



**World Health
Organization**



Forecasting pipeline ARVs for Paediatrics

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Medicines Patent Pool

- Currently does not include estimates of number of people who may need PrEP (e.g. number of IDUs at high risk of HIV acquisition) or TasP
- Borrows average usage forecast from currently available forecasts till 2018
- Borrows epidemiological estimates from available estimates till 2018
- Assumptions:
 - Linear regression on market share increase
 - Healthy and timely generic competition
 - Introduction of new drugs based on projected development timelines of generic manufacturers and estimated inclusion in WHO Guidelines
 - Price considerations: lower priced medicines would potentially have higher usage
 - Country inclusion: accounts for all low and middle income countries including those with well established ARV treatment programs such as Brazil
 - Accounts mainly for the public market

Considered three possibilities:

Scenario 1: Status Quo

- WHO Guidelines remain consistent with current guidelines
- New products when introduced show only a marginal uptake
- Use of Integrase Inhibitors (INIs) limited to 3rd line

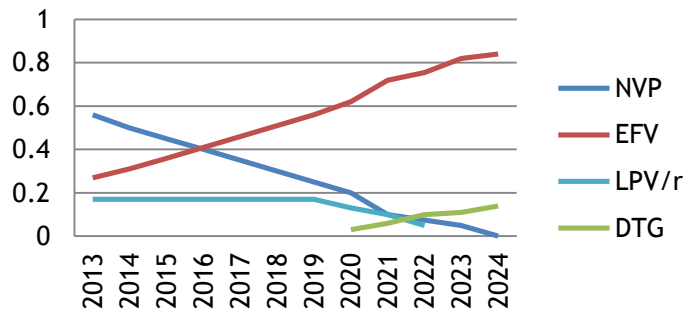
Scenario 2: Likely Use

- WHO Guidelines accept and recommend new products using the treatment optimisation framework
- New products have a good uptake; assumed that new FDCs such as those containing DTG, TAF and heat stable DRV/r are made available as generics
- Use of INIs is recommended as preferred options in 2nd and 3rd line in initial years, and later progressing to 1st line use (when more safety data is available)

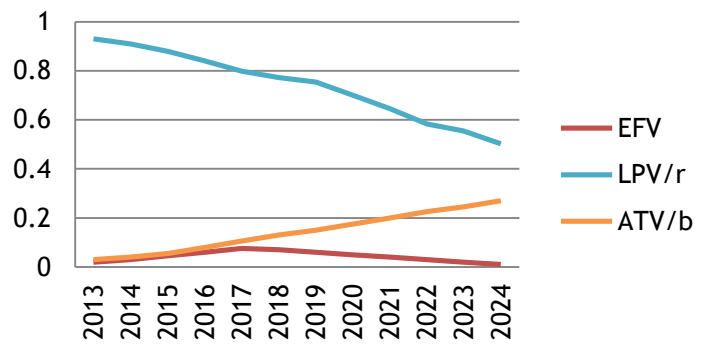
Scenario 3: Aggressive Adoption

- WHO Guidelines recommend aggressive use of new products
- Use of INIs as preferred option recommended in 1st line

