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Fighting for an AIDS-free generation



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## Quantification and Budgeting for Rapid and Sustainable Access to New Pediatric Antiretroviral Therapies

### 1. Introduction

To improve health and save lives, children diagnosed with HIV need immediate and sustainable access to child-friendly formulations of antiretrovirals (ARVs) that are safe, effective, affordable, and palatable. The World Health Organization (WHO) recommends a preferred first-line treatment of Raltegravir-based (RAL) regimens for neonates, and dolutegravir-based (DTG) regimens for children for whom approved DTG dosing is available. For children weighing 20kg or more, DTG-containing regimens can be delivered using available 50mg DTG tablets. For children weighing 30 kg or more, TLD should be used (TDF + 3TC (or FTC) + DTG). However, in situations where DTG formulations and dosing for infants and children are absent, the WHO recommends the use of lopinavir/ritonavir (LPV/r)-containing regimens.<sup>1</sup>

For children living with HIV who weigh less than 20kg, an originator DTG 5mg dispersible tablet (DT), manufactured by ViiV, received United States Food and Drug Administration (US FDA) approval in June 2020. The product, which is available in limited supplies and at a relatively high cost, paved the way for the approval of more affordable, generic DTG dispersible formulations. By the end of 2020, two additional child-friendly ARV formulations are expected to receive US FDA approval. They are an LPV/r 4-in-1 fixed-dose combination (FDC) of

ABC+3TC+LPV/r in granular form and a generic DTG 10mg scored dispersible tablet (DTG 10mg DT).

Several key steps are needed at the country level to prepare for the introduction of new pediatric ARV formulations. These include estimating the quantities of new ARVs needed, creating transition and rollout plans, updating national treatment guidelines and essential medicines lists, developing or updating job aids and educational materials for healthcare workers and caregivers, training of healthcare workers, and strengthening the supply chain and pharmacovigilance systems.

Among these steps, early and accurate quantification and budgeting are critical for ensuring rapid and sustainable access to optimal pediatric ARVs while minimizing overstocks or stock-outs. Quantification of pediatric ARVs should focus on the full range of products needed to implement WHO recommended antiretroviral therapy (ART) regimens, including the optimized nucleoside reverse-transcriptase inhibitor (NRTI) backbone products. Quantification also should take into consideration the existing regimens in use, pediatric ARVs already in stock at both central warehouse and facility levels, current orders in the procurement pipeline, lead times for the availability of newly-approved formulations for children, as well as

<sup>1</sup> Considerations for introducing new antiretroviral drug formulations for children: policy brief. Geneva: World Health Organization; July 2020 (<https://www.who.int/publications/i/item/9789240007888>, accessed July 2020)

the production capacity of manufacturers.<sup>2,3</sup> If production capacity is insufficient for a particular formulation (e.g. LPV/r tablets), then national programs should consider revising their quantification to ensure that sufficient amounts of recommended regimens are available through a combination of different formulations (e.g. LPV/r tablets and granules).

## 2. Special Considerations for Quantifying Pediatric ARVs

Despite relatively small numbers of HIV-positive children compared to adults, many national programs face challenges in quantifying pediatric ARV products by regimen, age group, and weight band. Historical rates of consumption may not accurately reflect changing policies or the rapidly evolving epidemiology of pediatric HIV infections. Additionally, quantification must take into account factors such as declining mother-to-child transmission (MTCT) rates due to increased coverage of maternal ART as well as improved access to HIV diagnoses for newborn infants and young children.<sup>4</sup>

In addition to the challenges above, some key factors should be considered when quantifying pediatric ARVs.<sup>5</sup>

They include:

- The relatively high cost of pediatric formulations
- The need to take several different drugs together to produce a complete regimen

- Complications caused by the availability of different formulations including liquid, pellets, granules, capsules, and tablet formulation
- The need to adjust formulations and dosages over time as the child's weight changes
- Delays in transitioning caused by an overstock of sub-optimal legacy products (e.g. Nevirapine)
- If adult formulations are used for children, the potential need to cut a tablet to meet pediatric dosing requirements
- Adherence challenges caused by complicated dosing, large volumes that need to be administered more than once per day, the foul taste of some formulations, and the inability of small children to swallow whole tablets combined with the advice not to crush or split some tablets
- The need for extra storage space for some pediatric ARVs and refrigeration for others
- Packaging of pediatric ARVs in quantities that do not match dosing requirements, which complicates prescribing and dispensing
- Wastage due to the reconstitution of pediatric doses at the service delivery level. Reconstituted formulations must be discarded after a certain period. The volume of use within that period is unpredictable and can vary from site to site.



