Non-Essential Formulations in Transition

	Volu	ume (Packs)		
Formulation	2010	2015	% Change	Countries
3TC (50/5 mg/ml) Oral Solution - 240	861,668	105,743	-88%	11
ABC (20 mg/ml) Oral Solution - 240	478,346	14,646	-97%	9
EFV (200 mg) Capsule - 90	302,046	27,166	-91%	8
EFV (30 mg/ml) Oral Solution - 180	15,349	744	-95%	3
EFV (50 mg) Capsule - 30	627,761	51,151	-92%	6

Product Phase-Out/Phase-in:

In Addition to Product Phase-Out, PAPWG Poised to Assist With Product Phase-In

New Pediatric ARV Formulations

ABC/3TC (120/60 mg) Tablet (Disp) – 30

- Manufactured by Mylan
- Approved 10/23/2014

LPV/r (40/10 mg/ml) Oral Pellet – 120

- Manufactured by Cipla
- Approved 5/21/2015

Relevant Policy Briefs

- 1) IATT. "Fact sheet on Lopinavir and Ritonavir (LPV/r) Oral Pellets 40mg/10mg per capsule". Sept 2015.
- 2) IATT. "Supply Planning for New Dosage Form of Lopinavir and Ritonavir Oral Pellets, 40mg/10mg per capsule, pack of 120 capsules". Sept 2015.

Supply Security:

Suppliers Appear to Have Sufficient Orders for Active Production of Key Products; With Some, Possible Concern With Reliance on One Supplier

Products under Active Production

Product	No. of Suppliers with Active Production (SRA approvals)
ABC/3TC (60/30 mg) Tablet (Disp) - 60	2(2)
AZT/3TC (60/30 mg) Tablet (Disp) - 60	2(3)
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	3(3)
LPV/r (100/25 mg) Tablet (HS) – 60	2(3)
 NVP (50/5 mg/ml) Oral Solution - 100	2(2)
EFV (200 mg) Tablet (Scored) – 90	1(1)
LPV/r (80/20 mg/ml) Oral Solution - 300	1(1)
NVP (50 mg) Tablet (Disp) - 30	1(1)
ABC/3TC (120/60 mg) Tablet (Disp) - 30	0(1)
ABC (60 mg) Tablet (Disp) – 60	1(1)
ATV (150 mg) Capsule – 60	1(3)
DRV (75 mg) Tablet – 480	1(1)
ETV (100 mg) Tablet – 120	1(1)
ETV (25 mg) Tablet – 120	1(1)
ATV (100 mg) Capsule – 60	
TDF (200 mg) Tablet – 30	-
r (80 mg/ml) Oral Solution – 90	-

Supply Security:

Supplier Reported Plans for Discontinuation Highlight Need for Transition Planning

Products Marked for Discontinuation and Ordered by the PAPWG in 2015

Product	2015 Volume (pa <u>c</u> ks)
LPV/r (80/20 mg/ml) Oral Solution - 160	168
AZT (50/5 mg/ml) Oral Solution - 100	591
3TC (50/5 mg/ml) Oral Solution - 240	756
ABC (20 mg/ml) Oral Solution - 240	2,309
ABC/3TC (60/30 mg) Tablet - 60	95,514
AZT (50/5 mg/ml) Oral Solution - 240	1,532

Prioritizing Products:

Several Products Appear To Have Sufficient Volumes Through PAPWG Where Close Coordination May Not Be Required To Regularly Meet Batch Size

No of batches in 201E

Formulation	(total volume/batch size)
ABC/2TC (60/20 mg) Tablet (Disp) 60	153
ABC/3TC (60/30 mg) Tablet (Disp) - 60	24
AZT/3TC (60/30 mg) Tablet (Disp) - 60	41
A21/31C (00/30 Hig) Tablet (Disp) - 00	15
AZT/2TC/NVD (60/20/50 mg) Tablet (Disp) 60	73
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	62
EFV (200 mg) Tablet (Scored) - 90	13
LPV/r (100/25 mg) Tablet (HS) - 60	12
	5
LPV/r (80/20 mg/ml) Oral Solution - 300	6
NVP (50 mg) Tablet (Disp) - 30	5
NVD (EQ/E mg/ml) Oral Solution 100	20
NVP (50/5 mg/ml) Oral Solution - 100	14
3TC (50/5 mg/ml) Oral Solution - 240	8
ABC/3TC (60/30 mg) Tablet – 60**	10
AZT (50/5 mg/ml) Oral Solution - 240	7
EFV (50 mg) Capsule - 30	8

