Addressing ART Program Needs and Constraints:

Opportunities to Enhance Patient Outcomes and Simultaneously Reduce the Costs of Treatment

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CLINTON HEALTH ACCESS INITIATIVE

Optimizing ARV regimens, improving procurement practices, and rapid uptake of new products will enable better patient outcomes as well as cost savings

The following slides summarize opportunities to:

→ Save costs and improve patient outcomes

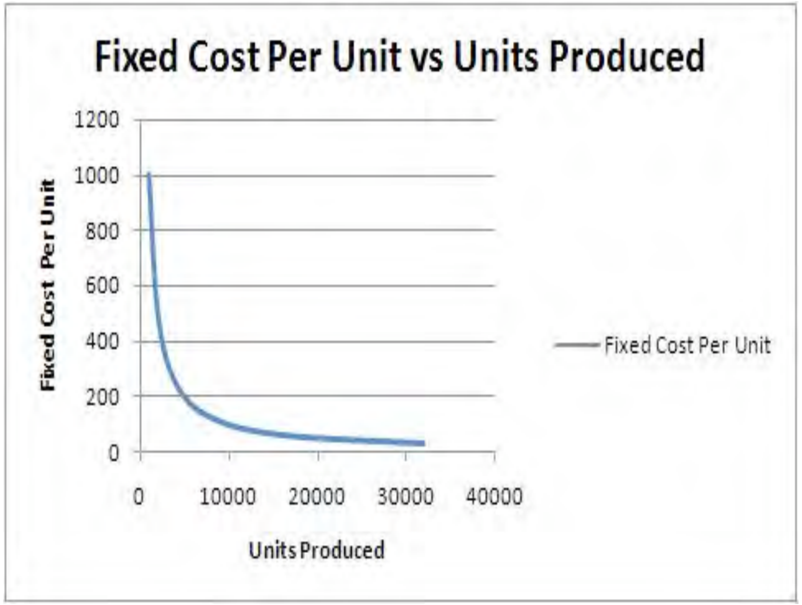
OR

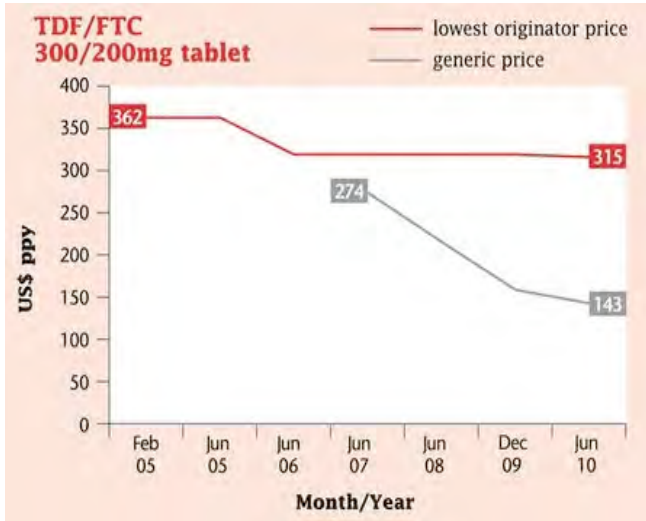
→ Save costs with similar patient outcomes

Agenda

- Introduction
- Adult ART regimen optimization
- Procurement practices
- New product introductions

Improvements in the cost and clinical effectiveness of ART provides immense leverage to improve outcomes but policies that impact uptake and determine the costs of treatment lag behind





- ❑Key policies that impact uptake and cost include:
  - ❑Choice of regimen
  - ❑Procurement practices and drug registration
  - ❑Pace of new product uptake

Incentives to consider and implement best practice polices would improve patient outcomes and save costs

- ❑ The regimen optimization opportunities are in line with the 2010 WHO ART Guidelines, but go one step further and consider issues of cost, product availability, convenience, and dosing

- ❑ Experience with the UNITAID program provides practical evidence for the impact of procurement practices

- ❑ Innovator pharmaceutical companies now have Access Programs that can accelerate availability of new products

A program to define best practices polices coupled with incentives for adoption has the potential to impact access to medicines and the cost effectiveness of treatment

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- Introduction
- Adult ART regimen optimization
- Procurement practices
- New product introductions

