

ARV Procurement Working Group (APWG): Progress Review

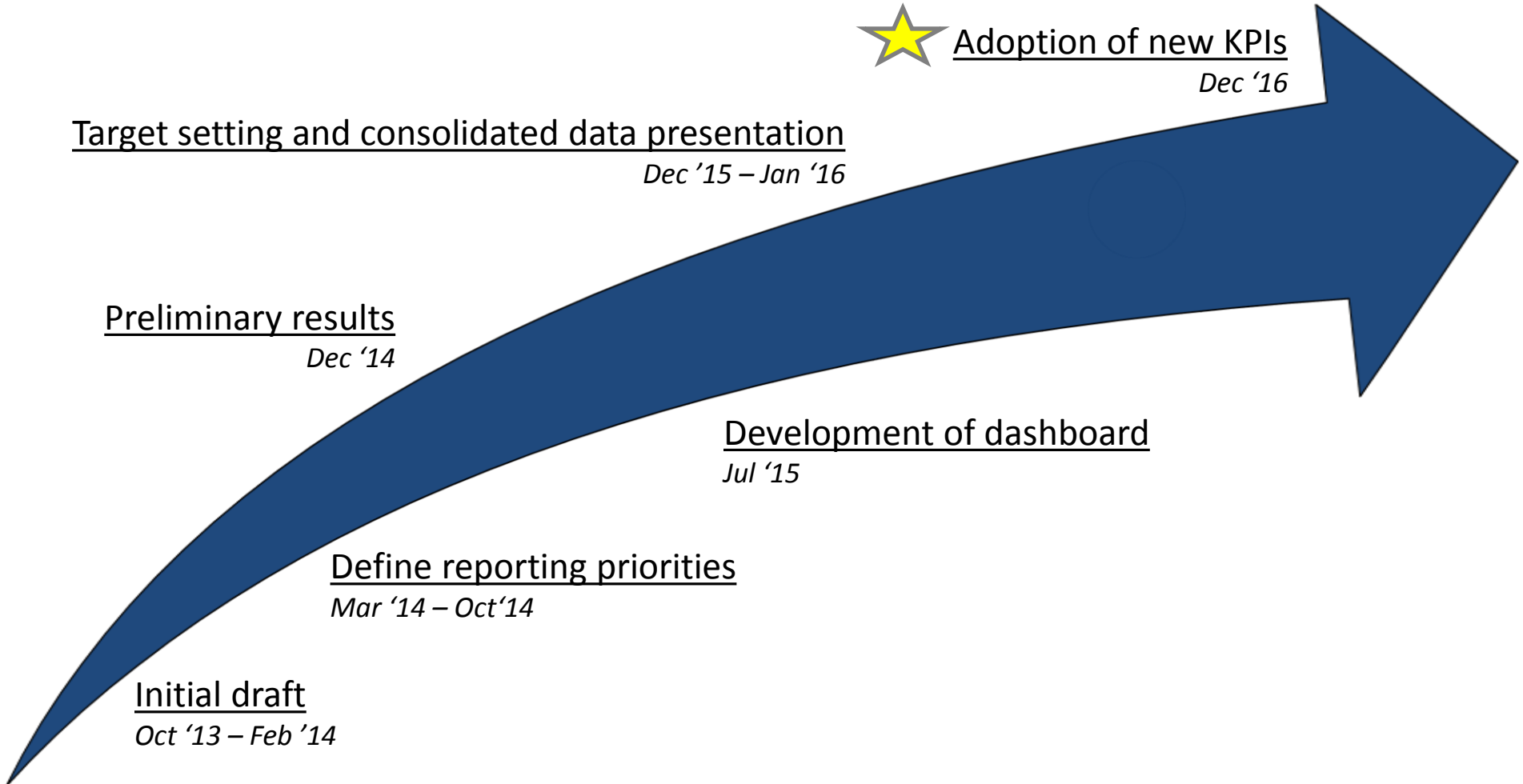
March 27, 2017

Geneva

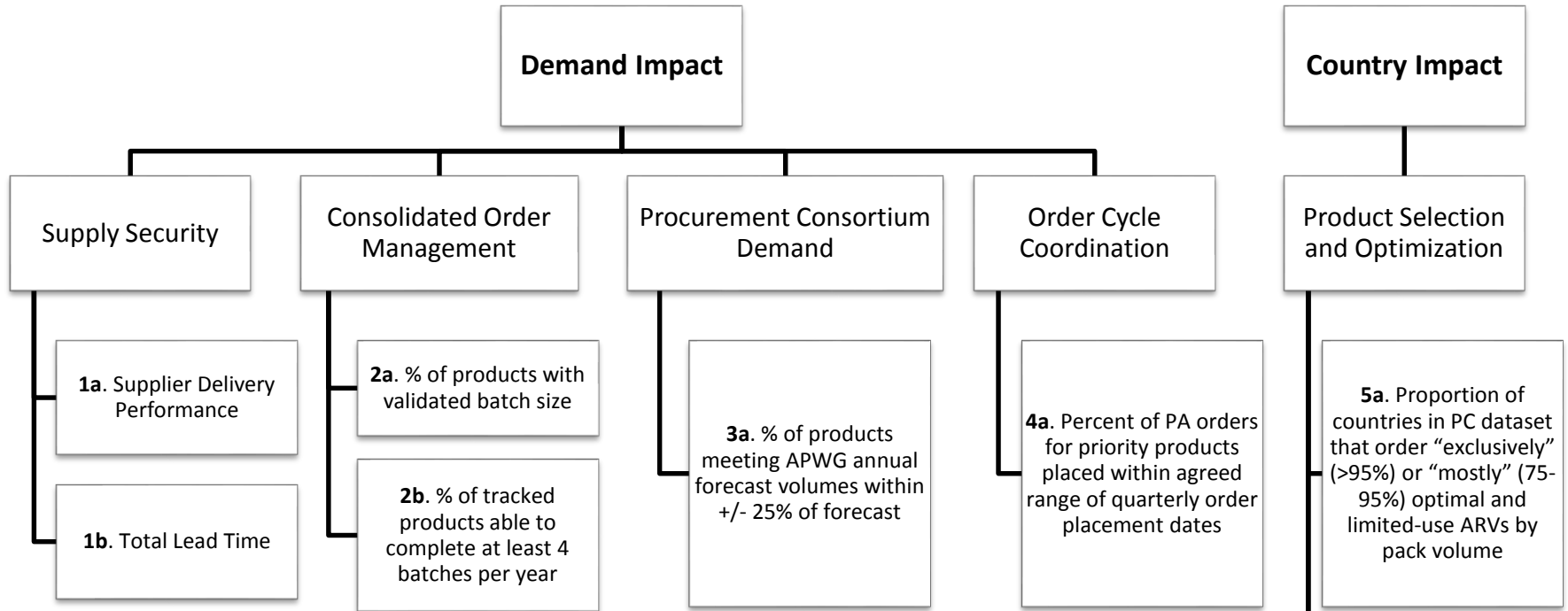
CONFIDENTIAL



APWG Reporting Indicators Through Time



2016 APWG KPIs



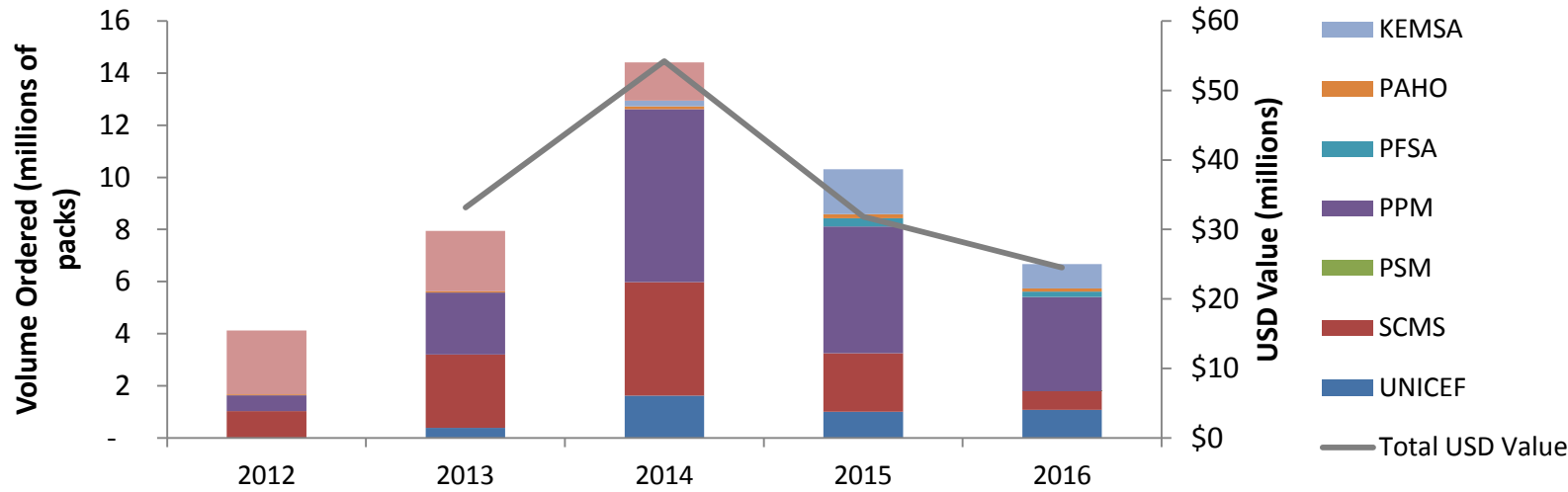
Non-KPI figures to track

<u>Demand</u>	<u>Reach</u>	
Volume of ARVs ordered by the PC	Estimated number of total patients and children specifically reached by Procurement Consortium	Number of countries represented by Procurement Consortium for all ARVs and specifically pediatric formulations
\$ Value of ARVs ordered by the PC	Estimated number of adults reached by the Procurement Consortium during the first two calendar years of new product introduction	