12 Products through 17 Suppliers Identified with >4 batches/yr of orders through PAPWG

^{**}Non-dispersible product; likely to decline in favor of dispersible

Analysis for products with known batch sizes only. Excluded products with unknown batch size are LPV/r (80/20 mg/ml) Oral Solution – 160 (Abbvie); EFV (30 mg/ml) Oral Solution – 180 (MSD); RAL (25 mg) Tablet – 60 (MSD); TDF (40mg) Oral Powder, scoop (Gilead)

Prioritizing Products:

Low Volume (<4 batches/ year) Products to be Prioritized for Quarterly Order Cycles Moving Forward

No. of batches in 201	5
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Formulation	(total volume/batch size)
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	3
NVP (50 mg) Tablet (Disp) - 60	3
LPV/r (80/20 mg/ml) Oral Solution – 160	<1
ABC (60 mg) Tablet (Disp) - 60	2
ATV (150 mg) Capsule - 60	2
AZT (50/5 mg/ml) Oral Solution - 100	<1
DRV (75 mg) Tablet - 480	<1
r (80 mg/ml) Oral Solution - 90	<1
ATV (100 mg) Capsule – 60	-
AZT (60 mg) Tablet (Disp) - 60	-
ETV (100 mg) Tablet -120	-
ETV (25 mg) Tablet – 120	-
TDF (200 mg) Tablet - 30	-

(Marked for discontinuation)

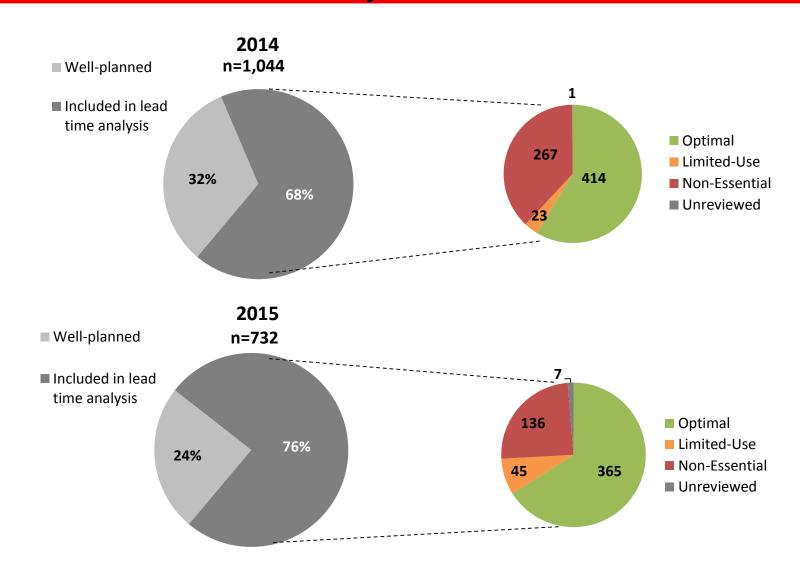
Remaining Limited Use Products (unknown batch size)

		2015 Volume
Formulation		(packs)
	RAL (100 mg) Tablet (Scored) - 60	77

Items in grey have another supplier with > 4 batches/year listed on previous slide

Lead Times:

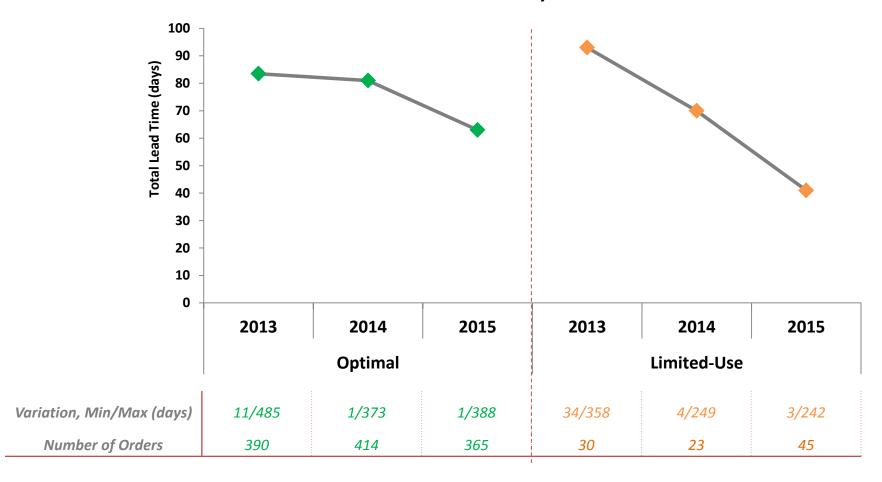
Lead Time Calculations: <30% of Orders Were Well Planned and Excluded From Analysis