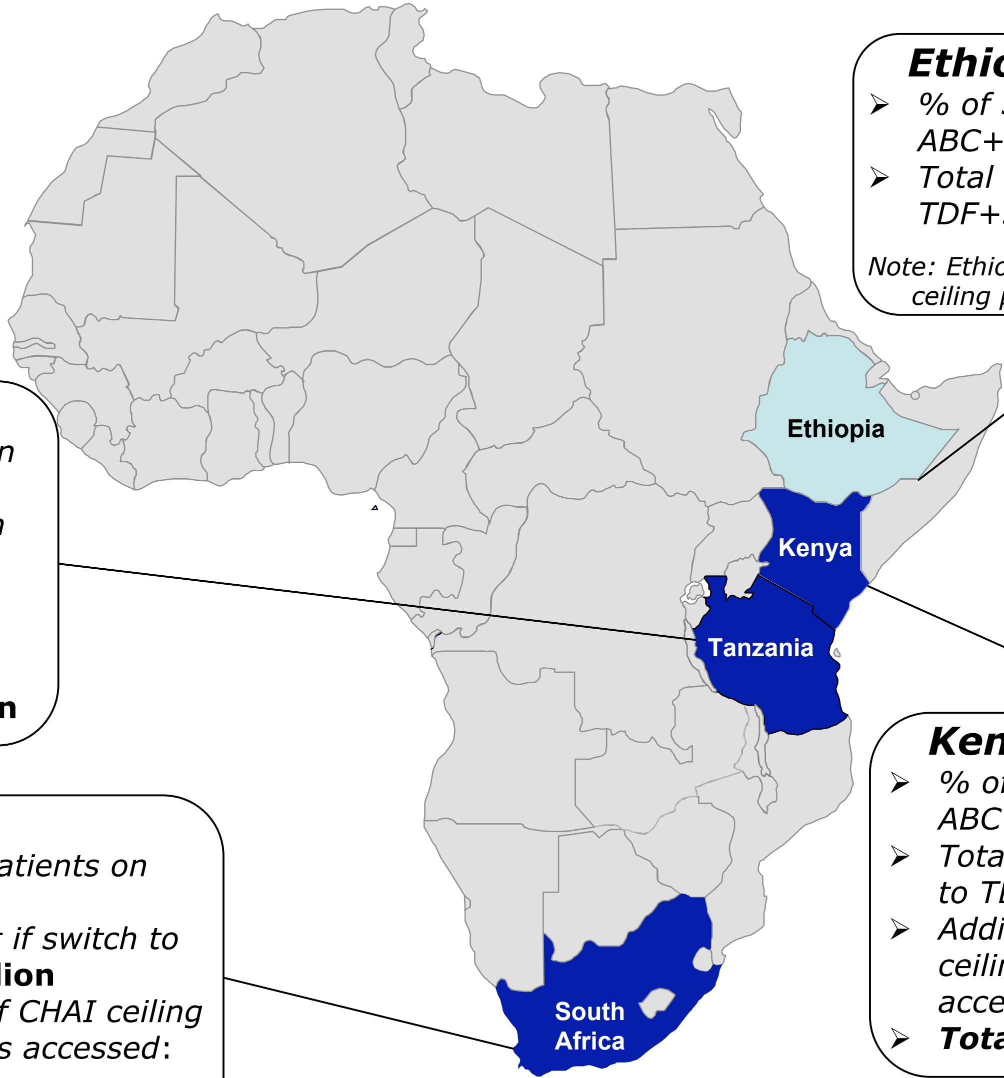
TDF+3TC instead of ABC+ddI: Potential for $80-90 million in savings over the next five years

Highest Opportunity: Market Impact $10M+

High Opportunity: Market Impact $5-9M

Medium Opportunity: Market Impact <$5M

Major Opportunities for Regimen Optimization



Ethiopia:
- *% of Second-Line Patients on ABC+ddI*: **~11%**
- *Total 5-Year Impact if switch to TDF+3TC*: **$1.5 million**

Note: Ethiopia is already accessing CHAI ceiling prices for TDF+3TC

Tanzania:
- *% of Second-Line Patients on ABC+ddI*: **~70%**
- *Total 5-Year Impact if switch to TDF+3TC*: **$18 million**
- *Additional Savings if CHAI ceiling price for TDF+3TC is accessed*: **$1 million**
- ***Total Savings:* $19 million**

Kenya:
- *% of Second-Line Patients on ABC+ddI*: **~85%**
- *Total 5-Year Impact if switch to TDF+3TC*: **$33 million**
- *Additional Savings if CHAI ceiling price for TDF+3TC is accessed*: **$4 million**
- ***Total Savings:* $37 million**

South Africa:
- *% of Second-Line Patients on ABC+ddI*: **~28%**
- *Total 5-Year Impact if switch to TDF+3TC*: **$29 million**
- *Additional Savings if CHAI ceiling price for TDF+3TC is accessed*: **$5 million**
- ***Total Savings:* $34 million**

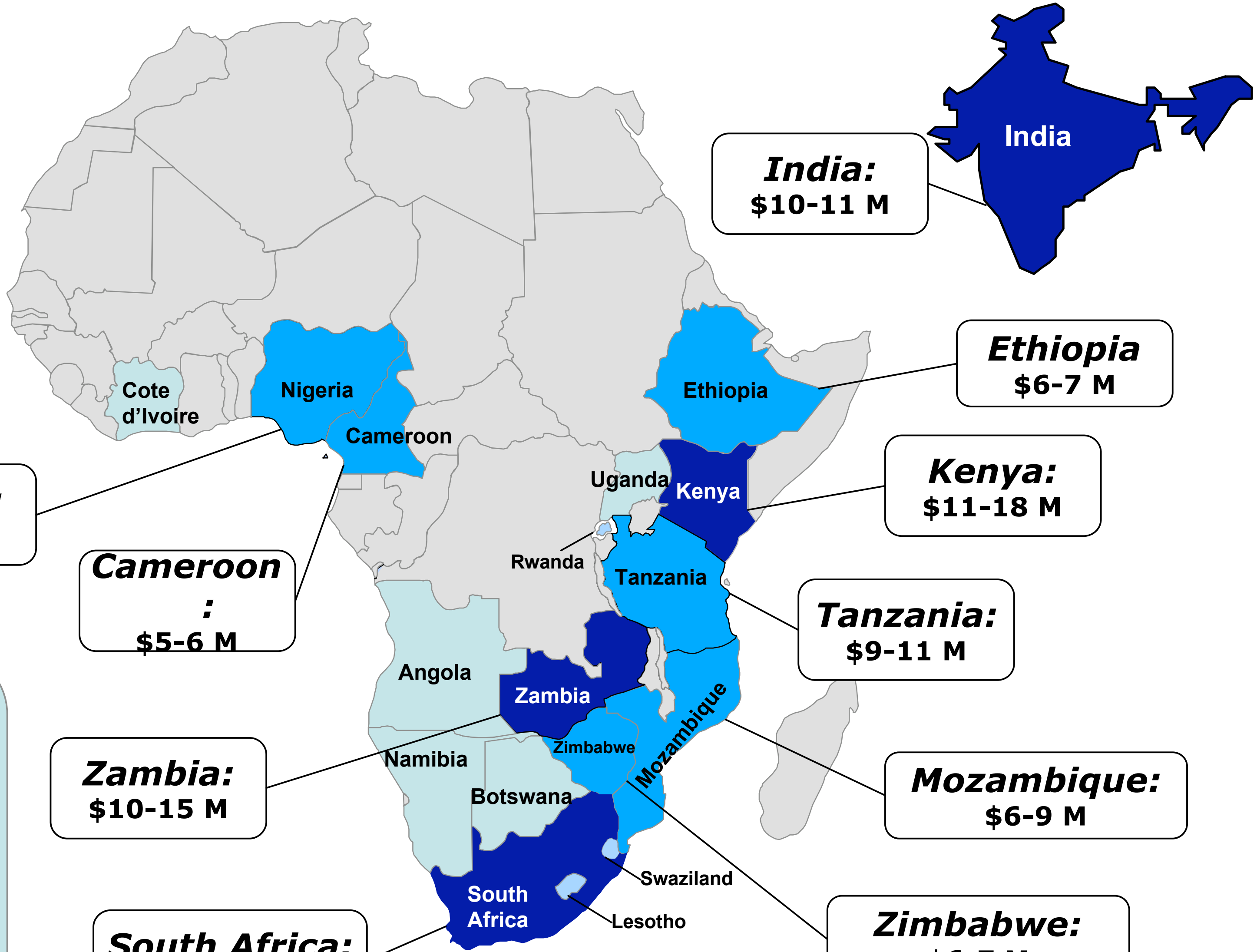
ATV/r instead of LPV/r: Potential for $150-210 million in savings over the next five years