Photo: Eric Bond, 2018

- 2 Considerations for introducing new antiretroviral drug formulations for children: policy brief. Geneva: World Health Organization; July 2020 (<https://www.who.int/publications/i/item/9789240007888>, accessed July 2020)
- 3 2018 updated recommendations on first-line and second-line antiretroviral regimens and postexposure prophylaxis and recommendations on early infant diagnosis of HIV. Geneva: World Health Organization; 2018 (<https://www.who.int/hiv/pub/guidelines/antiretroviral-drug-2018-update/en>, accessed July 2020).
- 4 WHO. Transitioning to an Optimal Pediatric ARV Formulary: Implementation Considerations. WHO Policy Brief. Geneva, Switzerland: WHO; 2018. <https://www.who.int/hiv/pub/paediatric/transition-paediatric-arv-formulary/en/> accessed July 2020
- 5 Allers, Claudia, and Yasmin Chandani. 2006. Guide for Quantifying ARV Drugs. Arlington, Va.: DELIVER, for the U.S. Agency for International Development.

### 3. Guidance for Quantification, Budgeting, and Supply Planning for Pediatric ARVs

Quantification is the process of estimating the quantities and costs of products and determining when they should be delivered to ensure an uninterrupted supply of ARVs for all children who need them. The four-phase process of quantification takes into account the expected demand for commodities, unit costs, existing stocks, the stock

already on order, expected expiries, lead times between ordering and delivery, minimum and maximum stock levels, and shipping costs. With this information in hand, the total commodity requirements and costs can be calculated and compared with the available financial resources to determine the quantities to procure.<sup>6</sup>

The flow of data in quantification is shown in the figure below.

**FIGURE 1.** Quantification and Budgeting Phases, Inputs and Outputs

#### PHASES



#### INPUTS

<ul style="list-style-type: none"> <li>• Program policies, strategies, and priorities</li> <li>• Product characteristics and use</li> <li>• Program expansion plans; policy changes</li> <li>• Historical data on consumption, services, morbidity, demographics</li> <li>• Forecasting assumptions (quantify factors affecting demand for services/commodities)</li> </ul>	<ul style="list-style-type: none"> <li>• Forecasted consumption for each year of the quantification</li> <li>• Stock on hand at the time of the quantification</li> <li>• Lead times by product and supplier</li> <li>• Max-min stock levels</li> <li>• Quantities on order</li> <li>• Shipping/handling costs</li> <li>• Product unit cost at time of quantification</li> </ul>	<ul style="list-style-type: none"> <li>• Funding sources for each product</li> <li>• Suppliers for each product</li> <li>• Shipment intervals</li> </ul>	<ul style="list-style-type: none"> <li>• Timing and amounts of funding commitments for each product, for each year of the quantification</li> </ul>
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#### OUTPUTS

<ul style="list-style-type: none"> <li>• Forecasted consumption for each year of the quantification</li> </ul>	<ul style="list-style-type: none"> <li>• Total estimated quantity required of each product</li> <li>• Total estimated cost per product</li> <li>• Total estimated cost of all products required</li> </ul>	<ul style="list-style-type: none"> <li>• Shipment quantities</li> <li>• Shipment delivery schedules for each year of the quantification</li> </ul>	<ul style="list-style-type: none"> <li>• Total funding gap</li> <li>• Funded shipments</li> <li>• Unfunded shipments</li> </ul>
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Source: JSI. *Quantification of Health Commodities (2017)*

6 JSI. *Quantification of Health Commodities. A guide to forecasting and supply planning for procurement.* January, 2017 (<https://www.jsi.com/resource/quantification-of-health-commodities-2017>).

The four phases of quantification can be applied to pediatric ARV products as follows.

### Phase 1 - Forecasting Consumption for the Full Range of Optimal Pediatric ARV Products

Forecasting is the process of estimating the quantities of products that will be dispensed to children during a specific future period. Forecasting for the full range of pediatric ARV products involves analyzing different types of data such as product consumption, morbidity, and/or demographic data, as well as making assumptions around historical program data and future program performance. It also involves selecting an appropriate forecasting method (consumption-based and/or morbidity-based<sup>7</sup>) and

calculating forecasted consumption for each product using appropriate software and database (e.g. [CHAI Simple Tool](#), [Quantimed](#) and [PipeLine](#)). The choice of methodology and software should be based on country needs, programmatic targets, and available data. The two methodologies are not mutually exclusive and can be used together. However, the morbidity method is likely to produce more accurate forecasts for pediatric ARVs.