Year-Over-Year Volumes Shift With Member Order Planning

Global reach has remained consistent with 60+ countries since 2013

Pediatric volumes ordered by APWG members (2012-2016)



Number of Countries	49	69	76	70	70
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↑
**PAHO, PFSA, KEMSA
 joined APWG**

SCMS orders brought forward to 2014*

*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 APWG Member Data 2010-2016.

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

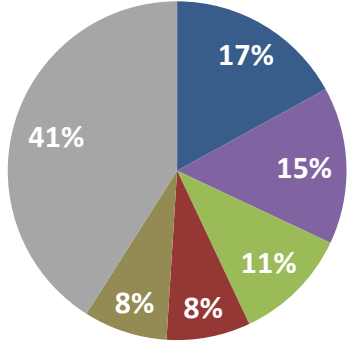
USD value based on PPM prices from Q1 of the corresponding year. Only those products with GF listed prices were included in the value calculation

Successful Consolidation Around Fewer Pediatric Products

2010

Total Volume = 7.8M

Unique Formulations Procured
(excluding pack size) **34**



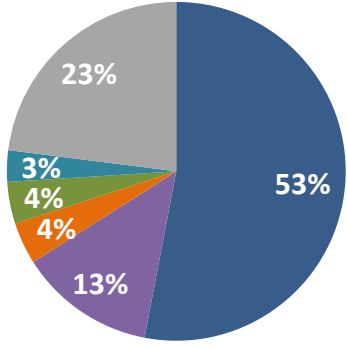
- AZT/3TC/NVP (60/30/50 mg) Tablet (Disp)
- NVP (50/5 mg/ml) Oral Solution
- 3TC (50/5 mg/ml) Oral Solution
- EFV (50 mg) Capsule
- d4T/3TC/NVP (6/30/50 mg) Tablet (Disp)
- Other

2013

Total Volume = 7.9M

Total Value: US\$33.2M

Unique Formulations Procured
(excluding pack size) **34**



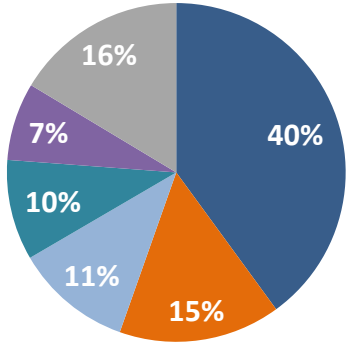
- AZT/3TC/NVP (60/30/50 mg) Tablet (Disp)
- NVP (50/5 mg/ml) Oral Solution
- ABC/3TC (60/30 mg) Tablet (Disp)
- NVP (50 mg) Tablet (Disp)
- EFV (200 mg) Tablet (Scored)
- Other

2016

Total Volume = 6.7M

Total Value: US\$24.5M

Unique Formulations Procured
(excluding pack size) **26**

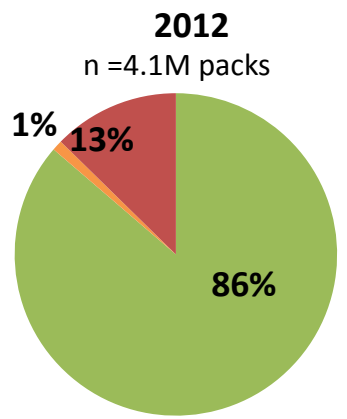
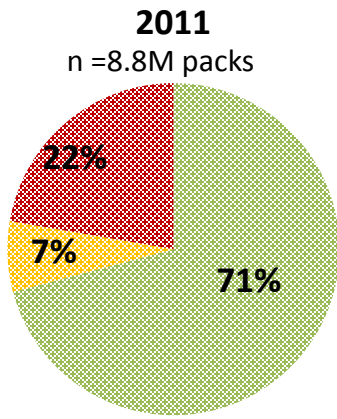
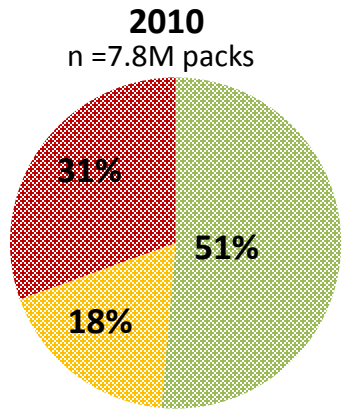


- AZT/3TC/NVP (60/30/50 mg) Tablet (Disp)
- ABC/3TC (60/30 mg) Tablet (Disp)
- AZT/3TC (60/30 mg) Tablet (Disp)
- EFV (200 mg) Tablet (Scored)
- NVP (50/5 mg/ml) Oral Solution
- Other

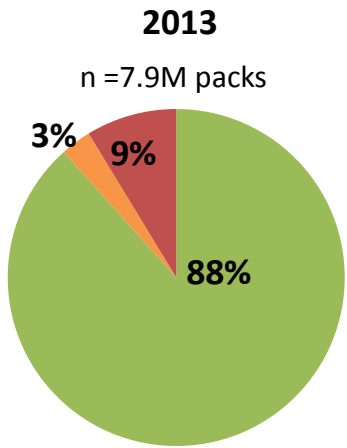
Non-Essential Orders Have Continued To Decrease; AZT/3TC/NVP (60/30/50 mg) Tablet Remains In Flux

APWG Volumes Distribution by IATT Status

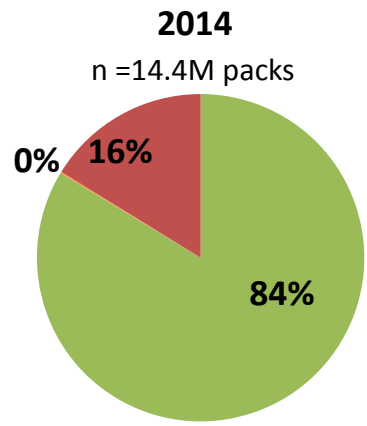
- Optimal
- Limited-Use
- Non-Essential



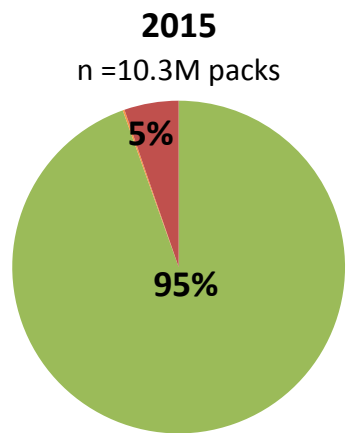
No. IATT Optimal products: 14



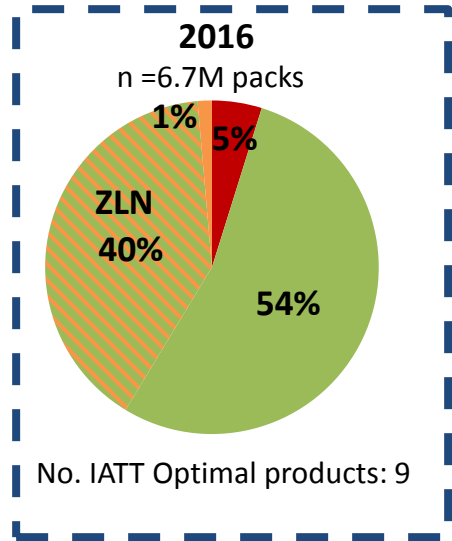
No. IATT Optimal products: 14



No. IATT Optimal products: 10



No. IATT Optimal products: 8



No. IATT Optimal products: 9

Data source: Current APWG Member Data 2010-2016

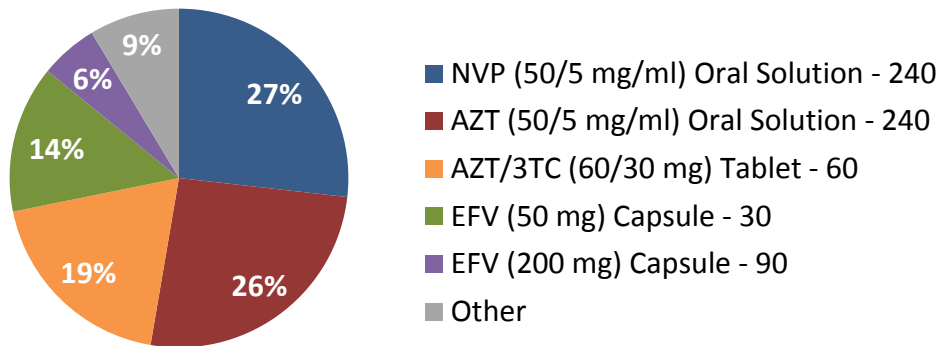
Product categorization: 2010-2013: 2011 IATT List; 2014 orders: 2013 IATT list; 2015 orders: 2015 IATT list; 2016 orders: 2016 IATT list