Highest Opportunity: Market Impact $10M+

High Opportunity: Market Impact $5–9M

Medium Opportunity: Market Impact <$5M

Major Opportunities for Regimen Optimization



Additional Opportunities:

- Uganda: $4.7-11 M
- Botswana: $3.7-7 M
- Namibia:$3.4-5 M
- Rwanda: $2.8-3.5 M
- Cote d'Ivoire: $2-2.5 M
- Angola: $1-1.5 M
- Swaziland: $2-3.5 M
- Lesotho: $900K - $2.6M

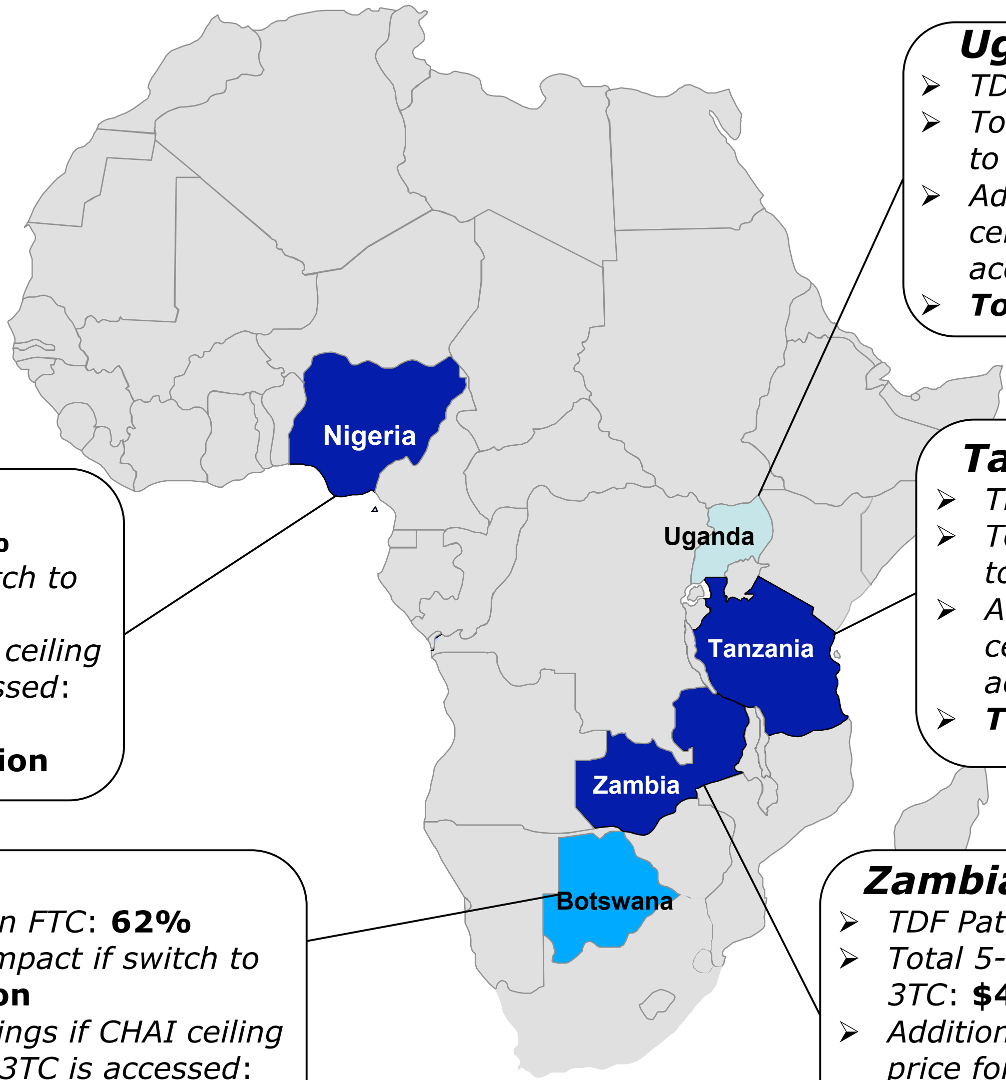
3TC instead of FTC: Potential for $80-110 million in savings over the next five years

Highest Opportunity: Market Impact $10M+

High Opportunity: Market Impact $5-9M

Medium Opportunity: Market Impact <$5M

Major Opportunities for Regimen Optimization



Uganda:

- *TDF Patients on FTC*: **16%**
- *Total 5-Year Impact if switch to 3TC*: **$1.4 million**
- *Additional Savings if CHAI ceiling price for TDF+3TC is accessed*: **$600k**
- ***Total Savings:* $2 million**