Lead Times:

Lead Times Overall Have Decreased for Both Optimal and Limited-Use Products

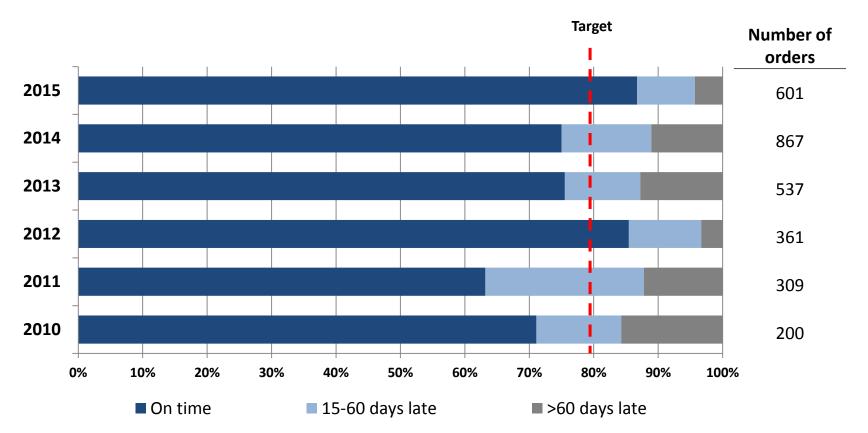
Median Total Lead Time by 2015 IATT Status



Lead Times:

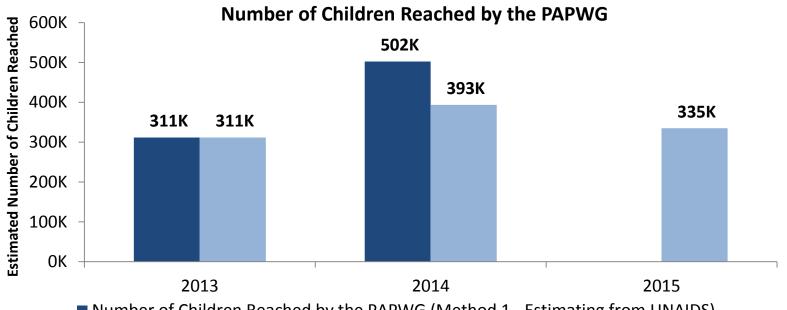
2015 On Time Delivery Target Was Met

On Time Delivery (All Products, PPM and SCMS only)



On Time Delivery Target: >80% of orders delivered on time (≤ 14 days after the vendor promise date)

PAPWG Estimated to Reach >300K Children on ARVs Globally



- Number of Children Reached by the PAPWG (Method 1 Estimating from UNAIDS)
- Number of Children Reached by the PAPWG (Method 2 Implied Patients)

Two Methodologies Used for Calculation of PAPWG Patient Reach

<u>Method 1:</u> Based on UNAIDS patient estimates for children (0-14 yrs). Inclusion of country estimates in total based on product mix ordered and volume relative to number of children on treatment. Older children included in UNAIDS total may be on adult ARVs due to their weight/age. This method should be considered the upper-bound estimate for the number of children reached by the PAPWG.

<u>Method 2:</u> Based on dosing for a 10-13.9kg child using PI/ NNRTI volume for actual PAPWG orders. Countries placing orders through the PAPWG who do not order NNRTIs or PIs are not included. DRV and RTV products are excluded.