Forecasting of the full range of optimal pediatric ARVs, including the NRTI backbone products, should take into consideration the WHO recommended dosing of optimal formulations as well as the challenges and solutions in Table 1. Refer to Appendix A for dosing of optimal ARVs.

**TABLE 1.** Pediatric ARVs forecasting challenges and proposed solutions

Forecasting Challenges	Proposed Solutions
Ensuring pediatric treatment regimens are included in national treatment guidelines and are based on current WHO treatment guidelines <sup>8</sup> , as well as estimating the expected number of patients per regimen	<ul style="list-style-type: none"> <li>Update national treatment guidelines and essential medicines lists (EML) to include the new optimal pediatric ARV formulations based on current WHO treatment guidelines</li> <li>Adhere to national treatment guidelines and/or EMLs to ensure that new products are used as intended and to enhance the accuracy of the procurement forecasts</li> </ul>
Obtaining data on product formulations (e.g. dispersible tablets, oral solutions, pellets, granules), doses by age group and/or weight band, and developmental milestones (e.g. age/weight when children can swallow tablets)	<ul style="list-style-type: none"> <li>Define targets for disaggregating data by pediatric formulations (weight bands/ages)</li> <li>Include weight, age, and formulation data in relevant national databases (e.g. electronic medical records)</li> <li>Improve data systems for pediatric ARVs at both the facility and central warehouse levels</li> </ul>
Balancing backbone NRTI drug supply needs with the need for single formulation products as well as fixed-dose combination products	Increase investment in research and development of simplified pediatric ARVs, such as fixed-dose combination products
Estimating transition rates from first-line to second-line regimens and from second-line to third-line, as well as the need for alternative formulations	<ul style="list-style-type: none"> <li>Develop simple guidance for first-, second- and third-line pediatric ARV regimens</li> <li>Provide data to estimate intolerance and treatment failure rates among children</li> </ul>
Predicting timelines for future product approvals and introductions (e.g. tentative US FDA approval of DTG 10mg dispersible tablets is expected in Q4 2020)	<ul style="list-style-type: none"> <li>Share regular updates from stringent regulatory authorities (SRAs) on expected approval timelines of new products</li> </ul>

7 **Consumption-based** methodology uses historical consumption data (actual quantities of a product consumed within a specified period) to predict future needs. **Morbidity-based** methodology estimates the needs based on the incidence and prevalence of a disease and patient populations and population growth rates

8 WHO. *Update of recommendations on first and second line antiretroviral regimens*. WHO Policy Brief. Geneva, Switzerland: WHO; 2019 <https://www.who.int/hiv/pub/arv/arv-update-2019-policy/en/>

## Phase 2 – Estimating Total Commodity Requirements and Costs

Estimating total commodity requirements over a future period involves identifying the quantities of pediatric ARVs to be procured to meet forecasted consumption and ensure the supply pipeline has adequate stocks. This step takes into consideration the following:

- Forecasted consumption
- Available stock in-country and their expiry dates
- Orders in the pipeline and expected delivery dates
- Maximum-minimum stock levels for the entire pipeline
- Supply availability from manufacturers

For this phase, the [PipeLine](#) software is highly recommended to facilitate the preparation of the supply plan.

When estimating costs, the following should be considered:

- Product cost based on updated supplier prices and packaging information (see Appendix B)
- Procurement agent fees
- Shipping and handling costs
- Customs clearance fees
- In-country storage and distribution costs
- Sampling/quality testing costs

ART in children involves the use of different classes of drugs to form a complete regimen. Therefore, programs should consider the full cost of treatment (full regimen) in the budgeting process. Appendix C compares the current regimen prices per year for various pediatric ARV formulations for a 10kg child. Table 2 lists the common challenges encountered during this phase and some proposed solutions.