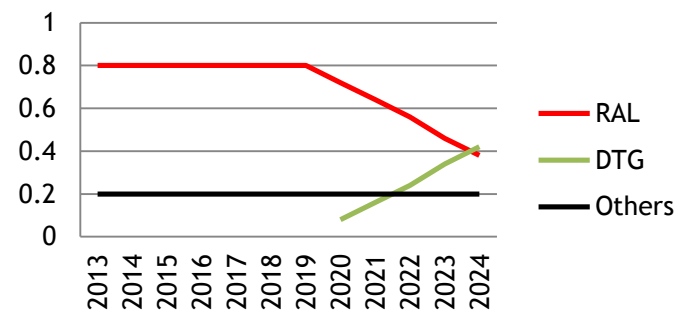
1st line: Ped



2nd line: Ped



3rd line: Ped



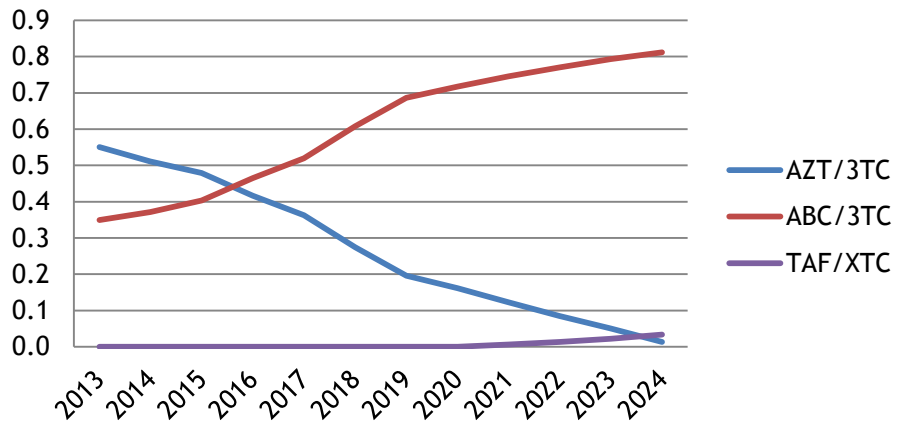
Guidelines remain consistent with current recommendations

In this scenario:

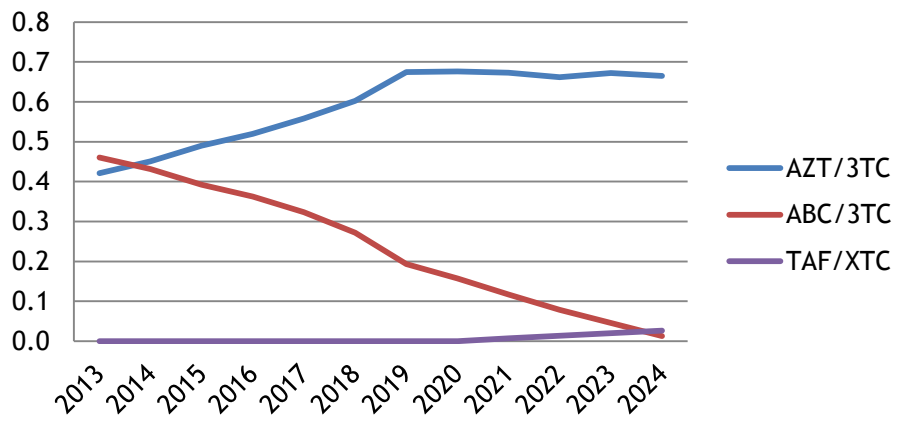
- 1st line:
 - Continues to be NNRTI based
 - INI-based regimens used as an alternative, low uptake
 - Marginal use of LPV/r in children, only for <3yrs, due to lack of widespread availability of suitable formulations
 - DTG replaces LPV/r in 1st line
- 2nd line
 - LPV/r is slowly replaced by ATV/b
 - ATV/b use increases due to its approval in CLHIV >3mos; QD dosing and the potential low cost
- 3rd line
 - DTG slowly replaces RAL

This scenario is less likely, as generics are already developing low cost FDCs which may be compelling for potential use in developing countries