Appendix

Increase in SRA Approvals for Pediatric Products Since 2010

No. of Unique Suppliers with SRA Approval

	2010 (Product	2015 (Product
2015 IATT Status	Variation)	Variation)
Optimal	5 (8)	7 (19)
Limited-Use	7 (10)	10 (14)
Non-Essential	15 (63)	18 (90)
Unreviewed*	2 (2)	5 (8)
AZT and NVP Oral Solutions	5 (6)	8 (10)

Formulation	No. of SRA-approved Suppliers (2010)	No. of SRA-approved Suppliers (2015)
ABC/3TC (120/60 mg) Tablet (Disp)	0	1
ABC/3TC (60/30 mg) Tablet (Disp)	0	2
AZT/3TC (60/30 mg) Tablet (Disp)	1	3
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp)	1	3
EFV (200 mg) Tablet (Scored)	1	1
LPV/r (100/25 mg) Tablet (HS)	3	4
LPV/r (80/20 mg/ml) Oral Solution	1	2
NVP (50 mg) Tablet (Disp)	1	3
NVP (50/5 mg/ml) Oral Solution - 100	1**	2**

Based on 2015 IATT list

^{*}Unreviewed category includes unreviewed and yet to be reviewed products Data source: CHAI SRA Approvals database, Jan 2016;

²²

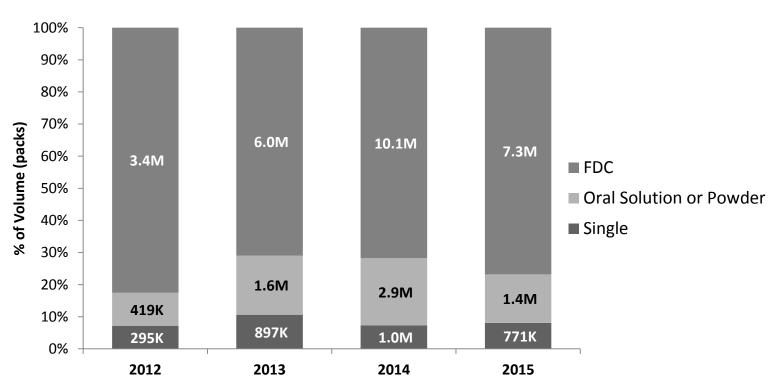
Majority of Orders Account for 4 Formulations

of 2015 PAPWG orders were for 4 formulations

Top 9 Formulations Procured by the PAPWG in 2015*	% of Total Procured
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp)	42%
ABC/3TC (60/30 mg) Tablet (Disp)	19%
NVP (50/5 mg/ml) Oral Solution	12%
AZT/3TC (60/30 mg) Tablet (Disp)	10%
EFV (200 mg) Tablet (Scored)	5%
LPV/r (100/25 mg) Tablet (HS)	3%
3TC (50/5 mg/ml) Oral Solution	1%
NVP (50 mg) Tablet (Disp) - 100	1%
ABC/3TC (60/30 mg) Tablet	1%

Variation in Formulation Type Likely not Impacting Volumes Over Time Fixed-Dose Combinations (FDCs) a significant proportion of orders

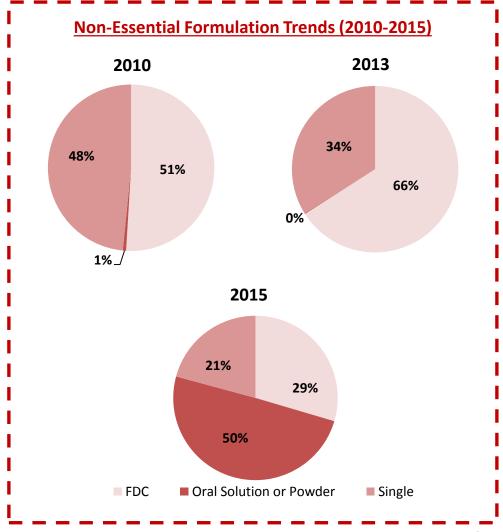
Distribution by Formulation Type



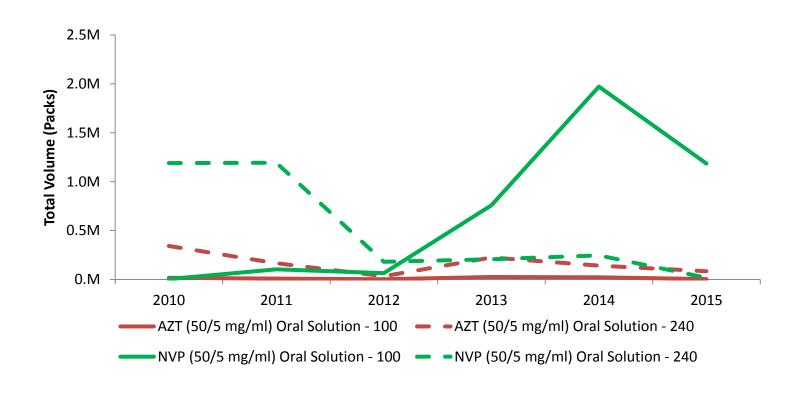
Historical Non-Essential Split by Product Type

