Supporting Sustained Supply through the Coordinated Procurement of ARVs

ARV Procurement Working Group Newsletter

November 2018

Introduction

Through quarterly order cycles and business calls, the APWG has continued to support the ARV market in low- and middle-income countries (LMICs) via coordinated procurement, strategically managed demand, and reduced fragmentation. As a supplement to our routine work, the APWG publishes a biannual newsletter that provides an update on some of the key topics and issues facing the ARV market.

In mid-2018, the APWG launched a new website at https://www.arvprocurementworkinggroup.org/ in both French and English. The website will host all relevant APWG documents including the quarterly demand forecast, product recommendations and memos, newsletters, and other resources. Please check back often for updates.

The November 2018 edition of the APWG newsletter includes:

- Updated WHO treatment guidelines and optimal paediatric formulary
- Update on TLD rollout and supply
- Update on the supply of LPV/r (40 mg/10 mg) solid oral dosage formulations
- Recent conference summaries
- APWG webinars to the field
- Key partner publications

Updated WHO Treatment Guidelines and Optimal Paediatric Formulary

Updated Adult Treatment Guidelines

At AIDS 2018, the WHO released an update to the 2016 Consolidated Guidelines with new information regarding the use of DTG-containing regimens. **For most adults and adolescents, the preferred 1L regimen is now TDF+3TC+DTG**. See below for a summary of the recommendations:

Adult Population	Preferred 1L Regimen
Adult men and adolescent boys	TDF + 3TC + **DTG**
Pregnant (from eight weeks after conception) and breastfeeding women and adolescent girls	
Women and adolescent girls with effective contraception or not of childbearing potential	
Women and adolescent girls of childbearing potential who want to become pregnant and have no effective contraception	TDF + (3TC or FTC) + EFV600

Failing 1L Regimen	Preferred 2L Regimen	Alternate 2L
2 NRTIs + DTG	2 NRTIs + (ATV/r or LPV/r)	2 NRTIs + DRV/r
2 NRTIs + EFV (or NVP)	2 NRTIs + **DTG**	2 NRTIs + (ATV/r or LPV/r or DRV/r)

DTG is currently not recommended as preferred for women and adolescent girls of childbearing potential who want to become pregnant and are not able to access effective contraception. The main driver for this recommendation was the preliminary finding of low but elevated rates of neural tube defects among children born to women taking DTG-based regimens during the time of conception in the ongoing observational Tsepamo study

in Botswana[1]. Additional data from the Tsepamo study of pregnant women taking DTG during the time of conception is expected by the end of March 2019 to further inform the potential effects of DTG during conception. In planning for TLD rollout and when designing national ARV treatment programs, the WHO recommends a women-centered approach which ensures that the needs of women, their families, and communities are taken into consideration. The promotion of human rights and gender equality underpin this recommended women-centered approach.

Updated Paediatric Treatment Guidelines

Similar to the recommendations for adults, the WHO recommends DTG for all children living with HIV older than 4 weeks old (once the safety and efficacy of the appropriate dose has been established for children under 25kg). This focus on DTG is especially important for children given data on NNRTI resistance in paediatric populations. See below for a summary of the WHO guideline updates for paediatric patients:

- **DTG listed as preferred 1L** for all children at least 4 weeks old (when approved dosing/products available for small children), with RAL preferred for neonates, replacing previous focus on LPV/r and EFV for paediatrics. DTG also recommended as 2L therapy for children failing NNRTI- or PI-based 1L regimens
- **DTG (50 mg) tablets can be used down to 25 kg**, although US FDA and European Medicines Agency (EMA) labels still list 40 kg as the minimum weight for this dose
- **DTG to be introduced as soon as possible** to ensure children have access to the best medicine available
- **NNRTIs should only be used in special circumstances in children**, replacing previous guidance where EFV was preferred for patients aged 3-10

WHO-Preferred Paediatric 1L Treatments

Treatment Line	Neonates	Children
Preferred 1L	AZT + 3TC + RAL	ABC + 3TC + DTG
Alternative 1L	AZT + 3TC + NVP	ABC + 3TC + (LPV/r or RAL)
Special Circumstances	AZT + 3TC + LPV/r	ABC (or AZT) + 3TC + EFV (or RAL) AZT + 3TC + (LPV/r or RAL or NVP)

WHO-Preferred Paediatric Sequencing

Population	1L Regimens	2L Regimens	3L Regimens
Children	Two NRTIs + DTG or RAL	Two NRTIs + (ATV/r or LPV/r)	DRV/r + DTG ± 1-2 NRTIs (if possible, consider optimization using genotyping)
	Two NRTIs + LPV/r	Two NRTIs + DTG	
	Two NRTIs + NNRTI	Two NRTIs + DTG	

The WHO, along with national treatment programs, is hosting workshops in many sub-Saharan African countries over the coming months to support rapid uptake of these guideline updates.