Tanzania:

- *TDF Patients on FTC*: **80%**
- *Total 5-Year Impact if switch to 3TC*: **$24 million**
- *Additional Savings if CHAI ceiling price for TDF+3TC is accessed*: **$2.5 million**
- ***Total Savings:* $26.5 million**

Nigeria:

- *TDF Patients on FTC*: **81%**
- *Total 5-Year Impact if switch to 3TC*: **$10 million**
- *Additional Savings if CHAI ceiling price for TDF+3TC is accessed*: **$8 million**
- ***Total Savings:* $18 million**

Botswana:

- *TDF Patients on FTC*: **62%**
- *Total 5-Year Impact if switch to 3TC*: **$6 million**
- *Additional Savings if CHAI ceiling price for TDF+3TC is accessed*: **$9 million**
- ***Total Savings:* $15 million**

Zambia:

- *TDF Patients on FTC*: **70%**
- *Total 5-Year Impact if switch to 3TC*: **$40 million**
- *Additional Savings if CHAI ceiling price for TDF+3TC is accessed*: **$11 million**
- ***Total Savings:* $51 million**

An aggregate view shows that TDF+3TC is displacing TDF+FTC

Indian Export Database: Exports Packs of 30 *(in thousands)*

Formulation	2007	2008	2009	2010*
TDF + 3TC	83	843	2,790	6,092
TDF + FTC	235	1,384	1,364	1,491
Share of TL	26%	38%	67%	80%

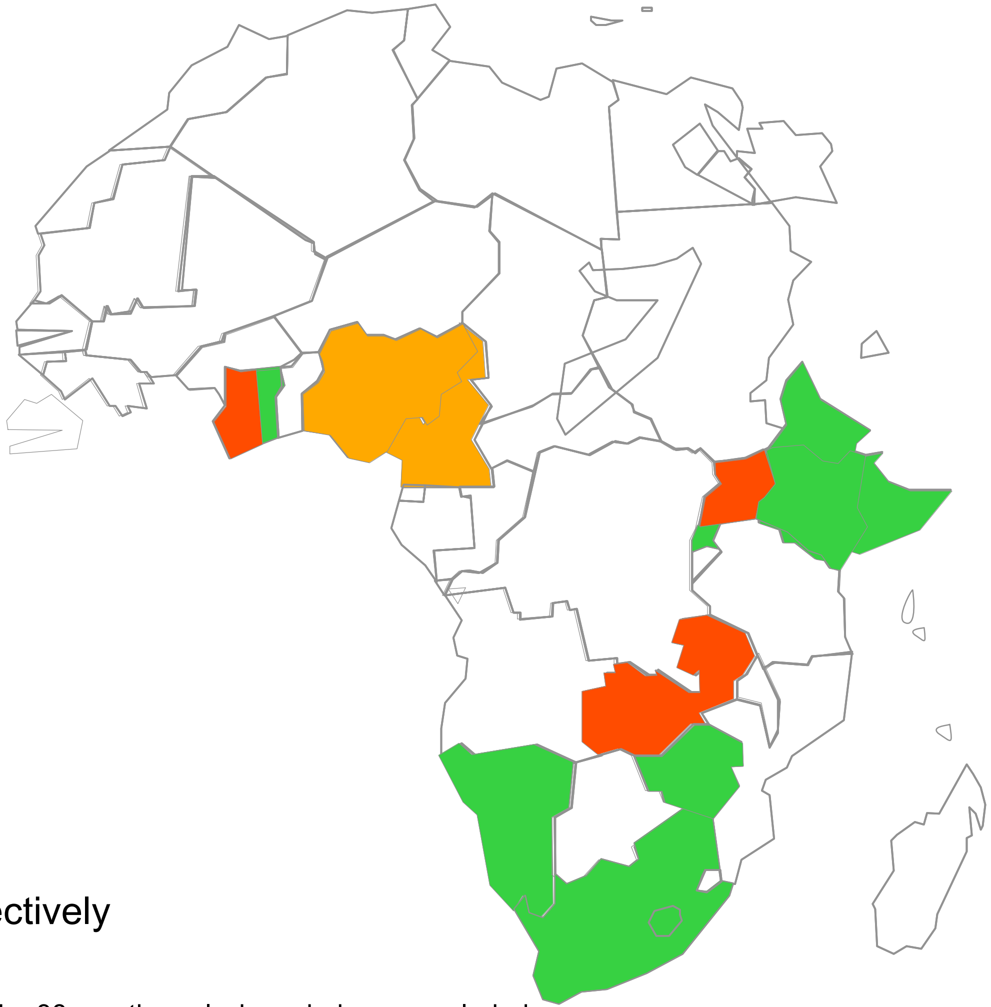
- Recent 2010 Prices from the Indian Export Database database show that TL is 13% cheaper vs. TE

*2010 figures from the Indian export database are linear extrapolations to represent the full year.

Country level trends for TDF+3TC vs. TDF+FTC

Share of TDF+ 3TC Exports**

COUNTRY	2007	2008	2009	2010
GHANA	NA	100%	37%	43%
UGANDA	4%	100%	92%	71%
ZAMBIA	6%	0%	37%	0%
ETHOPIA	NA	NA	100%	100%
KENYA	NA	100%	100%	99%
NAMIBIA	100%	100%	100%	100%
RWANDA	NA	100%	100%	100%
SOUTH AFRICA	NA	100%	100%	100%
TOGO	100%	100%	100%	100%
ZIMBABWE	100%	100%	100%	100%
NIGERIA	47%	46%	99%	96%
CAMEROON	29%	49%	55%	NA
TOTAL	25%	36%	69%	82%



Switching back to TE

Consistently TL Only Importers

Switch to TL appears to be happening effectively

*Countries that imported less than 30,000 packs of TL and/or TE over the 38 month analysis period were excluded due to data availability.