Non-Essential Formulations Procured in 2015 by Volume

1	3TC (50/5 mg/ml) Oral Solution - 240	105,743
2	ABC/3TC (60/30 mg) Tablet - 60	95,514
3	AZT (50/5 mg/ml) Oral Solution - 240	84,155
4	AZT/3TC (60/30 mg) Tablet - 60	53,160
5	EFV (50 mg) Capsule - 30	51,151
6	EFV (200 mg) Capsule - 90	27,166
7	3TC (50/5 mg/ml) Oral Solution - 100	26,793
8	AZT (100 mg) Capsule - 100	24,496
9	NVP (50/5 mg/ml) Oral Solution - 240	16,390
10	ABC (20 mg/ml) Oral Solution - 240	14,646
11	ATV (200 mg) Capsule - 60	1,546
12	FTC (10 mg/ml) Oral Solution - 170	1,093
13	EFV (30 mg/ml) Oral Solution - 180	744
14	AZT (100 mg) Tablet - 60	184
15	TDF (40mg) Oral Powder, scoop	79
16	DRV (150 mg) Tablet - 240	27
17	RAL (25 mg) Tablet - 60	8



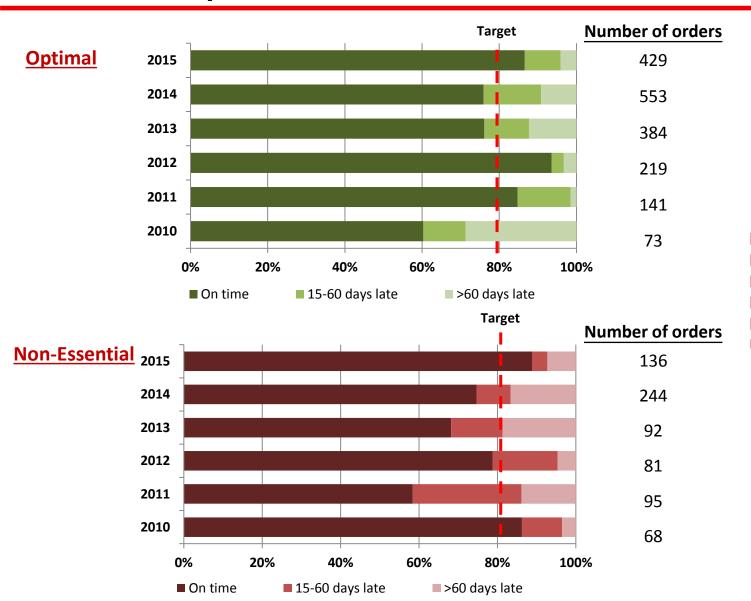
NVP Oral Solution Transitioning Well from 240ml to 100ml



2015 Procurement by SRA Approved Supplier Portfolio Mix

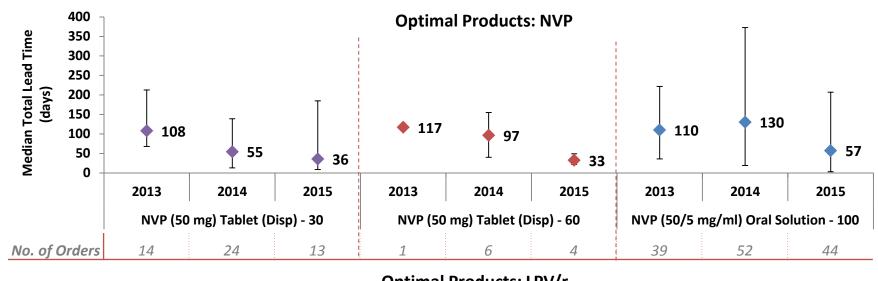
	Total SRA Approved ARV Portfolio	Of approved, which procured in 2015	% of SRA Approved Formulations Procured
AbbVie	3	3	100%
Strides	2	2	100%
Hetero	6	3	50%
Cipla	23	10	43%
Gilead	5	2	40%
Janssen-Cilag	5	2	40%
Microlabs	8	3	38%
MSD	8	3	38%
Aurobindo	25	9	36%
Emcure	3	1	33%
Mylan	17	5	29%
ViiV	6	1	17%
Ranbaxy	7	1	14%
BMS	10	0	0%
Macleods	3	0	0%