In order for DTG to be used below 25 kg, the global community will need to determine the appropriate dosing for weight bands below 25 kg. Data to support the dosing for these weight bands, from the P1093 and ODYSSEY studies, is expected to become available in late 2019. In addition to the lack of dosing guidelines, no *generic* DTG formulation exists for patients below 25 kg. To that end, CHAI and Unitaid released an RfP in Q4 2017 to accelerate access to and affordability of generic paediatric DTG. Mylan and Macleods were selected as the awardees to receive a financial incentive from Unitaid and technical assistance from ViiV to accelerate development of a 10 mg dispersible and scored tablet of dolutegravir for paediatric use.

The table below depicts the potential future sequencing of paediatric ART, and is based on the WHO's updated guidelines and optimal paediatric formulary. The "Short-Term Future" column reflects treatment under the

[1] Zash R et al. Surveillance for neural tube defects following antiretroviral exposure from conception, the Tsepamo study (Botswana). AIDS 2018. 23–27 July 2018. Symposia session TUSY15. http://programme.aids2018.org/Programme/Session/1589

updated WHO treatment guidelines with currently available formulations. The "Medium-Term Future" column reflects treatment under the new WHO guidelines and with the development of generic paediatric DTG formulations.

<table>
<tr><th colspan="4">Theoretical Future Sequencing of Paediatric ART</th></tr>
<tr><th>Weight (kg)</th><th>2016 WHO Recommendations</th><th>Short-Term Future</th><th>Medium-Term Future</th></tr>
<tr><td>0 – 2.9
(neonates)</td><td>AZT OS + 3TC OS +
NVP OS</td><td>AZT OS + 3TC OS +
RAL granules</td><td>AZT OS + 3TC OS +
RAL granules</td></tr>
<tr><td>3.0 – 5.9</td><td>ABC (or AZT)/3TC
(disp & scored) +
LPV/r OS</td><td>ABC/3TC (120 mg/60 mg)
(disp & scored)
+ LPV/r OS</td><td rowspan="3">ABC/3TC (120 mg/60mg)
(disp & scored) +
DTG (10 mg) tab
(disp & scored)
Dose for fixed dose combination product will be released by WHO in Q1.</td></tr>
<tr><td>6.0 – 9.9</td><td>ABC (or AZT)/3TC
(disp & scored) +
LPV/r pellets/granules</td><td>ABC/3TC (120 mg/60 mg)
(disp & scored) +
LPV/r pellets/granules
(ABC/3TC/LPV/r (30 mg/15 mg/40 mg/10 mg) "4-in-1" FDC expected)</td></tr>
<tr><td>10.0 – 13.9
14.0 – 19.9
20.0 – 24.9</td><td>ABC/3TC (disp & scored) +
EFV scored tab</td><td>ABC/3TC (120 mg/60 mg)
(disp & scored)
+ LPV/r tab
(or DTG depending on dosing recommendations)</td></tr>
<tr><td>25.0 – 29.9</td><td rowspan="2">ABC/3TC (adult) + EFV</td><td>ABC/3TC (adult) + DTG (50 mg)</td><td>ABC/3TC (adult) + DTG (50 mg)</td></tr>
<tr><td>30.0 – 34.9</td><td>TDF/3TC (adult) + DTG (50 mg)</td><td>TDF/3TC (adult) + DTG (50 mg)</td></tr>
</table>

In addition to the above updates on treatment guidelines, the WHO also released a new Optimal Formulary and Limited-Use List for Paediatric ARVs (replacing the 2016 IATT Paediatric ARV Formulary and Limited-Use List). While the complete updated list can be found in the Appendix of this newsletter, a few notable changes are worth highlighting:

- **LPV/r (80 mg/20 mg/ml) oral solution and EFV (200 mg) scored tablets demoted from "optimal" to "limited-use" list** due to a focus on paediatric DTG, high levels of paediatric NNRTI resistance, and a move toward LPV/r solid oral dosage forms such as granules or pellets
- **ABC/3TC (60 mg/30 mg) dispersible tablets demoted from "optimal" to "non-essential"** to consolidate the market around ABC/3TC (120 mg/60 mg) dispersible tablets while reducing pill burden
- **RAL (100 mg) granules have been added to the limited-use list**, as RAL is now the preferred first-line treatment for neonates. However, this product (along with RTV (25 mg) tablets) has yet to be widely commercialized. The AWPG is working to make both of these products readily available from manufacturers and requests that HIV program managers planning on adopting and using these products please reach out to Wesley Kreft or Christine Malati. Based on the latest market intelligence, the APWG recommends that country programs plan for 8-9 months lead time from order to delivery for MSD's RAL (25 mg) tablets, RAL (100 mg) tablets, and RAL (100 mg) granules
    - Additionally, EGPAF in coordination with the US Government and CHAI are working on a pilot study in Eswatini to address concerns related to the introduction of RAL (100 mg) granules. Data collected during this study will be used to develop tools for other countries interested in introducing this product

Update on the Rollout and Supply of TLD

As mentioned above, the early safety signal data from Botswana has caused some countries to be more conservative with their rollout of TLD. However, despite the Botswana data, nearly 30 million packs of TLD are anticipated to be delivered in LMICs between Q4 2018 and Q2 2019 based on APWG forecasts.

Importantly, the Republic of South Africa has included TLD in their latest ARV tender. The tender is calling for between 147–175 million packs to be provided over the three-year validity period.

See below for the current approval status of generic TLD as of time of publication. Several of those with Global Fund ERP[2] approval are expected to obtain WHO PQ or US FDA tentative approval soon. The APWG does not anticipate that there will be TLD supply security issues at this time given the large number of approved suppliers.

US FDA Tentative Approval	Global Fund ERP Recommendation
Aurobindo	Cipla
Hetero	Laurus Labs
Mylan	Macleods
	Sun Pharmaceuticals

Update on the Supply of LPV/r (40 mg/10 mg) Solid Oral Dosage Forms

In the last newsletter, we discussed Cipla's process variation filed with the US FDA to scale up production of their LPV/r (40 mg/10 mg) oral pellets. Since then, Cipla's process variation was approved, and Cipla expects to have an increased capacity of ~45K bottles of 120 capsules per month by Q1 2019. Additionally, since the last newsletter, Mylan received tentative US FDA approval of their LPV/r (40 mg/10 mg) oral granules in August of this year. Mylan's manufacturing capacity will be about 25K boxes of 120 sachets per month. Differences between granules and pellets are relevant; granules will be supplied in sachets, whereas pellets are supplied in capsules. It is also important to note the differences between administration of granules and pellets. The APWG recommends that programs recognize the differences in implementation and consider adopting only one product (whether granules or pellets) in order to avoid confusion at facilities, and ensure there is relevant planning and discussions with procurement agents. The USAID LPV/r pellet toolkit provides many useful resources about the product and information for product introduction. Mylan is also developing educational materials for the oral granules.

Bottle of LPV/r oral pellets

Sachet of LPV/r oral granules

Despite these increases in capacity for LPV/r (40 mg/10 mg) solid oral dosage forms, supply constraints remain, and further capacity increases will likely be required to support the full global market need for these formulations (children less than 10 kg or unable to swallow tablets). As such, the APWG's guidance on paediatric LPV/r products from last year remains valid today and the group continues to recommend programs hold off on any large scale-up or transition plans until there is greater security in the supply. Lead times are still expected to be long; thus, the

[2] The Global Fund Expert Review Panel (ERP) is a group of independent experts who review the potential risks and benefits associated with the use of finished pharmaceutical or diagnostic products and make recommendations to the Global Fund on their use. See the Global Fund website for more information on the GF ERP.

APWG recommends that programs place orders with as much advance notice as possible and build in buffer time for expected deliveries.

Eventually, the above LPV/r (40 mg/10 mg) pellets or granules may no longer be needed once a '4-in-1' FDC of ABC/3TC/LPV/r is commercialized. The APWG is aware that Cipla and Mylan are developing 4-in-1 formulations, in the form of granules, with plans to file with the US FDA in 2019. The role the 4-in-1 will play in the market depends on the timing of market entry of paediatric DTG, first as a single and eventually as an FDC, as DTG is preferred per the updated WHO guidelines.