1st line backbone - Peds



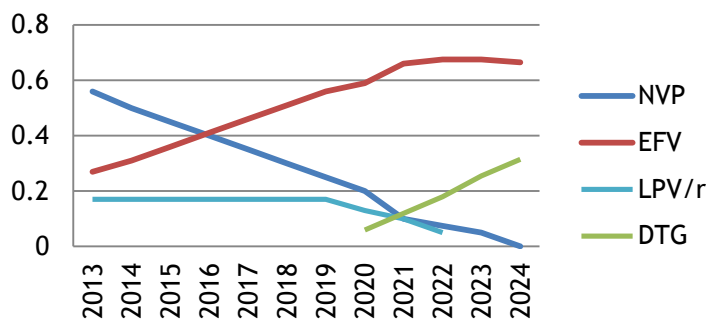
2nd line backbone - Peds



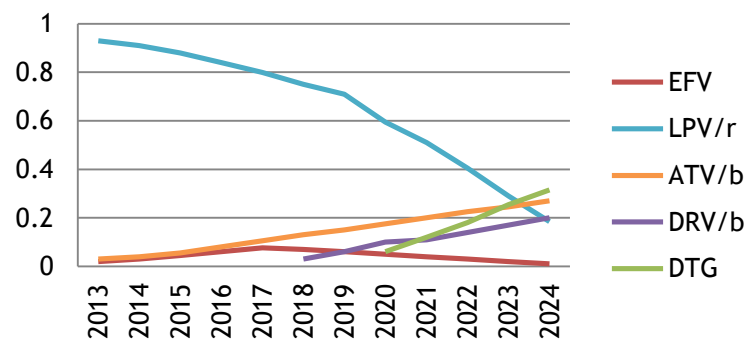
Consistent with current Guidelines

- Uptake of ABC increases, becoming the main backbone in 1st line
- Due to higher use of ABC in 1st line, AZT becomes preferred option in 2nd line
- Minimal uptake of TAF for children <10years

1st line: Peds



2nd line: Peds



3rd line: Peds



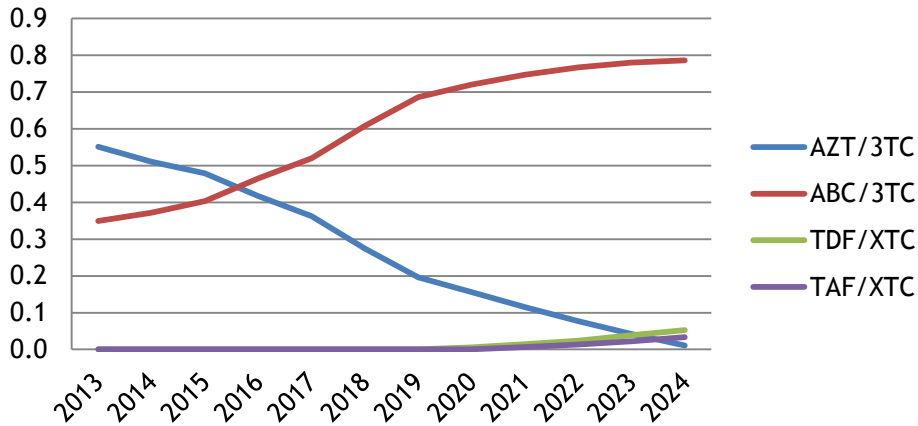
INIs introduced in 1st and 2nd line from 2020 (post availability of data)

In this scenario:

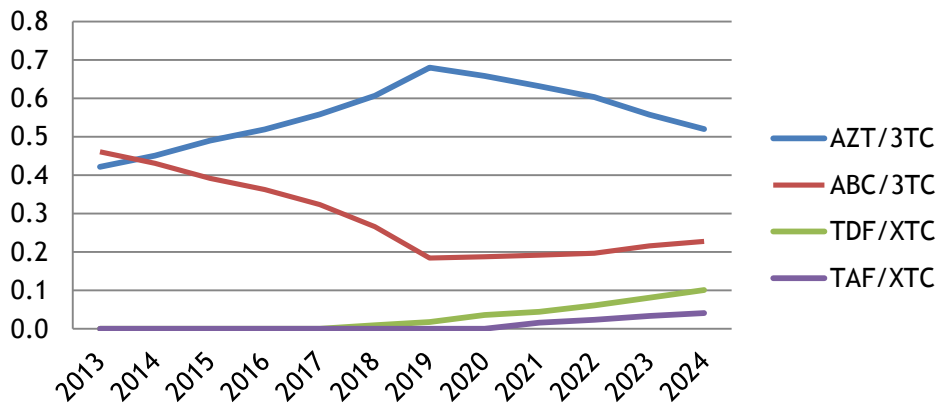
- 1st line
 - Continues to be NNRTI based
 - INI-based regimens used as an alternative
- 2nd line
 - bPIs used with NRTIs (as per current Guidelines)
 - ATV gains market share from LPV due to low cost and QD dosing
 - INIs used as an alternative to PIs
- 3rd line
 - Mainly RAL-based, as DTG is used in 1st line

Some clinical trials are exploring some of these ARVs in naïve and experienced patients. This may be a likely scenario in the initial years