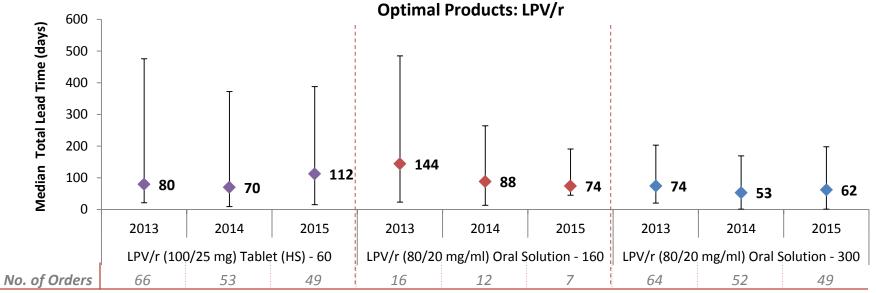
No Significant Difference in On Time Delivery Performance between Optimal and Non-Essential Products



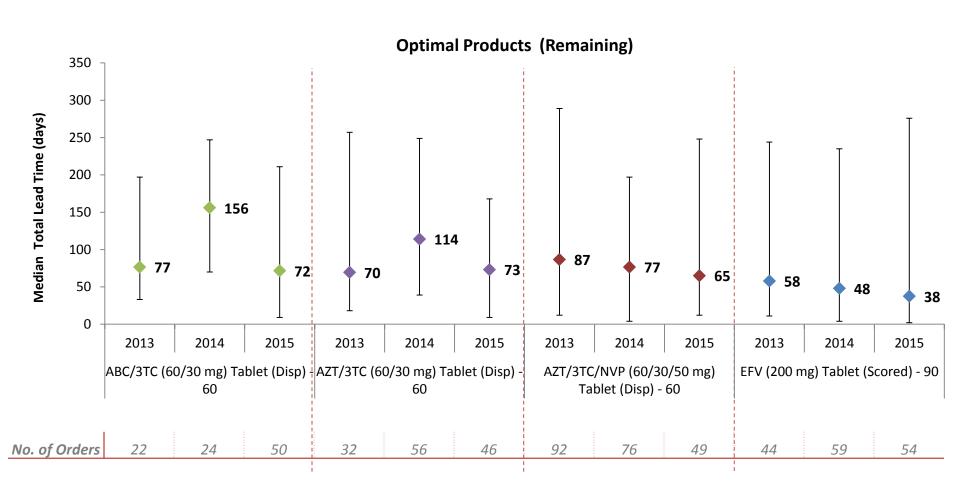
On Time Delivery Target: >80% of orders delivered on time (≤ 14 I days after the vendor promise date)