Non-Essential Procurement Declining And At 5% Of 2016 Volumes Orders are mostly for 240ml bottle size of oral solutions

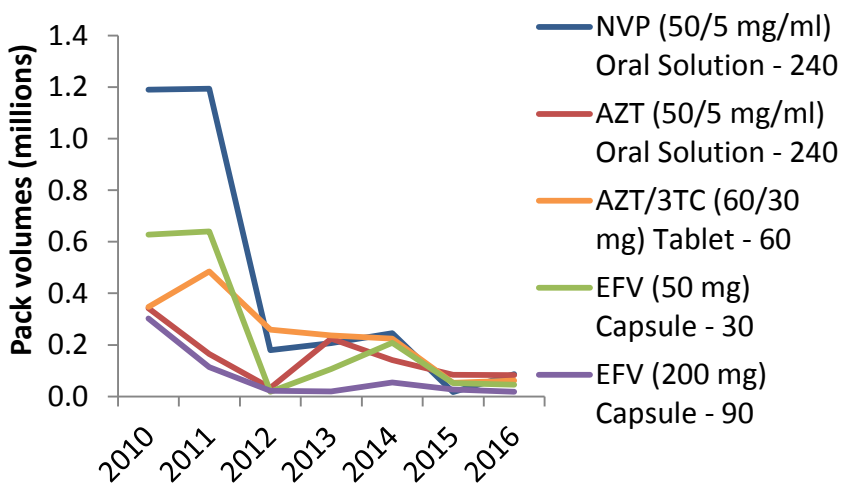
Non-Essential Formulations Procured in 2016 by Volume

1	NVP (50/5 mg/ml) Oral Solution - 240	85,988
2	AZT (50/5 mg/ml) Oral Solution - 240	83,092
3	AZT/3TC (60/30 mg) Tablet - 60	61,392
4	EFV (50 mg) Capsule - 30	45,129
5	EFV (200 mg) Capsule - 90	17,674
6	ABC (20 mg/ml) Oral Solution - 240	13,374
7	EFV (200 mg) Capsule - 30	5,500
8	AZT (100 mg) Tablet - 60	4,910
9	ETV (100 mg) Tablet - 120	2,740
10	AZT (100 mg) Capsule - 100	623
11	EFV (30 mg/ml) Oral Solution - 180	468
12	DRV (150 mg) Tablet - 240	20

Top 5 Non-Essential Products by Volume, 2016



Top 5 Non-Essential Product Procurement Trends



Data source: Current APWG Member Data 2010-2016

“Less Actively Monitored” Products Continue To See High Procurement Relative To Minimum Batch Sizes

Formulation	No. of batches in 2016* <i>(total volume/batch size)</i>
ABC/3TC (60/30 mg) Tablet (Disp) - 60	49
	28
AZT/3TC (60/30) Tablet (Disp) - 60	31
	11
EFV (200 mg) Tablet (Scored) - 90	12
LPV/r (100/25 mg) Tablet (HS) - 60	103
	12
NVP (50/5 mg/ml) Oral Solution – 100	13
	45
3TC (50/5 mg/ml) Oral Solution – 240	13
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) – 60	88
	27
NVP (50/5 mg/ml) Oral Solution - 240	5

← *Transitioning to 100mL*

*Analysis for products with known batch sizes only.

Some “Actively Monitored” Products Did Not Meet 4 Minimum Batch Sizes Delivered in 2016

Actively Monitored Products:

Not Meeting At Least 4 Minimum Batch Sizes Delivered in 2016*

Formulation	No. of batches delivered in 2016 <i>(total volume/batch size)</i>
ABC/3TC (120/60 mg) Tablet (Disp) - 30	0
NVP (50 mg) Tablet (Disp) - 30	1.8
NVP (50 mg) Tablet (Disp) - 60	0
3TC (50/5 mg/ml) Oral Solution - 100	2.1
AZT (50/5 mg/ml) Oral Solution - 100	0.6
r (25 mg) Tablet - 60	0
	3.7
AZT (50/5 mg/ml) Oral Solution 240	0.9
	2.0

Meeting At Least 4 Minimum Batch Sizes Delivered in 2016*

Formulation	No. of batches delivered in 2016 <i>(total volume/batch size)</i>
LPV/r (40/10 mg) Oral Pellet - 120	23
LPV/r (80/20 mg/ml) Oral Solution – 300	14
NVP (50 mg) Tablet (Disp) - 30	8
ABC (60 mg) Tablet (Disp) - 60	5
AZT (50/5 mg/ml) Oral Solution 240	11

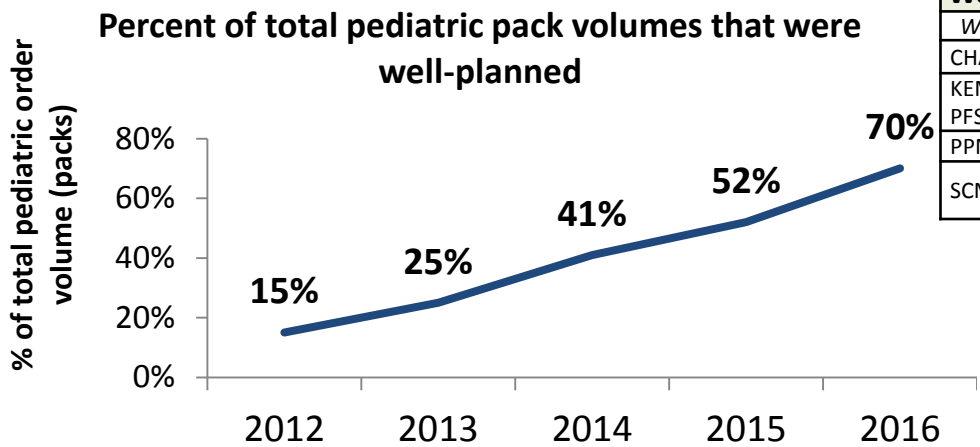
Products meeting at least 4 minimum batch sizes, like LPV/r oral pellets and LPV/r oral solutions, still require further monitoring due to potential supply constraints

*Analysis for products with known batch sizes only.

Procurement Generally Taking Advantage Of All Available Suppliers; Some Possible Concern With Reliance on One Supplier

Product	No. of SRA-approved Suppliers
ABC/3TC (60/30 mg) Tablet (Disp) - 60	2
AZT/3TC (60/30 mg) Tablet (Disp) - 60	2
LPV/r (100/25 mg) Tablet (HS) – 60	3
NVP (50/5 mg/ml) Oral Solution - 100	2
ABC/3TC (120/60 mg) Tablet (Disp) - 30	2
EFV (200 mg) Tablet (Scored) – 90	1
LPV/r (40/10 mg) Oral Pellet – 120	1
LPV/r (80/20 mg/ml) Oral Solution - 300	1
NVP (50 mg) Tablet (Disp) - 30	2
NVP (50 mg) Tablet (Disp) - 60	3
RAL (100 mg) Tablet – 100mg	1
3TC (50/5 mg/ml) Oral Solution - 100	1
ABC (60 mg) Tablet (Disp) – 60	1
AZT (50/5 mg/ml) Oral Solution - 100	1
r (80 mg/ml) Oral Solution – 90	1
3TC (50/5 mg/ml) Oral Solution – 240	5
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) – 60	3
ATV (100 mg) Capsule – 60	2
AZT (60 mg) Tablet (Dispersible) - 60	1
DRV (75 mg) Tablet – 480	1
RAL (25 mg) Tablet – 60	1
r (25 mg) Tablet – 60	2