**TABLE 2.** Pediatric ARV total requirements and costs challenges and proposed solutions

Requirements and Costs Challenges	Proposed Solutions
Matching the demand for pediatric ARVs with the production capacity of manufacturers. A mismatch of supply and demand can lead to oversupply and/or undersupply of pediatric ARV stocks	<ul style="list-style-type: none"> <li>• Improve forecasting of pediatric ARV formulations as explained in Phase 1 above</li> <li>• Share national forecasts with the <a href="#">ARV Procurement Working Group (APWG)</a> and monitor the APWG website for updates on supply availability and manufacturer capacity constraints (see: <a href="https://www.arvprocurementworkinggroup.org">https://www.arvprocurementworkinggroup.org</a>)</li> <li>• Conduct frequent reviews (i.e. quarterly) of pediatric ARV stocks in-country and in the procurement pipeline</li> </ul>
Disposing of overstocks of sub-optimal legacy products. In some countries, disposal or wastage of legacy products is not planned for and/or not allowed	<ul style="list-style-type: none"> <li>• Begin quantifying for new pediatric ARVs at least six months before stringent regulatory approval (e.g. U.S. FDA) of a product</li> <li>• Place more frequent and smaller orders to allow for adjustments in both the types of formulations and quantities, if needed</li> <li>• Plan in advance to transition out sub-optimal legacy products and to transition to new products</li> <li>• Allow and budget for disposal of existing, sub-optimal legacy stocks</li> </ul>
Budgeting for the relatively high cost of pediatric ARV formulations and regimens	<ul style="list-style-type: none"> <li>• Minimize wastage, expiries of pediatric ARVs, and reduce programmatic costs caused by ARV stock outs and shortages through accurate quantification and careful product transition planning</li> </ul>

### Phase 3 — Developing a Supply Plan for Optimal Pediatric ARVs

Supply planning involves determining the total product quantities, costs, and delivery schedule required to ensure an uninterrupted supply of ARVs to meet treatment demand. Data required for supply planning includes stock on hand of existing formulations, forecasted consumption, minimum and maximum stock levels, supplier prices, packaging information, lead times, funding information, procurement mechanisms, shipping and customs clearance costs, storage and distribution costs, and desired arrival dates of shipments.

A supply plan entails coordinating the timing of funding disbursements from multiple funding sources with procurement lead times (production, shipping, customs clearance, and transport to the warehouse) and supplier delivery schedules. A supply plan ensures a continuous supply of products and aims to maintain stock levels between the established maximum and minimum levels. Shipments should be scheduled to arrive when the stock level reaches the nationally defined minimum months of stock on hand. A good supply plan takes into account the procurement lead times to minimize the risk of stockouts.

The overall quantities of ARVs needed for children are typically lower than for adults. However, regimen and dosage requirements change rapidly as a child's weight changes. For example, an individual child could experience three regimen changes, and more than six dosage changes by the time they reach 14 years of age. Also, stringent

regulatory approval of a new, child-friendly formulation during a procurement cycle can affect the quantification of other ARVs. For example, a new fixed-dose combination formulation might reduce the quantity of backbone NRTI drugs needed. These fluctuations in demand pose challenges for pediatric ARV quantification and, therefore, require a more agile supply planning approach. For this reason, the pediatric ARV supply plan should be flexible and reviewed at least every six months and, if feasible, every three months.

By the time they are 14 years of age, a child could experience:



National programs should consider the following actions to address the challenges identified in the supply-planning phase.

**TABLE 3.** Pediatric ARV supply planning challenges and proposed solutions

Supply Plan Challenges	Proposed Solutions
Staying within the minimum and maximum supply levels at both central warehouses and healthcare facilities for a portfolio of pediatric ARV products in relatively small quantities compared to the quantities of ARVs needed for adults.	<ul style="list-style-type: none"> <li>Place orders early (at least 6 months in advance) with suppliers</li> <li>Plan for quarterly orders and/or staggered deliveries</li> <li>Negotiate with manufacturers to allow adjustable shipment dates and quantities as well as order cancellation.</li> <li>If needed, use overstock of products in other populations (e.g. adults)</li> <li>Allow for the destruction of inferior products once an adequate supply of superior replacement is in-country</li> <li>Train healthcare workers on stock management and monitoring</li> </ul>
Matching supply plans to the production and delivery capacity of manufacturers	<ul style="list-style-type: none"> <li>As with forecasts, supply plans should be shared with <a href="#">the APWG</a> to ensure alignment of supply and demand globally and to avoid production capacity constraints for new and low-volume products.</li> <li>Improve manufacturers' capacity and commitment</li> </ul>
Aligning supply plans with the budgeting and funding cycles of national governments and donors	<ul style="list-style-type: none"> <li>Advocate for more frequent ordering and deliveries in smaller quantities for pediatric ARVs to allow for adjustments in the mix and quantities of ARVs over time</li> </ul>

## Phase 4 – Comparing Available Funding to Total Commodity Costs

The availability of funding determines the quantities to procure. Additional resources should be mobilized if

available funding is insufficient. If additional resources cannot be mobilized, then the quantification steps should be repeated to align quantification with available funds.