Total Lead Time: Optimal NVP and LPV/r

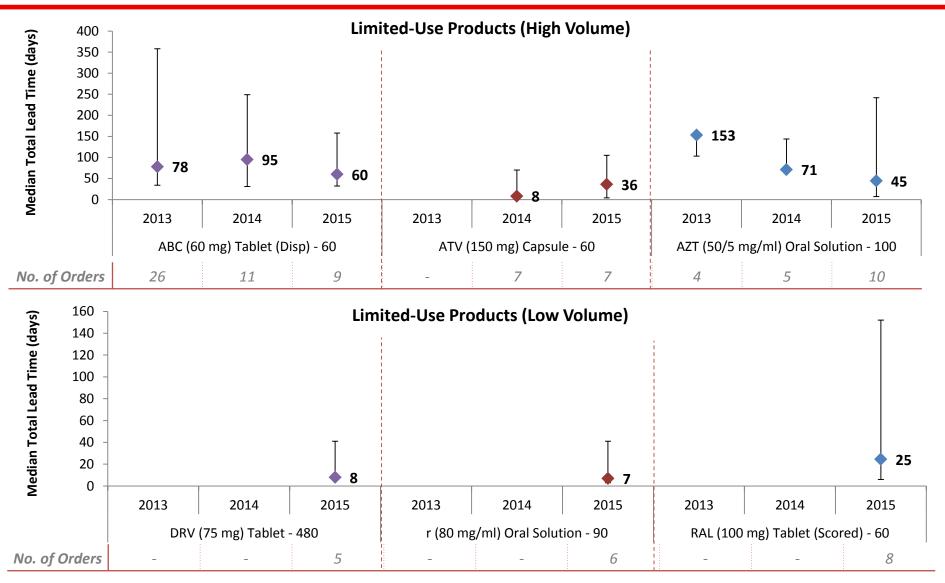




Total Lead Time: Remaining Optimal



Total Lead Time: Limited-Use



KPI 1: Lead times – Optimal vs Non-essential FDCs

Total Lead Time: FDC Formulations	2014		2015	
Iotal Lead Time: FDC Formulations	Median	Range	Median	Range
ABC/3TC (60/30 mg) Tablet - 60	99	33-200	88.5	78-99
ABC/3TC (60/30 mg) Tablet (Disp) - 60	156	70-247	71.5	9-211
AZT/3TC (60/30 mg) Tablet - 60	79	20-148		n/a
AZT/3TC (60/30 mg) Tablet (Disp) - 60	114	39-249	73	9-168
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	76.5	4-197	65	12-248
LPV/r (100/25 mg) Tablet (HS) - 60	70	9-372	112	15-388
LPV/r (80/20 mg/ml) Oral Solution - 160	88	13-264	74	45-191
LPV/r (80/20 mg/ml) Oral Solution - 300	53	1-169	62	1-198

KPI 1: Lead times – Oral Solutions

Total Lead Time: Oral Solutions	20	14	2015		
- Total Lead Time. Oral Solutions	Median	Range	Median	Range	
NVP (50/5 mg/ml) Oral Solution - 100	130	19-373	57	3-207	
NVP (50/5 mg/ml) Oral Solution - 240	79	4-278	71	61-125	
AZT (50/5 mg/ml) Oral Solution - 100	71	69-144	44.5	7-242	
AZT (50/5 mg/ml) Oral Solution - 240	85	28-426	52	3-225	
3TC (50/5 mg/ml) Oral Solution - 100	68	68	64	1-176	
3TC (50/5 mg/ml) Oral Solution - 240	75	3-208	49.5	4-194	
r (80 mg/ml) Oral Solution - 90	157.5	78-237	7	3-41	
TDF (40mg) Oral Powder, scoop	58	2-208	33	33-77	
ABC (20 mg/ml) Oral Solution - 240	261	189-261	36	4-141	
EFV (30 mg/ml) Oral Solution - 180		n/a	99	99	
FTC (10 mg/ml) Oral Solution - 170	78	78	48	48-77	

KPI 1: Lead times – Single Formulations

Total Lead Time: Single Formulations		20	14	2015		
	Total Lead Time: Single Formulations	Median	Range	Median	Range	
	EFV (200 mg) Tablet (Scored) - 90	48	4-235	37.5	2-276	
	EFV (200 mg) Capsule - 90	75.5	2-208	32	4-76	
	EFV (50 mg) Capsule - 30	74.5	3-208	33	13-186	
	NVP (50 mg) Tablet (Disp) - 30	54.5	13-139	36	9-185	
	NVP (50 mg) Tablet (Disp) - 60	96.5	40-155	32.5	22-49	
	AZT (100 mg) Capsule - 100	105.5	34-264	126	72-225	
	ABC (60 mg) Tablet (Disp) - 60	95	31-249	60	32-158	

KPI 2: % Tracked Products with Known Batch Size

Total number of products by manufacturer ordered by the PC in 2013	60
No. of products with validated batch size information	39
Percentage of products with validated batch sizes information	65%

Total number of products by manufacturer ordered by the PC in 2014	65
No. of products with validated batch size information	47
Percentage of products with validated batch sizes information	72%

Total number of products by manufacturer ordered by the PC in 2015	56
No. of products with validated batch size information	43
Percentage of products with validated batch sizes information	77%