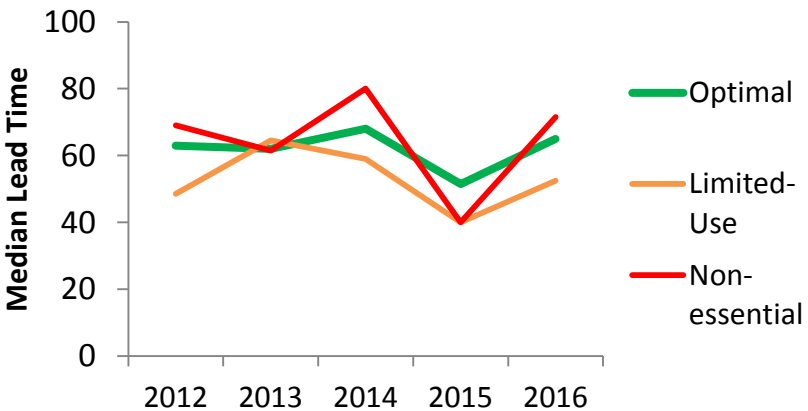
>65% Of Pediatric Pack Volumes Were Well-Planned In 2016



Well-Planned Order Methodology	
<i>Well-planned orders were identified using the following methods dependent on data source:</i>	
CHAI	Supplier invoice date to PO date and latest ETR to PO date are both >90
KEMSA, PAHO, PFSA, UNICEF	Indicated by procurement agent in data submission
PPM	Client requested delivery dates >120 days from the order date
SCMS	Well-planned orders are orders where the Supplier invoice date to PO date and Vendor promise date to PO date are both >90.

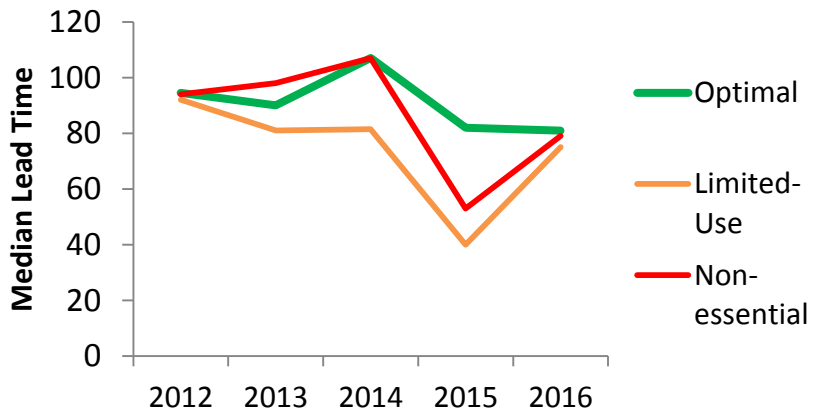
While the percentage of well-planned orders volumes has increased over the years, non-well-planned orders have fluctuated in lead times over the past few years

(a) Manufacturing lead time of non-well-planned orders



Orders (#)	2012	2013	2014	2015	2016
	408	862	724	562	348

(b) Total lead time of non-well-planned orders

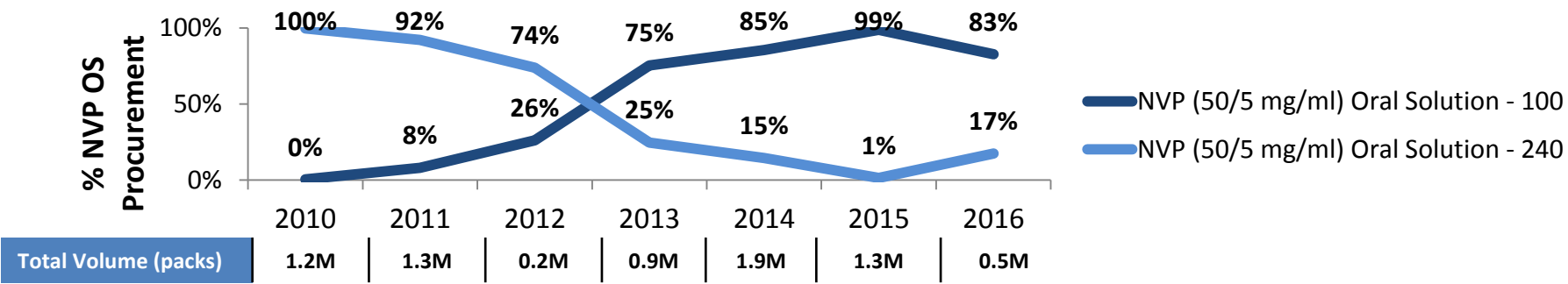


Orders (#)	2012	2013	2014	2015	2016
	462	877	826	631	419

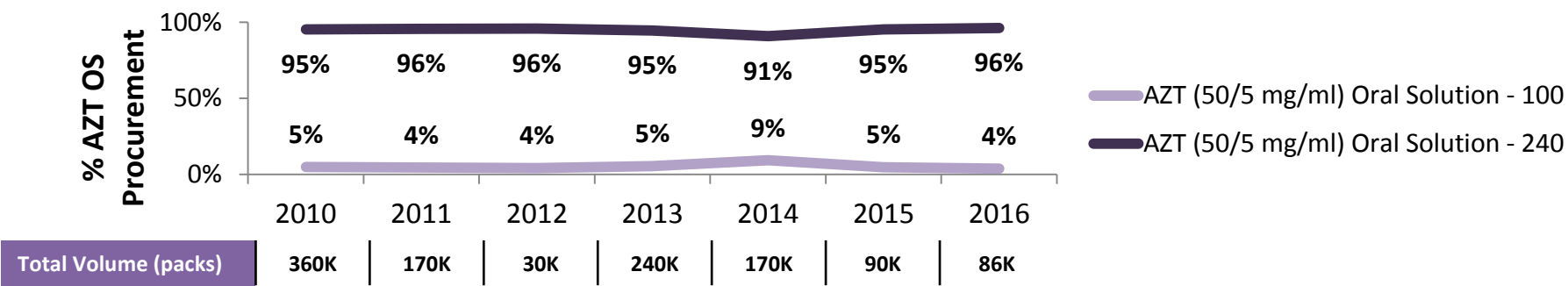
Data source: Current APWG Member Data 2010-2016

100ml Adoption Trends: High Share For NVP, AZT Has Stayed Flat, 3TC Share Has Grown