**TABLE 4.** Pediatric ARV funding challenges and proposed solutions

Funding Challenges	Proposed Solutions
Insufficient funds, or poor alignment of funding and procurement cycles, for procurement of optimal pediatric ARVs	Mobilize additional resources as needed (e.g. inclusion of sufficient budget for pediatric ARVs in the Global Fund Concept notes and PEPFAR Country Operational Plans.)

## 4. Conclusions and Recommendations

To ensure the timely and accurate quantification of WHO-recommended first- and second-line optimal pediatric ARVs and allow for rapid and sustainable transition, as well as an uninterrupted supply, it is recommended that national programs and procurement agents do the following:

- Start quantification at the same time, or before, updating treatment guidelines and essential medicines lists. If possible, include products that are expected to receive SRA approval within the next 6 to 12 months (i.e. start to quantify as soon as possible for LPV/r 4-in-1 and DTG 10mg DT, which are expected to receive U.S. FDA approval by December 2020)
- Collect and use quality data. Quality data are key to accurate and reliable forecasts and supply plans. Appendix D lists the core data needs for quantifying pediatric ARVs.
- Update data information systems for pediatric ARVs at both health facility and central warehouse levels (e.g. tracking of consumption by formulation, by age, by weight) to ensure more accurate forecasting and train relevant staff in the use of these systems
- Update forecasts and supply plans regularly
- Share forecasts and supply plans with [the APWG](#), which provides aggregated forecasts to suppliers to ensure alignment of supply and demand at the global level, to avoid any capacity constraints for new products, and monitor manufacturer production capacity through the APWG website
- Plan and place orders early (at least six months before needed in-country) with quarterly order cycles, as recommended by the APWG, to ensure timely delivery—taking into consideration lead times that may be slightly longer in the initial stage of transition before steady production is reached

- Avoid over quantification and/or stockpiling of optimal pediatric ARVs; instead, plan for frequent deliveries of orders to match procurement volumes with consumption—this mitigates the risk of wastage and expiries if transition plans do not run according to the anticipated schedule
- Stagger large orders into smaller deliveries to avoid overburdening suppliers with one large order representing a very significant volume
- When new, more optimal ARVs for children are available, the rapid transition to optimal products is preferable to exhausting existing stocks of an inferior product. Programs should plan for transitions to new products at least six months in advance to avoid the overstock of sub-optimal legacy products. If needed, programs should budget for appropriate destruction of legacy formulations, such as those containing Nevirapine (NVP), as per MOH and/or donor policies. However, this should only be initiated after adequate supplies of optimal replacement products are in the country<sup>9</sup>.

9 WHO. *Considerations for introducing new antiretroviral drug formulations for children*: WHO Policy Brief. Geneva: Switzerland; July 2020. <https://www.who.int/publications/i/item/9789240007888>

## APPENDIX A: Dosing of Optimal ARVs

Formulation (unit for dosing)	3-5.9kg		6-9.9kg		10-13.9kg		14-19.9kg		20-24.9kg		25-29.9kg		>30kg	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
ABC/3TC 120/60mg scored dispersible tablet (tablet)	1		1.5		2		2.5		3		1 adult tab (600/300mg)		1 adult tab (600/300mg)	
LPV/r 40/10 mg pellets (capsule)	2	2	3	3	4	4	5	5	6	6	—	—	—	—
LPV/r 40/10 mg granules (sachet)	2	2	3	3	4	4	5	5	6	6	—	—	—	—
LPV/r 100/25 mg tablets (tablet)	—	—	—	—	2	1	2	2	2	2	3	3	3	3
4-in-1 ABC/3TC/ LPV/r 30/15/40/10 mg granules (capsule)	2	2	3	3	4	4	5	5	6	6	—	—	—	—
DTG 5 mg Dispersible tablets (tablet)	1		3		4		5		—		—		—	
DTG 10 mg scored dispersible tablet (tablet)	0.5		1.5		2		2.5		—		—		—	
DTG 50 mg tablet (tablet)	—		—		—		—		1		1		1	
TDF/3TC (or FTC)/ DTG 300/300 (or 200)/50 mg tablet (tablet)	—		—		—		—		—		—		1	

Source: WHO. Considerations for introducing new antiretroviral drug formulations for children: WHO Policy Brief. Geneva: Switzerland; July 2020.