** Calculated as TL Export Quantity / (TL+TE Export Quantities)

ATV/r instead of LPV/r: Potential for $150-210 million in savings over the next five years

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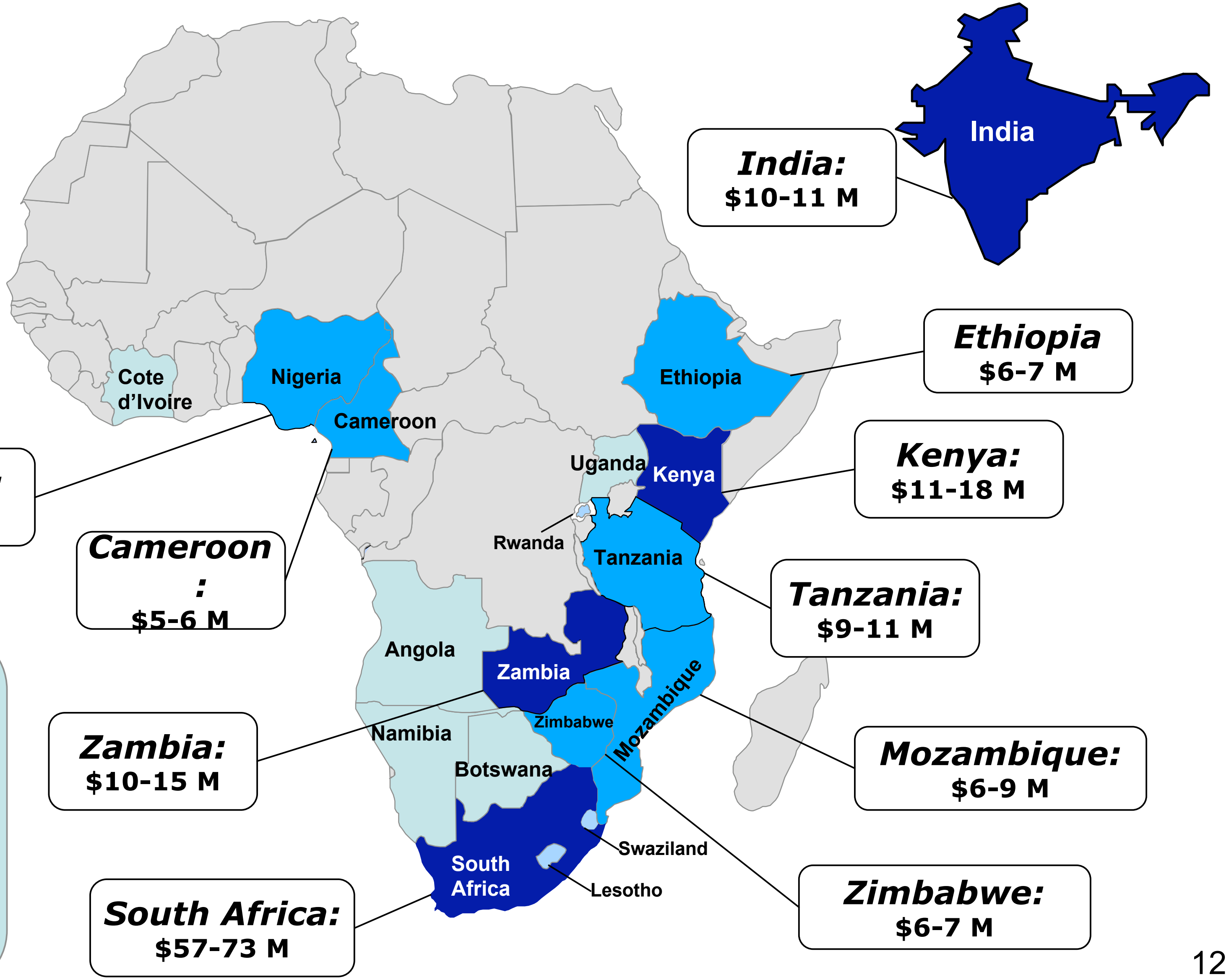

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Current public sector tenders may yield negative unintended consequences if they do not consider full market context

Feature	Description
Price is sole determinant of winner	Price competition is emphasized (perhaps to the detriment of other things of value?)
"Winner takes all"	One supplier is selected for all volumes

Key questions to consider:

- Are there possible negative consequences of this strategy given the context of the products / marketplace?
- Do I value things other than price? If so, how can the procurement program provide incentives?

Including non-price factors in selection scheme is a way to elicit desirable supplier behavior

Suggested criteria	Intended outcome
Price *(current selection criteria)*	*Price reductions*
Registrations	*Increased access*
Supplier performance	*Reliable supply-chain*
Quality *(eligibility criteria)*	*High-quality products*

Non-price factors

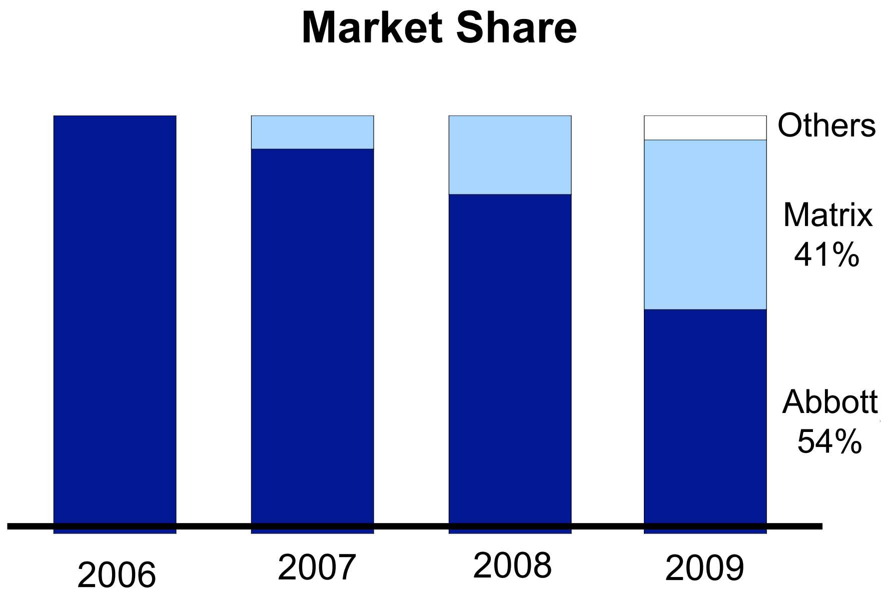
The UNITAID program implemented this scheme in 2009, seeking to encourage more widespread registration and better performance