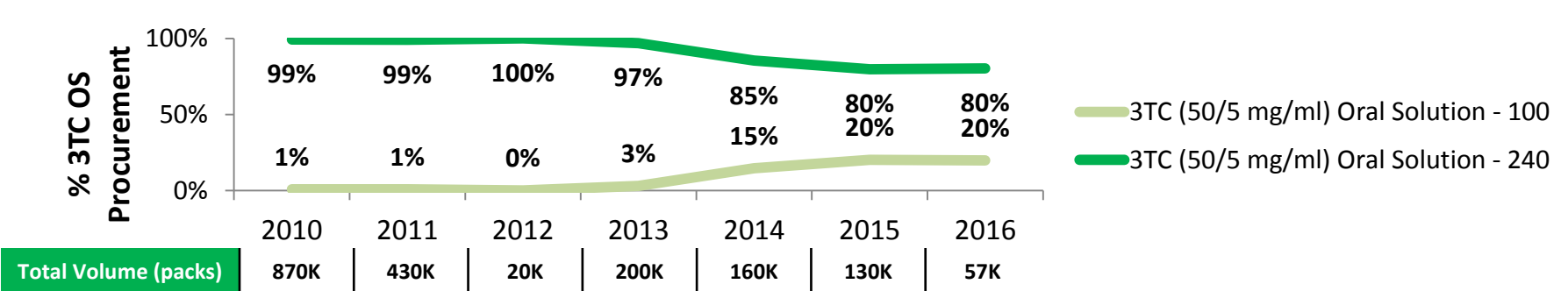
NVP Oral Solution



AZT Oral Solution

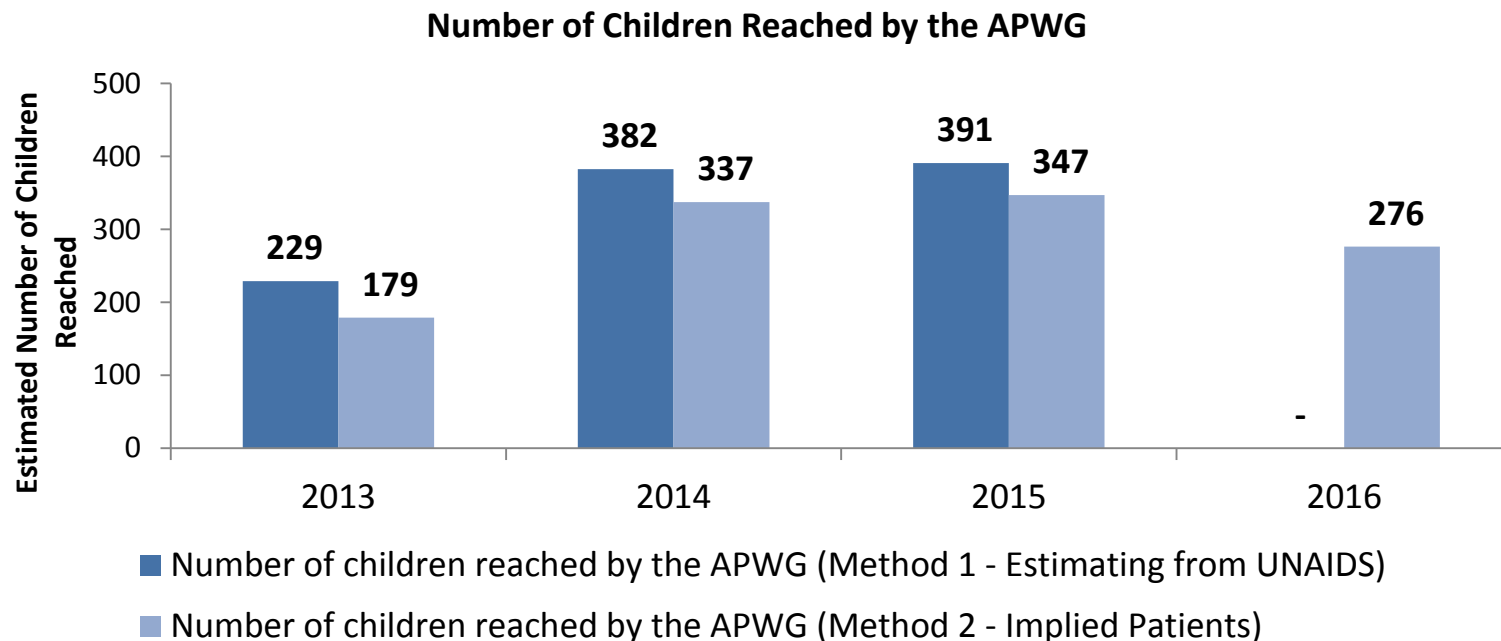


3TC Oral Solution



Data source: Current APWG Member Data 2010-2016

APWG Estimated to Reach >250K Children on ARVs Globally



Two Methodologies Used for Calculation of APWG Patient Reach

Method 1: Based on UNAIDS patient estimates for children (0-14 yrs). Inclusion of country estimates in total based on product mix deliveries 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 APWG.

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

APWG Poised to Assist With Key Optimal Pediatric Product Phase-In in 2017

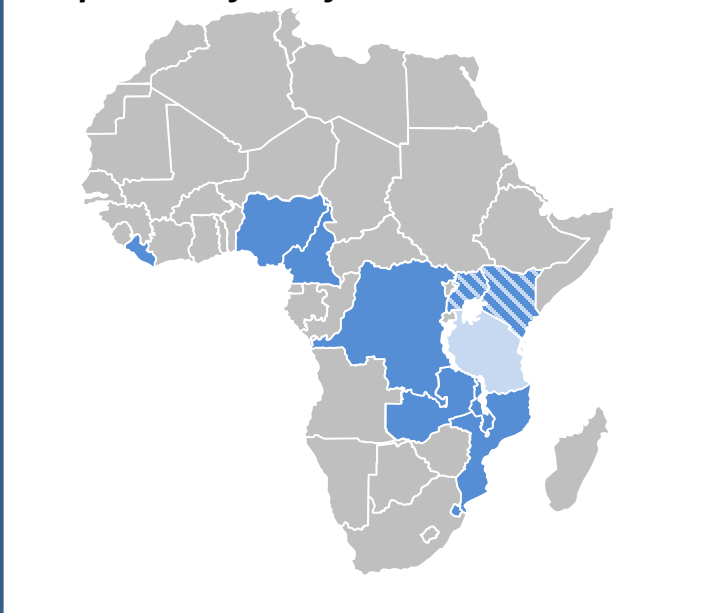
LPV/r (40/10 mg) Oral Pellet – 120
Manufacturer: Cipla
Procurement Plans Initiated in 2016:*
Cambodia, Cameroon, D R Congo, Haiti, Kenya, Liberia, Malawi, Mozambique, Nigeria, Swaziland, Uganda, Zambia

ABC/3TC (120/60 mg) Tablet (Disp) - 30
Manufacturer: Cipla, Mylan
Procurement Plans Initiated in 2016:*
Kenya, Tanzania, Uganda, Vietnam

Adoption Profile: Southeast Asia



Adoption Profile: Africa



Light blue: ABC/3TC (120/60 mg) Tablet (Disp) - 30
Dark blue: LPV/r (40/10 mg) Oral Pellet - 120
Diagonal lines: Both products

*Based on order data through Q1 2017 APWG Order Cycle

In 2016, The APWG Evolved To Track Adult Formulations That Are Either Low Volume Or In Transition

Tracked Adult Formulations

3TC (150 mg) Tablet – 60

ABC (300 mg) Tablet – 60

ATV (300 mg) Capsule – 30

AZT (300 mg) Tablet – 60

DRV (400 mg) Tablet – 60

DTG (50 mg) Tablet – 30

RAL (400 mg) Tablet – 60

r (100 mg) Tablet – 30

TDF (300 mg) Tablet – 30

TDF/3TC/EFV (300/300/400 mg) Tablet – 30*

Given DTG (50mg) and TLE400 currently have sole generic supplier, active monitoring of adoption will be needed in 2017 to ensure supply security

APWG Poised to Assist With Key Adult Product Phase-In In 2017 And Beyond

1 Tentative SRA Approval Timeline for EFV400 and DTG*

ARV	2016	2017		2018	
	H2	H1	H2	H1	H2
DTG	●	●	●	●	
TLD			● ●	● ●	
TLE400		●		●	

● Expected SRA approval of distinct generic suppliers

2 EFV400/DTG Demand in LMICs

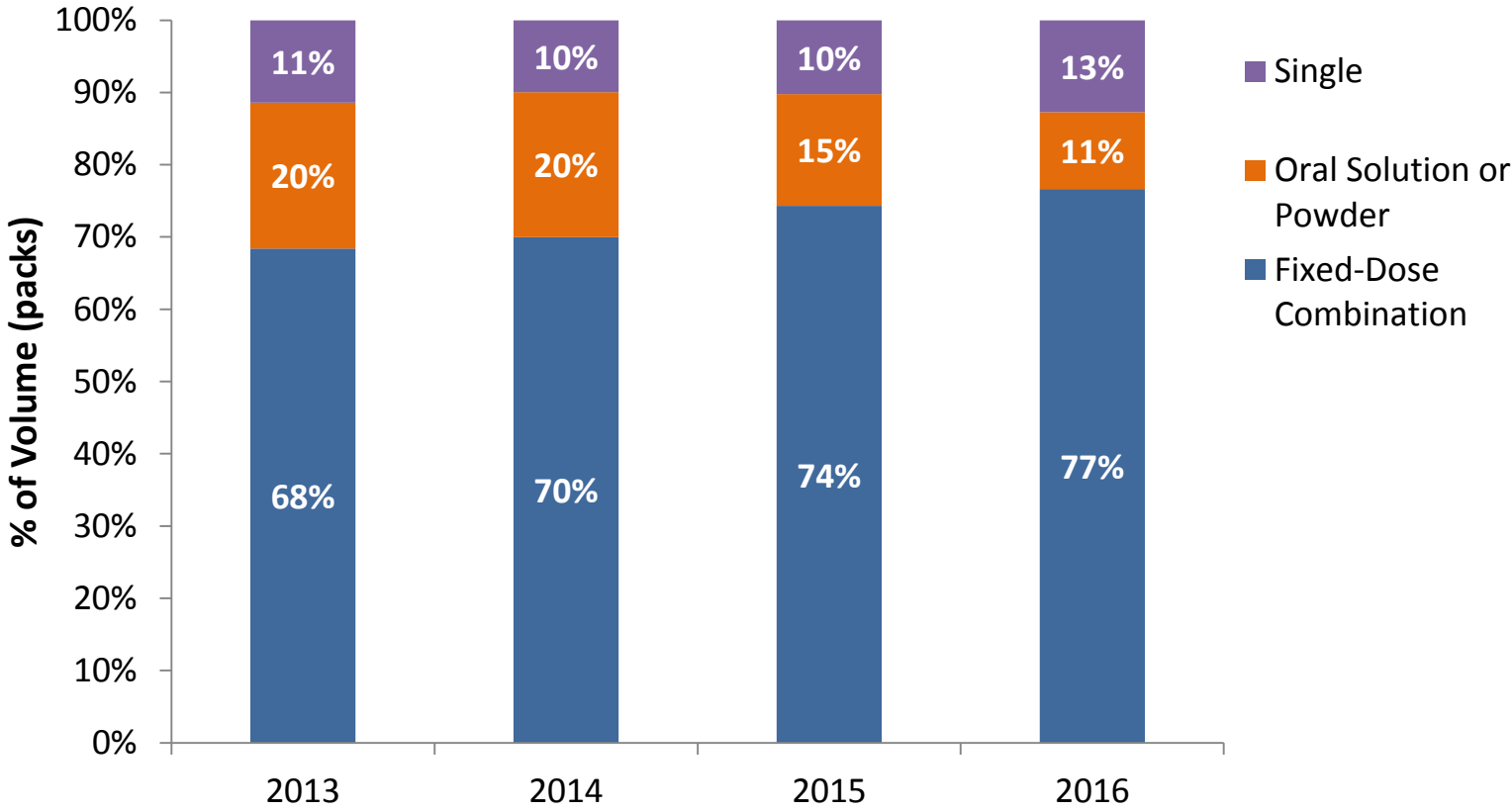
DTG and/or TLE400 formally incorporated in published national guidelines	Benin, Botswana, Cambodia, Kenya, Lesotho, Nigeria, Uganda, Zambia, Zimbabwe
Initiated procurement plan for DTG singles**	Botswana, Belarus, Cuba, D R Congo, Georgia, Kenya, Nigeria, Uganda, Ukraine, Uzbekistan
Initiated procurement plan for TLE400**	Nigeria, Zambia, Zimbabwe