1st line backbone - Peds



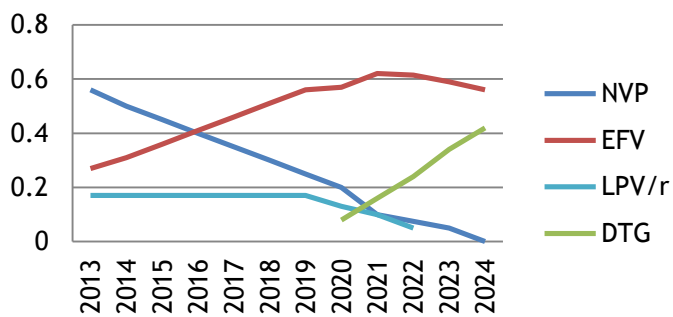
2nd line backbone - Peds



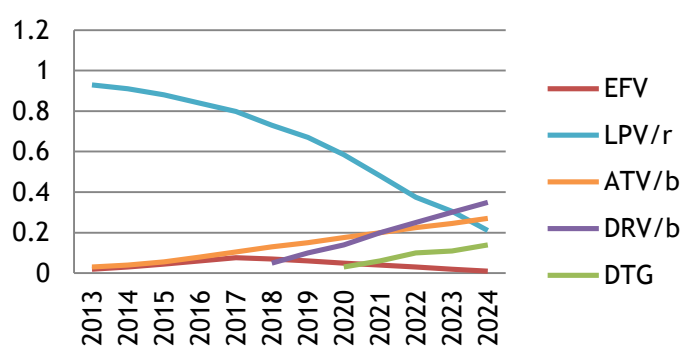
Introduction of INI in 1st and 2nd line

- Uptake of ABC increases, becoming the main backbone in 1st line
- Due to higher use of ABC in 1st line, AZT becomes preferred option in 2nd line
- Low uptake of TDF and TAF

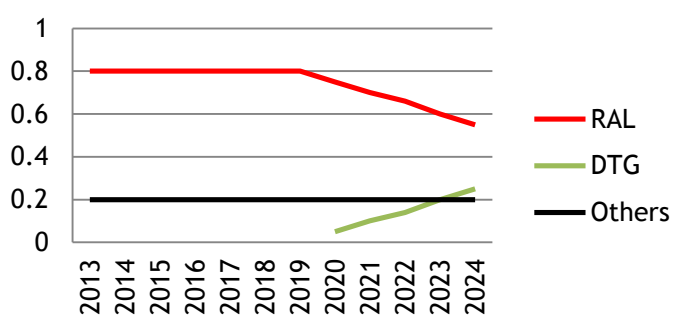
1st line: Ped



2nd line: Ped



3rd line: Ped



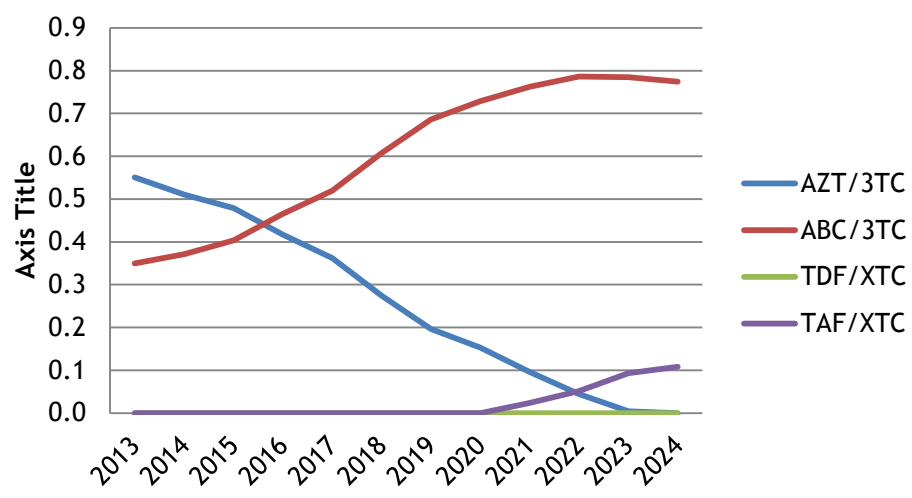
INIs recommended in 1st line based on low cost and FDC availability