## APPENDIX B: Estimated Pricing of Select Pediatric ARVs

Formulation	Packaging	Unit Of Measure	GHSC-PSM e-catalogue estimated price <sup>10</sup> (EXW, USD)	Global Fund PPM Reference price <sup>11</sup> (EXW, USD)
Lopinavir/Ritonavir 80/20 mg/mL Solution	5x60mL bottle	Case	30.82	30.82
Lopinavir/Ritonavir 40/10 mg Pellets	120 Capsules	Bottle	15.00	Not Available
Lopinavir/Ritonavir 40/10 mg Granule	120 Sachets	Pack	18.25	18.25
Lopinavir/Ritonavir 100/25 mg Tablet,	60 Tablets	Bottle	7.00	6.50
Lopinavir/Ritonavir 200/50 mg Tablet	120 tablets	Bottle	18.95	18.65
Dolutegravir 50 mg Tablet	30 Tablets	Bottle	3.50	2.60
Abacavir/Lamivudine 120/60 mg Scored Dispersible Tablet	30 Tablets	Bottle	3.30	3.30
Abacavir/Lamivudine 120/60 mg Scored Dispersible Tablet	60 Tablets	Bottle	6.50	Not Available
Dolutegravir/Lamivudine/ Tenofovir 50/300/300mg tablet	30 Tablets	Bottle	5.49	5.55
Dolutegravir/Lamivudine/ Tenofovir 50/300/300mg tablet	90 Tablets	Bottle	15.62	15.25 (no carton)
Dolutegravir/Lamivudine/ Tenofovir 50/300/300mg tablet	180 Tablets	Bottle	31.49	30.99 (no carton)
Abacavir/Lamivudine/ Lopinavir/ Ritonavir 30/15/40/10	120 Capsules	Bottle	15.00*	
Dolutegravir 5mg Dispersible Tablet	60 Tablets	Bottle	32.24	Not Available
Dolutegravir 10mg Scored Dispersible Tablet	90 Tablets	Bottle	5.00	Not Available

\*As announced by Unitaid on 29 November 2019

(<https://unitaid.org/news-blog/hiv-treatment-for-children-to-be-produced-for-under-one-dollar-a-day/#en>)

10 USAID Global Health Supply Chain – Procurement and Supply Management Single Award IDIQ. 2016. USAID GHSC-PSM e-Catalog, 2020. Washington, D.C.: Chemonics International Inc. <https://www.ghsupplychain.org/sites/default/files/2020-09/eCatalog%20Sept%202020.pdf>

11 The Global Fund – Pooled Procurement Reference Pricing: ARVs 14 October 2020 Geneva, Switzerland [https://www.theglobalfund.org/media/5813/ppm\\_arvreferencepricing\\_table\\_en.pdf?u=637384507675200000](https://www.theglobalfund.org/media/5813/ppm_arvreferencepricing_table_en.pdf?u=637384507675200000)

## APPENDIX C: Comparison of Current Regimen Prices Per Year for a 10kg Child

Combination Formulations*	Number of packs/bottles per patient per year**	Estimated Price per patient per year (USD)***
ABC/3TC 120/60mg (dispersible tablet), + LPV/r 80/20mg/mL (solution)	24 bottles of ABC/3TC tabs, 30's + 24 bottles of LPV/r solution, 60mL	\$ 227.14
ABC/3TC 120/60mg (dispersible tablet), + LPV/r 100/25mg tablet	24 bottles of ABC/3TC tabs, 30's + 18 bottles of LPV/r tabs, 60's	\$ 205.20
ABC/3TC 120/60mg (dispersible tablet), + LPV/r 40/10mg granules	24 bottles of ABC/3TC tabs, 30's + 24 packs of LPV/r sachets, 120's	\$ 517.20
ABC/3TC 120/60mg (dispersible tablet), + LPV/r 40/10mg pellets	24 bottles of ABC/3TC tabs, 30's + 24 bottles of LPV/r capsules, 120's	\$ 439.20
ABC/3TC/LPV/r 30/15/40/10mg granules	24 bottles of ABC/3TC/LPV/r capsules, 120's	\$ 360.00****
ABC/3TC 120/60mg (dispersible tablet), + DTG 5mg dispersible tablet	24 bottles of ABC/3TC tabs, 30's + 24 bottles of DTG 5mg tabs, 60's	\$ 852.96
ABC/3TC 120/60mg (dispersible tablet), + DTG 10mg dispersible tablet	24 bottles of ABC/3TC tabs, 30's + 8 bottles of DTG 10mg, 90's	\$ 119.20