*Assumes SRA approval received 9-12 months after filing date. Based on best available information of filing timelines as of October 2016 - subject to change

**Based on order data through Q1 2017 APWG Order Cycle and 2017 Consolidated APWG Forecast

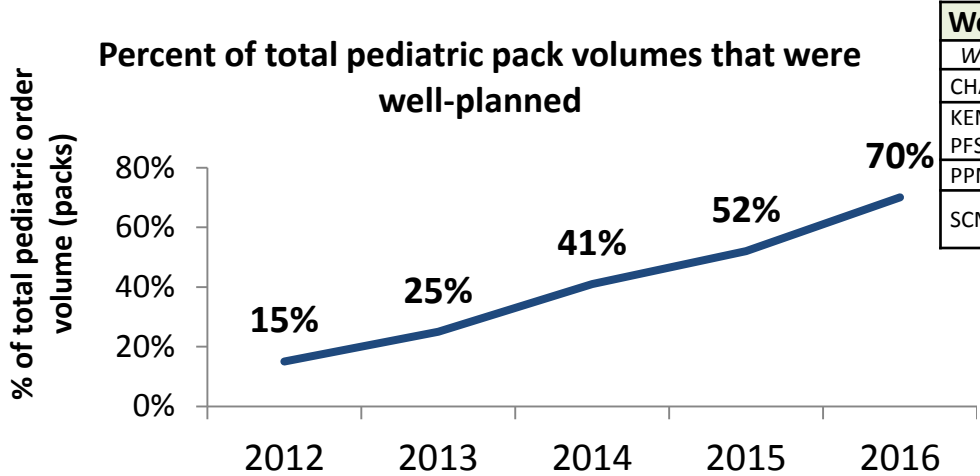
Appendix

Use of Pediatric Fixed-Dose Combinations (FDCs) Has Steadily Increased



High-use of AZT/3TC/NVP, ABC/3TC, and AZT/3TC dispersible tablets have driven increasing market share of FDCs

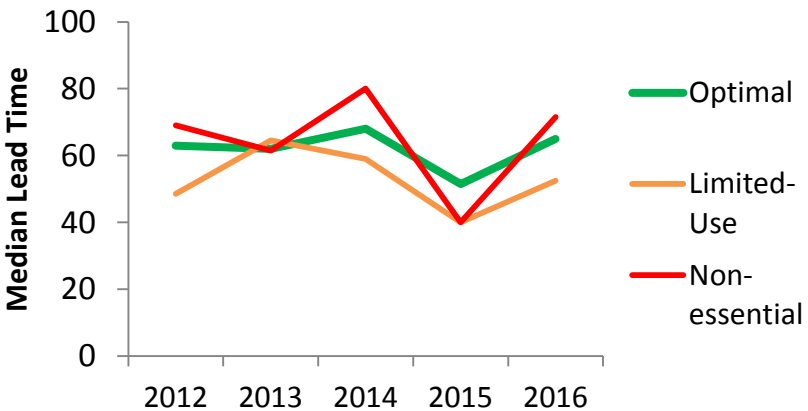
KPI 1a,1b: Median manufacturing and total lead times for the Procurement Consortium member orders



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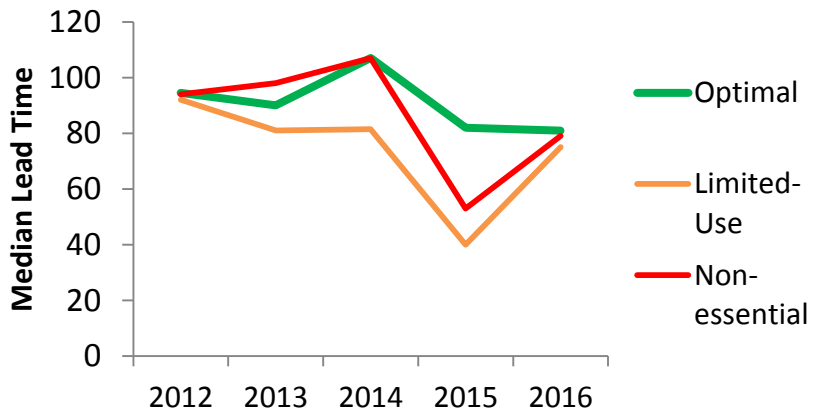
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Data source: Current APWG Member Data 2010-2016

KPI 2a: Percentage of tracked (i.e., priority) products with validated batch size information on file

Pediatric Products	2016
<i>Total number of pediatric priority products by manufacturer</i>	28
<i>No. of pediatric priority products with validated batch size information</i>	14
<i>Percentage products with validated batch size information</i>	50%

Adult Products	2016
<i>Total number of adult priority products by manufacturer</i>	47
<i>No. of adult priority products with validated batch size information</i>	35
<i>Percentage products with validated batch size information</i>	74%

Latest batch size information provided by UNICEF in Q4 2016

KPI 2b: Percentage of tracked products able to complete at least 4 batches per year – pediatric products (1/2)

Product	Batch Size	Number of Batches (2016)
ABC/3TC (120/60 mg) Tablet (Disp) - 30	n/a	n/a
	24,333	0
LPV/r (40/10 mg) Oral Pellet - HS - 120	950	23
LPV/r (80/20 mg/ml) Oral Solution - 160	n/a	n/a
	3,125	0.6
LPV/r (80/20 mg/ml) Oral Solution - 300	3,000	14
NVP (50 mg) Tablet (Disp) - 30	18,000	8
	n/a	n/a
NVP (50 mg) Tablet (Disp) - 60	n/a	n/a
	20,000	1.8
	2,300	0

Bold: >= 4 batch sizes per year

KPI 2b: Percentage of tracked products able to complete at least 4 batches per year – pediatric products (2/2)

Product	Batch Size	Number of Batches (2016)
3TC (50/5 mg/ml) Oral Solution – 100	5,000	2.1
ABC (60 mg) Tablet (Disp) – 60	5,000	5
ATV (100 mg) Capsule – 60	n/a	n/a
	n/a	n/a
AZT (50/5 mg/ml) Oral Solution – 100	5,000	0.6
AZT (60 mg) Tablet (Disp) – 60	n/a	n/a
r (25 mg) Tablet - 60	5,000	0
	n/a	n/a
ATV (150 mg) Capsule - 60	n/a	n/a
	n/a	n/a
	n/a	n/a
AZT (50/5 mg/ml) Oral Solution – 200	n/a	n/a
AZT (50/5 mg/ml) Oral Solution - 240	12,000	3.7
	5,000	0.9
	4,000	2
	1,680	11

Bold: >= 4 batch sizes per year

Of priority pediatric products with provided batch sizes, 36% were able to complete at least 4 batches in 2016.