In this scenario:

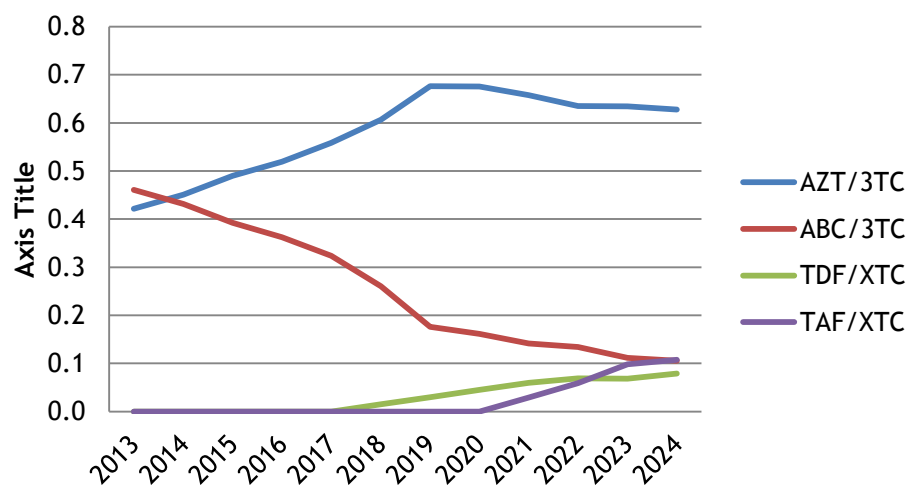
- 1st line
 - DTG is rapidly used in 1st line from year 2020, taking share from both NVP and EFV
- 2nd line
 - bPIs used with NRTIs (as per current Guidelines)
 - DRV/b becomes one of the main options, along with LPV/r and ATV/r
- 3rd line
 - Mainly RAL-based, as DTG is used in 1st line

This scenario may be a reality in future once WHO gets more data with respect to INIs

1st line backbone - Peds



2nd line backbone - Peds



INIs recommended in 1st line

- ABC replaces AZT in 1st line, becoming the main backbone
- AZT becomes preferred option in 2nd line
- Low uptake of TDF and TAF

CLHIVs using each formulation	2018	2019	2020	2021	2022	2023	2024
NVP/AZT/3TC	106,500	67,000	48,000	21,000	13,000	6,000	-
NVP/ABC/3TC	236,000	234,000	205,000	112,000	91,000	66,000	-
EFV/AZT/3TC	186,000	155,000	147,000	134,000	103,000	64,000	20,000
EFV/ABC/3TC	403,000	525,000	608,000	741,000	822,000	887,000	950,000
EFV/TAF/XTC	-	-	-	8,000	17,000	26,000	38,000
LPV/r/AZT/3TC	112,000	113,000	101,000	92,000	77,000	58,000	40,500
LPV/r/ABC/3TC	157,000	178,000	150,000	125,000	69,000	4,000	1,000
LPV/r/TAF/XTC	-	-	-	1,000	2,000	2,000	2,000
ATV/r/AZT/3TC	9,000	14,000	20,000	28,000	38,000	49,000	59,000
ATV/r/ABC/3TC	4,000	4,000	5,000	5,000	5,000	3,000	1,000
ATV/r/TAF/XTC	-	-	-	600	1,000	2,000	3,000
DRV/r/AZT/3TC	2,000	5,000	10,000	13,000	19,000	27,000	33,000
DRV/r/TDF/XTC	1,000	2,000	5,000	6,000	8,000	11,000	13,000
DRV/r/TAF/XTC	-	-	-	-	1000	1,500	2,000
DTG/ABC/3TC	-	-	75,000	155,000	237,000	342,000	428,000
DTG/TDF/XTC	-	-	9,000	23,000	42,000	71,000	101,000
DTG/TAF/XTC	-	-	-	2,000	5,000	12,000	21,000
DTG/DRV/r	-	-	2,000	4,000	7,000	10,000	14,000
RAL/DRV/r	12,000	16,000	16,000	17,000	17,000	19,000	20,000

Thank You