KPI 3: Anticipated Demand Forecast vs. Actual Orders

2015	Actual Procurement	Anticipated Demand
TOTAL QUANTITY (packs)	9,527,817	15,789,319
Optimal	9,003,787	12,253,728
ABC/3TC (120/60 mg) Tablet (Disp) - 30	-	900
ABC/3TC (120/60 mg) Tablet (Disp) - 60	-	15,186
ABC/3TC (60/30 mg) Tablet (Disp) - 60	1,846,024	1,500,227
AZT/3TC (60/30 mg) Tablet (Disp) - 60	977,510	1,666,029
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	3,968,558	6,066,539
EFV (200 mg) Tablet (Scored) - 90	521,392	1,560,183
LPV/r (100/25 mg) Tablet (HS) - 120	-	47,642
LPV/r (100/25 mg) Tablet (HS) - 60	304,994	418,229
LPV/r (80/20 mg/ml) Syrup - 160	6,950	52
LPV/r (80/20 mg/ml) Syrup - 300	61,800	241,797
LPV/r (80/20 mg/ml) Syrup - 60	-	81,999
NVP (50 mg) Tablet (Disp) - 30	78,787	25,438
NVP (50 mg) Tablet (Disp) - 60	53,641	55,418
NVP (50/5 mg/ml) Syrup - 100	1,184,131	574,087
Limited-Use	16,611	78,033
ABC (60 mg) Tablet (Disp) - 60	9,483	31,927
AZT (50/5 mg/ml) Syrup - 100	4,205	30,390
ETV (100 mg) Tablet - 120	-	15,716
ATV (150 mg) Capsule - 60	2,638	-
DRV (75 mg) Tablet - 480	29	-
r (80 mg/ml) Syrup - 90	179	-
RAL (100 mg) Tablet - 60	77	-
Non-Essential	502,895	3,457,559
Unreviewed	4,524	-

Bold: > +/- 40% variation from anticipated

KPI 4: Orders within Designated Order Cycles

2013	Q1 2013	Q2 2013	Q3 2013	Q4 2013
Orders within designated order cycle range	75	102	86	95
Total orders in quarter*	196	272	266	274
% of orders placed within agreed order cycle range	38%	38%	32%	35%
Number of countries with >1 order within agreed order cycle range	17	18	16	16

2014	Q1 2014	Q2 2014	Q3 2014	Q4 2014
Orders within designated order cycle range	88	121	60	62
Total orders in quarter*	353	306	297	212
% of orders placed within agreed order cycle range	25%	40%	20%	29%
Number of countries with >1 order within agreed order cycle range	22	24	20	18

2015	Q1 2015	Q2 2015	Q3 2015	Q4 2015
Orders within designated order cycle range	50	53	83	40
Total orders in quarter*	213	237	209	203
% of orders placed within agreed order cycle range	23%	22%	40%	20%
Number of countries with >1 order within agreed order cycle range	15	16	19	9

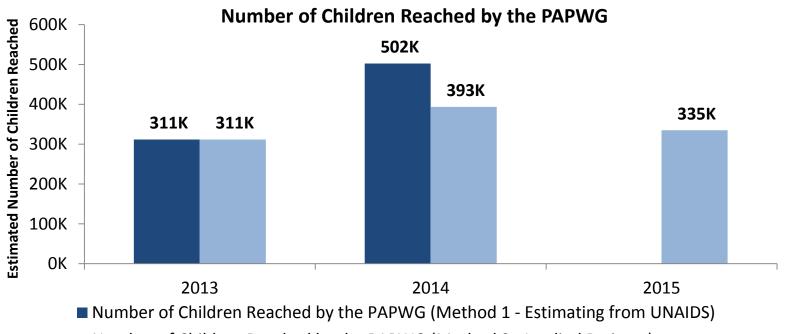
KPI 5: Number of Countries Ordering Optimal and Limited- Use Products Exclusively

	H1 2013	H2 2013
Total number of countries ordering optimal and limited-use products exclusively	34	32
% of total number of countries ordering optimal and limited use products exclusively through PAPWG	65%	62%

	H1 2014	H2 2014
Total number of countries ordering optimal and limited-use products exclusively	32	29
% of total number of countries ordering optimal and limited use products exclusively through PAPWG	48%	47%

	H1 2015	H2 2015
Total number of countries ordering optimal and limited-use products exclusively	30	25
% of total number of countries ordering optimal and limited use products exclusively through PAPWG	54%	47%

KPI 6a: Number of Children Reached by the PAPWG



■ Number of Children Reached by the PAPWG (Method 2 - Implied Patients)

Two Methodologies Used for Calculation of PAPWG Patient Reach

Method 1: Based on UNAIDS patient estimates for children (0-14 yrs). Inclusion of country estimates in total based on product mix ordered and volume relative to number of children on treatment. Older children included in UNAIDS total may be on adult ARVs due to their weight/age. This method should be considered the upper-bound estimate for the number of children reached by the PAPWG.

Method 2: Based on dosing for a 10-13.9kg child using PI/ NNRTI volume for actual PAPWG orders. Countries placing orders through the PAPWG who do not order NNRTIs or PIs are not included. DRV and RTV products are excluded.

KPI 6b: Number of Countries ordering through the PAPWG