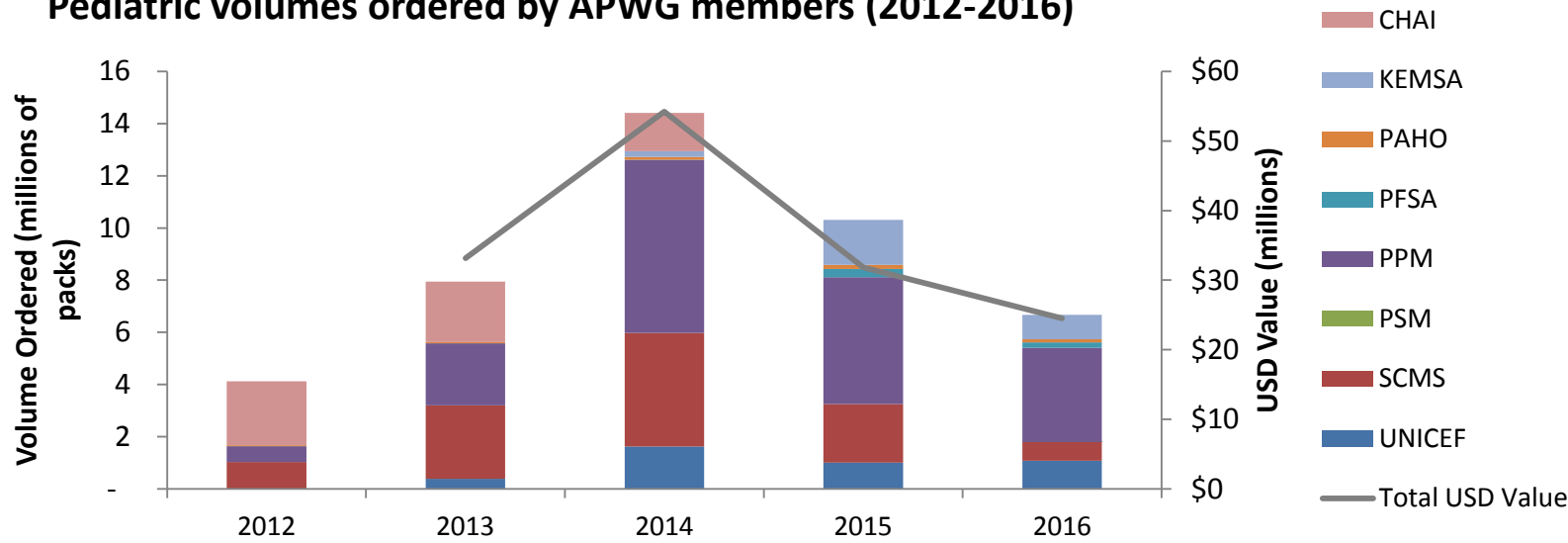
KPI 3a: Products meeting APWG annual forecast volumes within +/- 25% forecast

2016	Anticipated Demand	Actual Procurement
TOTAL QUANTITY (packs)	11,875,178	6,664,593
Optimal	7,485,122	3,587,611
ABC/3TC (120/60 mg) Tablet (Disp) - 30	-	156,769
ABC/3TC (60/30 mg) Tablet (Disp) - 60	3,750,457	1,056,085
AZT/3TC (60/30 mg) Tablet - 60	-	-
AZT/3TC (60/30 mg) Tablet (Disp) - 60	977,938	837,819
EFV (200 mg) Tablet (Scored) - 90	716,481	639,217
LPV/r (100/25 mg) Tablet (HS) - 120	2,250	-
LPV/r (100/25 mg) Tablet (HS) - 60	412,811	377,387
LPV/r (40/10 mg) Oral Pellet - HS - 120	-	73,438
LPV/r (80/20 mg/ml) Oral Solution - 160	6,102	13,100
LPV/r (80/20 mg/ml) Oral Solution - 300	84,251	58,396
LPV/r (80/20 mg/ml) Oral Solution - 60	87,585	-
NVP (50 mg) Tablet (Disp) - 30	611,022	93,926
NVP (50 mg) Tablet (Disp) - 60	-	9,192
NVP (50/5 mg/ml) Oral Solution - 100	803,154	409,052
RAL (100 mg) Tablet (Scored) - 60	-	-
Limited-Use	4,283,887	2,755,780
3TC (50/5 mg/ml) Oral Solution – 100	56,532	11,283
3TC (50/5 mg/ml) Oral Solution – 240	5,886	45,929
ABC (60 mg) Tablet (Disp) - 60	75,351	31,048
ATV (100 mg) Capsule - 60	-	-
AZT (50/5 mg/ml) Oral Solution - 100	61,867	3,270
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	4,083,404	2,663,228
DRV (75 mg) Tablet - 480	49	22
r (25 mg) Tablet - 60	-	-
r (80 mg/ml) Oral Solution - 90	800	1,000
RAL (25 mg) Tablet - 60	-	-
Non-Essential	106,157	320,910
Unreviewed	12	-

Bold: < +/- 25% variation from anticipated

Non-KPI: Volume and Value of ARVs ordered by the APWG Procurement Consortium

Pediatric volumes ordered by APWG members (2012-2016)



Number of Countries	49	69	76	70	70
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↑
PAHO, PFSA, KEMSA joined APWG

SCMS orders brought forward to 2014*

*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

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

USD value based on PPM prices from Q1 of the corresponding year. Only those products with GF listed prices were included in the value calculation

KPI 4a: Percent of PA orders for priority products placed within agreed range of quarterly order placement dates

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
2016	Q1 2016	Q2 2016	Q3 2016	Q4 2016
Orders within designated order cycle range	51	105	49	60
Total orders in quarter*	195	232	101	134
% of orders placed within agreed order cycle range	26%	45%	49%	45%
Number of countries with >1 order within agreed order cycle range	27	31	17	16

Data source: Current APWG Member Data 2010-2016

*Quarters determined based on order cycle submission dates not calendar divisions

KPI 5a: Proportion of countries in PC dataset that order “exclusively” (>95%) or “mostly” (75-95%) optimal and limited-use ARVs by pack volumes

	2013	2014	2015	2016
Proportion of countries ordering <u>exclusively</u> (>95%) ARVs by pack volumes	21%	43%	46%	52%
Proportion of countries ordering <u>mostly</u> (>75%-95%) ARVs by pack volumes	34%	27%	20%	25%
Total (>75%)	55%	70%	66%	77%

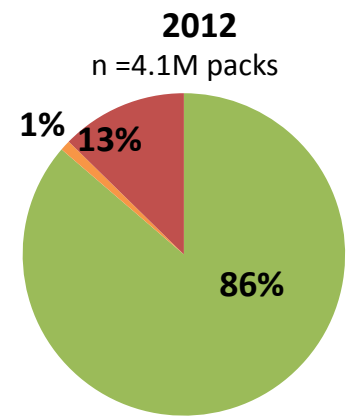
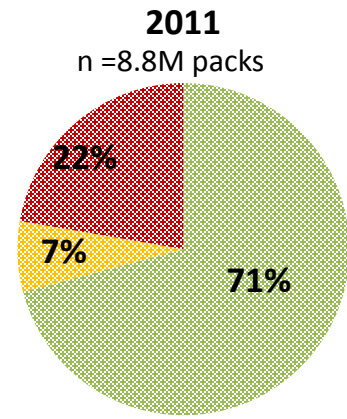
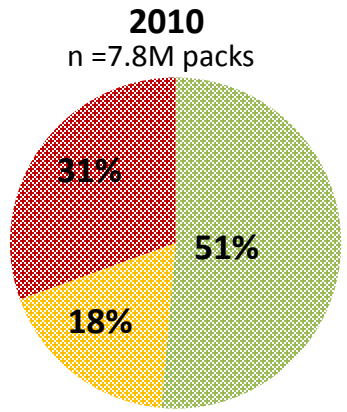
KPI 5b: Total variety of pediatric products procured in the APWG

	2010	2011	2012	2013	2014	2015	2016
Unique Formulations Procured <i>(excluding pack size)</i>	34	36	31	34	31	31	26

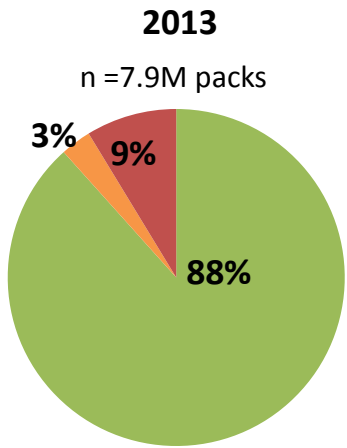
KPI 5b/c: Percentage of pediatric products by volume ordered through APWG that are optimal/limited-use