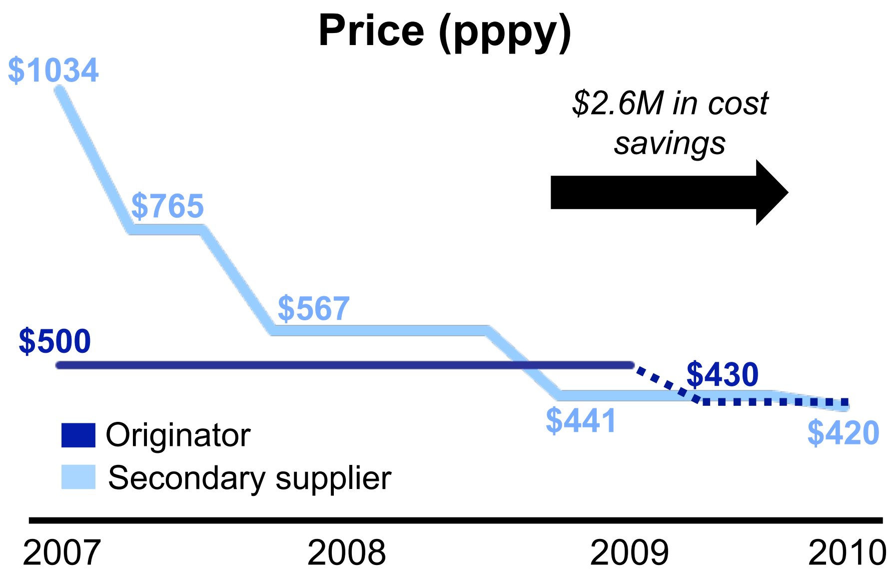
Splitting volumes and including non-price factors should be considered as selection techniques if market context is appropriate

Strategy	Description	Intended outcome
Split and allocate volumes	• Multiple sources instead of single supplier • Volumes allocated in advance	• Sustain multiple suppliers in the market in the long run • Prevent exit for slightly higher than lowest cost suppliers • Reliable planning and supply chain security
Inclusion of non-price factors in supplier selection	• Incentives for reliable and continuous supplies	• Encourage certain types of behavior • Weed out suppliers who do not deliver but win based on a lower bid

Splitting tenders and allocating volumes through the UNITAID program facilitated entry of new suppliers and resulted in cost reductions for LPV/r

Problem: Initially, the LPV/r market had only one supplier.
While generic suppliers existed, they were not price-competitive.

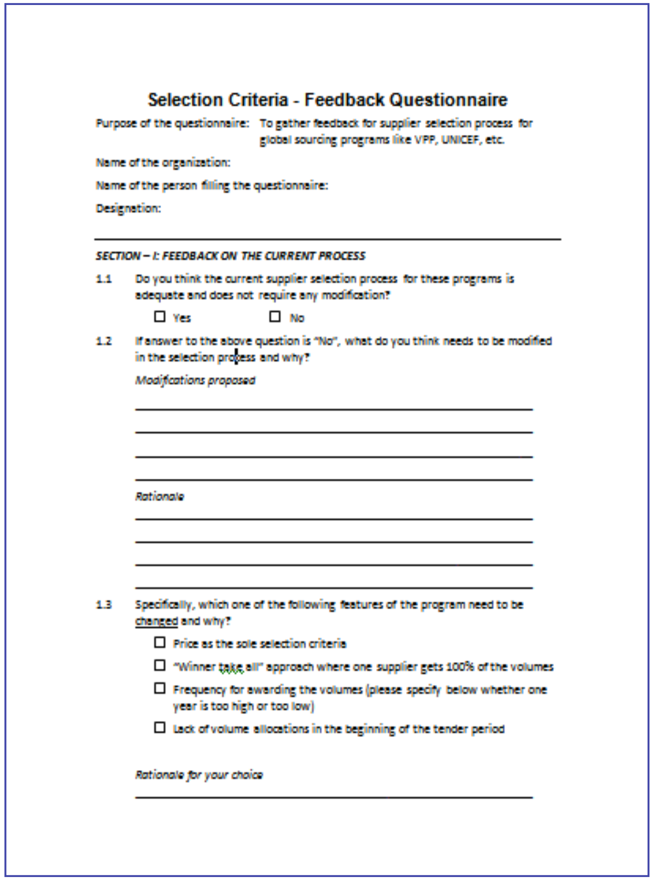




UNITAID split tenders to **facilitate the entry** of generic suppliers…

Source: CHAI-UNITAID order data; price for LPV/r (200mg/50 mg); cost savings based on patient volumes and price reductions relative to the innovator's original price ($500 pp/py).

Supplier input was gathered based on a standardized questionnaire



Selection Criteria - Feedback Questionnaire

Purpose of the questionnaire: To gather feedback for supplier selection process for global sourcing programs like VPP, UNICEF, etc.

Name of the organization:

Name of the person filling the questionnaire:

Designation:

SECTION – I: FEEDBACK ON THE CURRENT PROCESS

1.1 Do you think the current supplier selection process for these programs is adequate and does not require any modification?