\*Combination formulations as per WHO recommended preferred & alternative first line ART regimens<sup>12</sup>

\*\*Number of packs as per WHO Dosing of optimal ARVs (see Appendix A)

\*\*\*Price based on GHSC-PSM e-catalogue (see Appendix B)

\*\*\*\* Price based on Unitaid announcement on 29 November 2019 (see Appendix B)

## APPENDIX D: Core Data Needs for Quantifying Pediatric ARVs

Data Type	Data Requirements
General ART inputs	<ul style="list-style-type: none"> <li>• Number of pediatric patients on ART</li> <li>• New patients per each year of the quantification</li> <li>• Migration rates per year from one therapeutic line of treatment to another [First Line (1L) to Second Line (2L) to Third Line (3L)]</li> <li>• Attrition rates for each therapeutic line of treatment (for 1L, 2L, and 3L), which includes % lost to follow up due to death or voluntary discontinuation of treatment</li> <li>• National ART coverage rates</li> <li>• Nevirapine induction inclusion (Dual Induction means new ART initiates starting a NVP-based regimen will receive half the NVP dose for 14 days in order to minimize the side effects of the drug. This therefore requires quantification adjustments when a NVP-based regimen is available as a triple FDC)</li> <li>• Buffer stock requirements</li> </ul>
Protocols (Breakdown by Regimen)	<ul style="list-style-type: none"> <li>• All regimens currently in use and regimens to be used in the future</li> <li>• Number of baseline (“Year 0”) patients on each regimen</li> <li>• Percent of new patients that will be put on each regimen in future years</li> <li>• Number (or estimated number) of pediatric patients per weight band or by age</li> </ul>
ARV Substitutions (Proactive Switching of Protocols)	<ul style="list-style-type: none"> <li>• Relevant regimens as per the protocols</li> <li>• Month when proactive switching will start and stop</li> <li>• Percent of patients who will be switched over the course of the transition (as defined by the start and stop months above)</li> </ul>
Formulation/form breakdown by regimen	<ul style="list-style-type: none"> <li>• Percent of each regimen dispensed is accounted for by singles, duals, and triples</li> <li>• For example ABC+3TC+LPV/r is 100% dual plus a single for the forecast period</li> </ul>
Dosing	<ul style="list-style-type: none"> <li>• Pack size information</li> <li>• Weight band distribution by Active Pharmaceutical Ingredient (API) and formulation</li> <li>• Dose per day for weightband (refer to Appendix A)</li> </ul>
Monthly number of patients by regimen	<ul style="list-style-type: none"> <li>• Number of patients on each regimen (1L, 2L, and 3L) each month during the forecast period. (In the CHAI Simple Tool this number is automatically populated based on previous data inputs)</li> </ul>
Projected patient consumption by formulation (Theoretical demand)	<ul style="list-style-type: none"> <li>• Estimated monthly consumption of each formulation (In the CHAI Simple Tool this number is automatically calculated based on all previous formulations and data inputs entered by the users in the tool)</li> </ul>
Stock on Hand (SOH) and Order in Pipeline	<ul style="list-style-type: none"> <li>• Existing stock on hand (and expiration month)</li> <li>• Orders that have already been placed before the particular round of quantification</li> </ul>
Ordering	<ul style="list-style-type: none"> <li>• When the first orders should be delivered to ART sites (not to the country warehouses)</li> </ul>
Cost	<ul style="list-style-type: none"> <li>• Price per pack for each formulation of interest.</li> <li>• These can be actual prices paid or reference prices (refer to Appendix B).</li> </ul>
Partner Allocation	<ul style="list-style-type: none"> <li>• Each partner’s commitment for procuring various ARVs over the three-year forecast period</li> </ul>

Reference: CHAI Simple Tool for ARV Forecasting (2020) (<https://clintonhealth.app.box.com/s/sbar7zpk4mfi76rxc2hyfexcal2yu45r>)

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