APWG Volumes Distribution by IATT Status

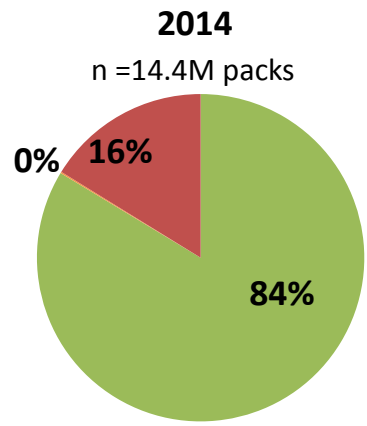
- Optimal
- Limited-Use
- Non-Essential



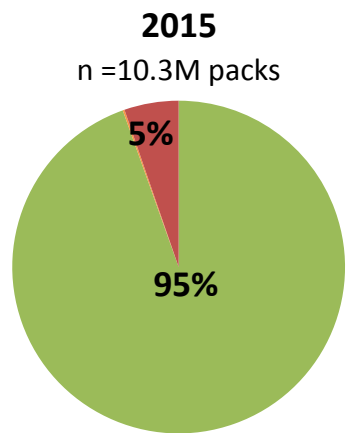
No. IATT Optimal products: 14



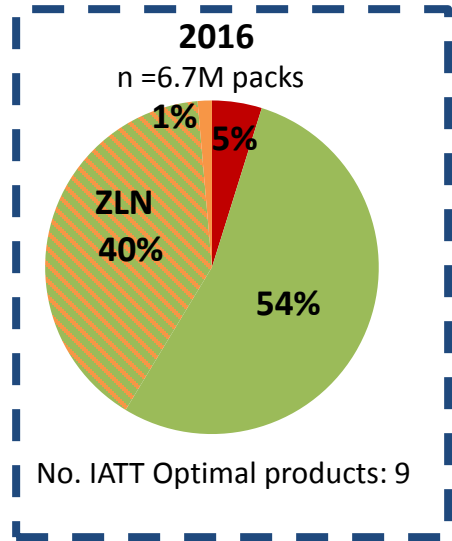
No. IATT Optimal products: 14



No. IATT Optimal products: 10



No. IATT Optimal products: 8



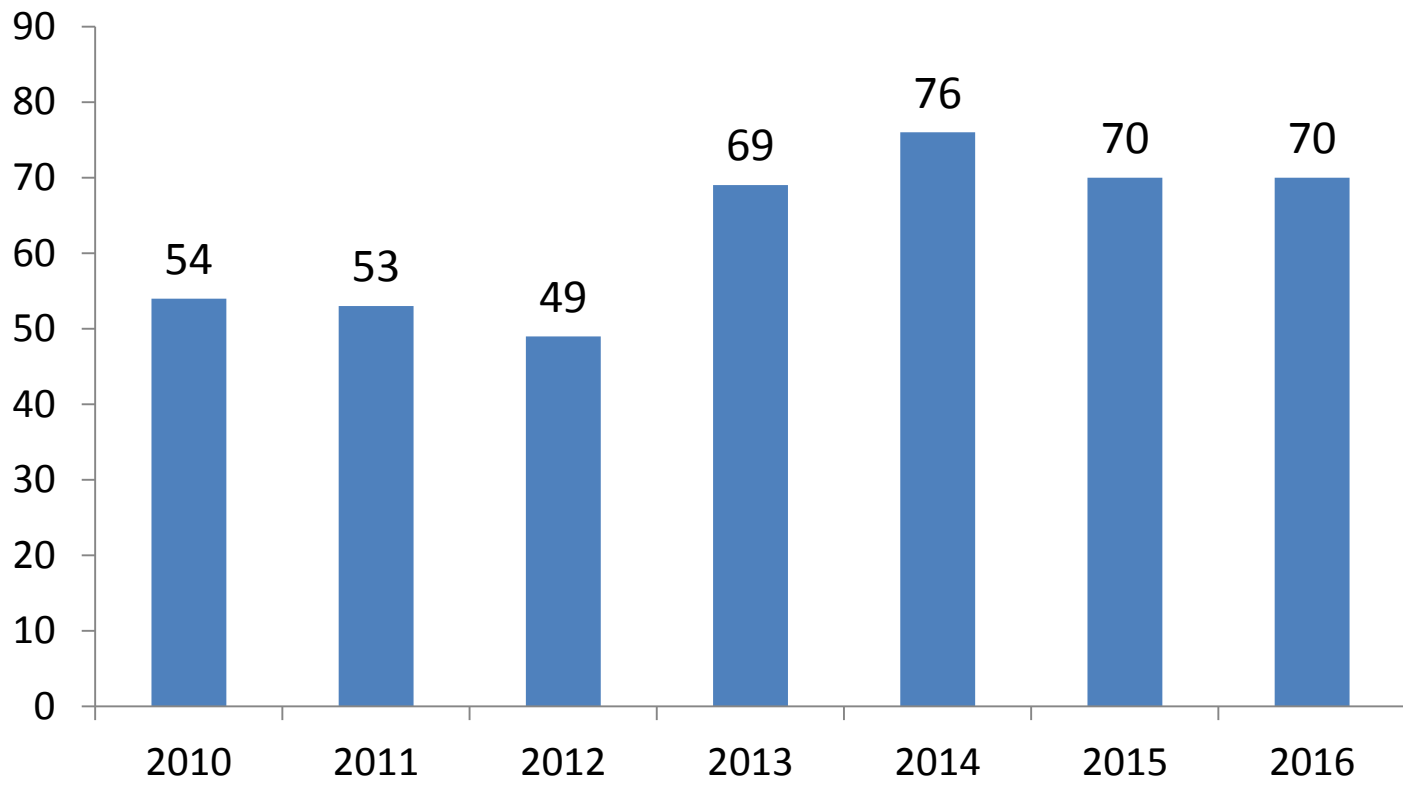
No. IATT Optimal products: 9

Data source: Current APWG Member Data 2010-2016

Product categorization: 2010-2013: 2011 IATT List; 2014 orders: 2013 IATT list; 2015 orders: 2015 IATT list; 2016 orders: 2016 IATT list

Non-KPI (Reach): Number of countries ordering through the APWG, specifically pediatric products

Number of Countries Ordering Pediatric Products Through The Procurement Consortium

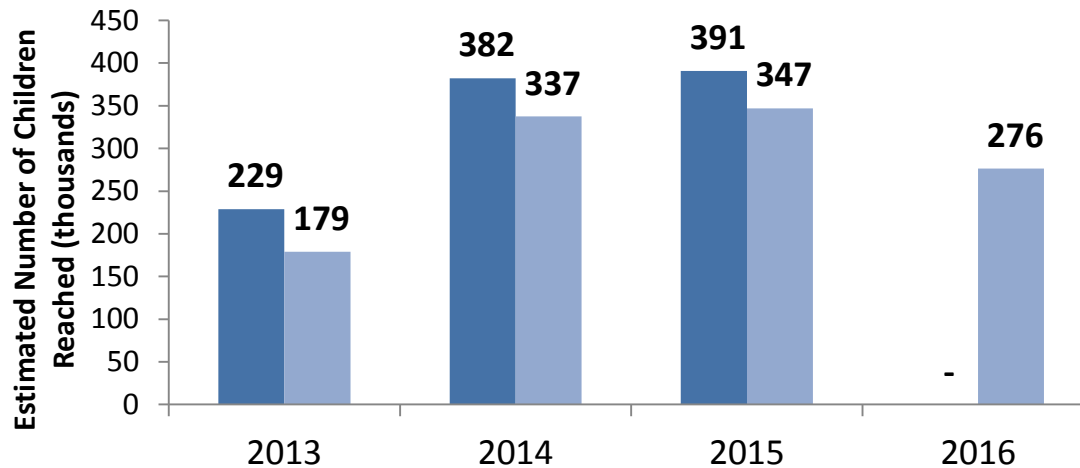


↑
PAHO, PFSA, KEMSA
joined APWG

Data source: Current APWG Member Data 2010-2016

Non-KPI (Reach): Estimated number of total patients and children specifically reached by Procurement Consortium

Number of Children Reached by the APWG



- Number of children reached by the APWG (Method 1 - Estimating from UNAIDS)
- Number of children reached by the APWG (Method 2 - Implied Patients)

~4.9M adult and pediatric patients were reached by the APWG Procurement Consortium in 2016*

Two Methodologies Used for Calculation of APWG Patient Reach

Method 1

- Based on UNAIDS patient estimates. Inclusion of country estimates in total based on product mix deliveries and volume relative to number of patients 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 adults and children reached by the APWG.

Method 2

- **Children:** Based on dosing for a 10-13.9kg child using PI/ NNRTI volume for APWG deliveries. Countries placing orders through the APWG who do not order NNRTIs or PIs are not included. DRV and RTV products are excluded.
- **Adult:** Based on adult dosing using PI/ NNRTI volumes for all APWG deliveries.

Non-KPI (Reach): Estimated number of adults reached by the Procurement Consortium over first two years

Not applicable for 2016's KPI analysis as no procurement and delivery of new products in 2016. DTG(50mg) will only be delivered in 2017