☐ Yes ☐ No

1.2 If answer to the above question is "No", what do you think needs to be modified in the selection process and why?

Modifications proposed

Rationale

1.3 Specifically, which one of the following features of the program need to be changed and why?

- ☐ Price as the sole selection criteria
- ☐ "Winner take all" approach where one supplier gets 100% of the volumes
- ☐ Frequency for awarding the volumes (please specify below whether one year is too high or too low)
- ☐ Lack of volume allocations in the beginning of the tender period

Rationale for your choice

Suppliers support the inclusion of non-price factors for ensuring a sustainable market for ARVs

"…there is a necessity of ***inclusion of non-price information*** *in order to* ***evaluate the best supplier****…"*

"…the selection process has led to unsustainable prices… ***suppliers will focus on other business if [modification in selection process] is not done****."*

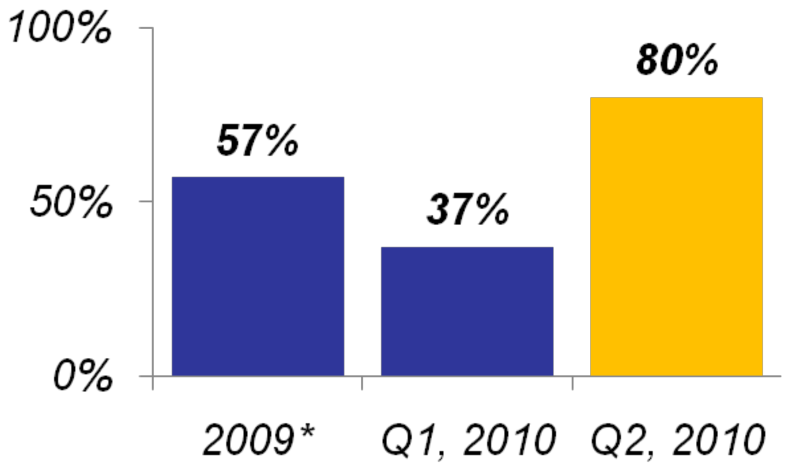
"It is easier to manage complex treatment programs when ***supplies are reliable and competitive*** *rather being low cost and erratic. "*

"Supplier selection should not be restricted to only pricing & regulatory status…"

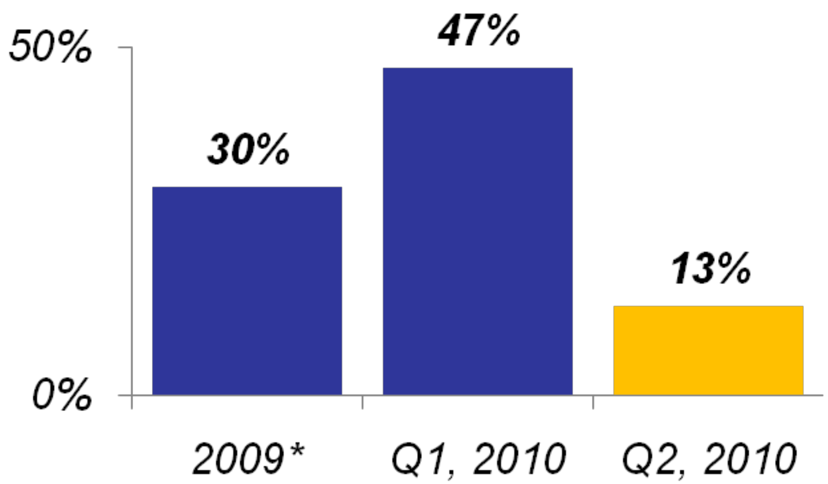
As a result, supply performance in the UNITAID-CHAI pediatric program has shown visible improvement on performance…

Current procurement year

On-time deliveries



Delays (> 2 weeks)



Pediatric supply performance has shown a steady improvement in the current procurement cycle, and excessive delays (more than 2 weeks) have decreased significantly.

…and registrations have shown a major increase

Country	December, 2009			June, 2010		
	Approved	Under Review	Total	Approved	Under Review	Total
Angola		1	1		3	3
Burkina Faso	12	6	18	18	5	23
Burundi	3	6	9	5	12	17
Cambodia	7	5	12	8	4	12
Cameroon	5	10	15	5	15	20
Chad		8	8	5	11	16
Cote d'Ivoire	9	11	20	11	12	23
D R Congo	4	11	15	4	20	24
Ethiopia	13	9	22	16	11	27
Ghana	8	3	11	11	9	20
Kenya	14	6	20	14	11	25
Lesotho	1		1	2		2
Liberia		4	4	1	8	9
Malawi	6	12	18	14	12	26
Mali	3	13	16	7	15	22
Mozambique	4	11	15	7	14	21
Namibia	5	13	18	12	5	17
Nigeria	17	3	20	18	6	24
Senegal	6	5	11	8	9	17
Swaziland	1		1	1	8	9
Tanzania	12	8	20	14	9	23
Togo	2	11	13	3	14	17
Uganda	15	6	21	17	9	26
Zambia	15	7	22	17	8	25
Zimbabwe	2	17	19	5	17	22
Grand Total	**164**	**186**	**350**	**223**	**247**	**470**

Applications have shown a major increase (from 350 to 470) over a 6-month period across the selected set of countries

Even low-volume countries are showing better registration coverage

Source: Based on select set of suppliers who were surveyed in June to get updated data

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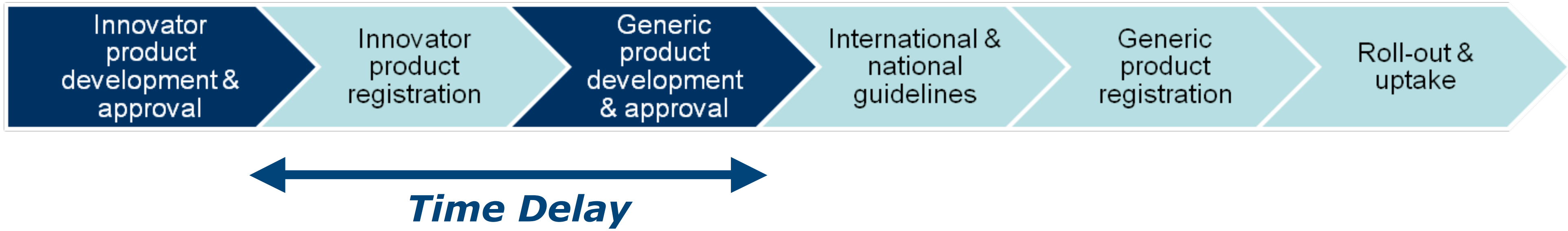
- Introduction
- Adult ART regimen optimization opportunities
  - ATV/r instead of LPV/r (in second-line)
  - TDF+3TC instead of ABC-DDI (in second-line)
  - 3TC instead of FTC (in first- and second-line)
- Procurement practices
- New product introductions

Under the traditional timeline, generic product approval may be delayed for up to 9 years following innovator product approval

Traditional Timeline



ARV/ Regimen	Year of Innovator Product Approval	Year of Generic Product Approval	*Time Delay*
LPV/r	2000	2009	*9 years*
TDF	2001	2007	*6 years*
TDF+FTC+EFV	2006	2009	*3 years*

Recent Access Policy announcements by Innovators with the leading ARV pipelines

July 2010: Voluntary license policy extended to 69 countries, and Generic companies offered royalty-free license for *all current ViiV Healthcare products and future pipeline*

Commitment since 2009 to apply their industry leading access policy enabling broad generic licensing of API and FPP covering 95 countries *to all products in the pipeline*

In partnership with Gilead for rilpivirine (TMC278) and likely to allow access in developing countries via licensing the FPP to generics and selling direct at not for profit prices

Early engagement with innovators can accelerate availability of key new drugs in developing world

Potential timeline under innovator collaboration

Product development and approval (innovator & generic) → Innovator product registration → International & national guidelines → Generic product registration → Roll-out and uptake

Innovator and generic activities can occur simultaneously…

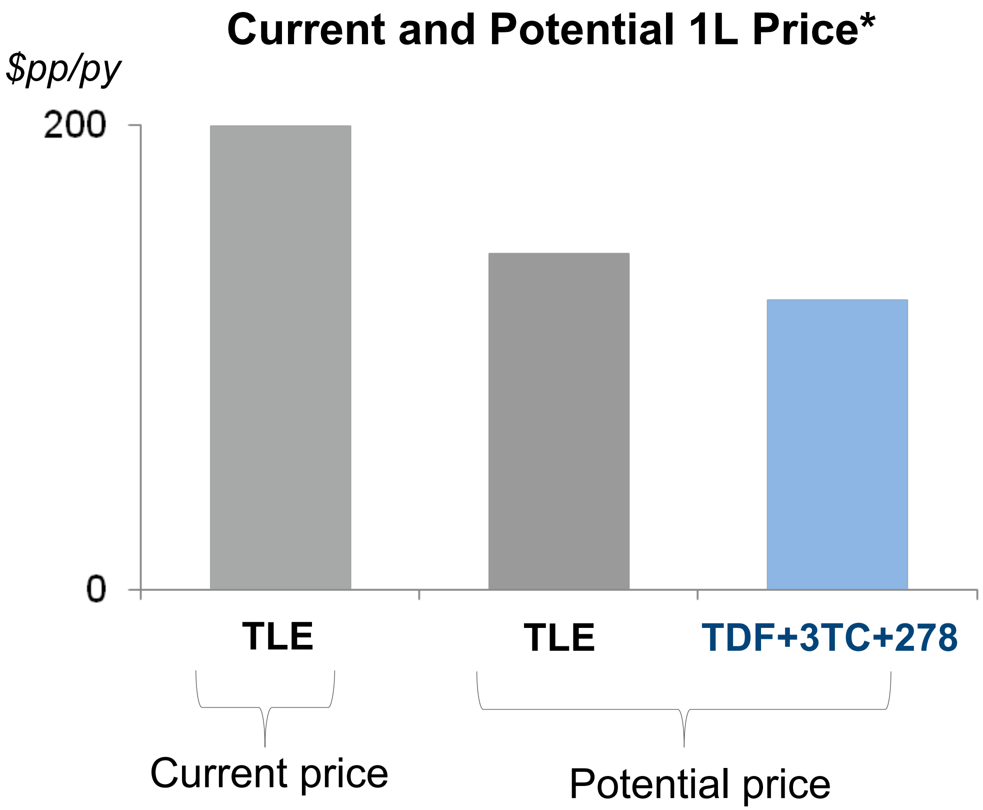
…and significantly reduce timelines

Innovator Commitments	CHAI Commitments
• Identify FDC options • Select generic licensee partners • Engage with regulators • Register new ARV in low and middle-income countries	• Identify appropriate generic licensees • Champion inclusion in international guidelines • Profile access initiative publicly • Engage with regulators to identify expedited pathways • Leverage demand-side stakeholders to accelerate adoption

TMC278 instead of EFV/NVP: Potential for >$100 million in savings in the first 2 years of uptake alone

Benefits of TMC 278

- Better tolerated than EFV
- Can be administered to women of childbearing age
- Lower cost and lower dose in comparison to EFV



*Based on projected generic-accessible patients on TDF-based 1L therapy and cost differential of $20 pp/py between TLE and TDF+3TC+278.

Incentives to consider and implement best practice polices would improve patient outcomes and save costs

- The regimen optimization opportunities are in line with the 2010 WHO ART Guidelines, but go one step further and consider issues of cost, product availability, convenience, and dosing
- Experience with the UNITAID program provides practical evidence for the impact of procurement practices
- Innovator pharmaceutical companies now have Access Programs that can accelerate availability of new products

A program to define best practices polices coupled with incentives for adoption has the potential to impact access to medicines and the cost effectiveness of treatment