Recent Conference Summaries

AIDS 2018

The 22nd annual International AIDS Conference was held in Amsterdam this year from July 23–27. As usual, the conference was a packed week where Ministries of Health, global partners, advocates, and others met to discuss key updates in the global AIDS response. Major LMIC-relevant updates from the conference include:

- **Treatment Updates**
  - As discussed above, the WHO released new treatment guidelines for adults and paediatric patients, as well as an updated optimal paediatric formulary and policy with recommendations on the process to transition to the optimal paediatric formulary

- **Prevention Updates**
  - Interim results from PREVENIR reported no new infections in men who used oral PrEP either daily or on-demand. Abstract
  - PrEP uptake was significantly associated with declines in HIV diagnoses in the USA. Abstract
  - Results from the PARTNER 2 study showed that the chance of any HIV-positive person with an undetectable viral load transmitting the virus to a sexual partner is scientifically equivalent to zero. Abstract
  - Epidemic control among adolescents and youth in sub-Saharan Africa unlikely to be met given new infection rates and anticipated youth population growth. Abstract

PEPFAR, the Global Fund, and the Republic of South Africa presented on forecasted ARV procurement, partner coordination, and the TLD transition to provide insight into procurement and transition plans from the three largest buyers of ARVs.

HIV Research for Prevention (HIVR4P) 2018

The HVIR4P Conference, "From Research to Impact", was held October 21–25 in Madrid. There were over 1,000 presentations that discussed an array of research and prevention topics spanning from emerging biological approaches to prevention to implementation of existing technologies.

- **Oral PrEP:** Uptake continues to increase and is demonstrating impact, but significant challenges remain in terms of fostering equitable access and supporting continued use amongst clients.
  - OA04 - Entry Into the PrEP Continuum. Link
  - OA19 - Stay With Me: Retention on PrEP. Link

- **Emerging Prevention Products:** Sessions and advocacy at the conference included strong themes of user choice and the need for more and better female-controlled prevention options, including options that can protect women without their partner's knowledge.
    - SA05 - Planning for Success: Next Steps for Dapivirine Ring. Link
    - OA05 - If I Choose, Will I Use? Products, People and Preferences. Link
    - SA12 - Voices in the Long-acting PrEP Movement: Fostering Dialog Between End-users and Product Developers During the Product Development Process. Link

HIV Glasgow 2018

The biennial HIV Glasgow conference was held in Glasgow from October 28–31. A summary of key presentations can be found below, and abstracts can be found here.

- O342: Although 48-week data from NAMSAL reported that DTG and low-dose EFV have been found to be equally effective in treatment, there were no baseline or treatment-emergent resistance mutations in patients treated with DTG compared to 9 in patients treated with low-dose EFV
- O211: 96-week data showed bictegravir to be just as effective at suppressing viral loads as DTG, and had fewer adverse reactions. However, the inability to use bictegravir in patients co-infected with TB potentially limits the utility of this ARV in LMICs
- O345: 48-week data showed that 15 of 40 extremely treatment-resistant patients on ibalizumab had suppressed viral loads

APWG Webinars on Optimal ARVs

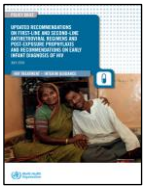
In early October, the APWG hosted a webinar for francophone countries on optimal paediatric ARV formulations. The webinar covered the 2018 WHO recommendations as well as the 2018 Optimal Formulary and Limited-Use List for Paediatric ARVs. Supply chain challenges and mitigation strategies were also discussed. A recording of the webinar can be found here, along with the slides. The slides from the earlier English-language APWG webinar on optimal ARVs can also be found on the APWG website.

The AWPG will host the above francophone webinar again for those unable to attend the first session, along with an additional webinar given in Spanish for countries in Latin and South America. The APWG will announce the timing of these webinars when they have been officially scheduled.

Partner Publications and APWG Resources

The APWG wanted to highlight some key publications and resources that provide useful programmatic guidance:

Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV



Ahead of AIDS 2018, the WHO released updated guidelines on ART, PEP, and EID. Highlights include the preferred status of DTG for all PLHIV older than 4 weeks old (with special considerations for women of childbearing potential), including in second-line, and a streamlined EID cascade.

The 2018 optimal formulary and limited-use list for paediatric ARVs

The WHO has revised the 2016 IATT Paediatric ARV Formulary and Limited-Use List to support the transition to optimal WHO-recommended regimens for paediatric patients. A summary of

the new updates can be found in the Appendix of this newsletter and in the above *New WHO Treatment Guidelines and Optimal Paediatric Formulary* section.

Transitioning to an optimal paediatric ARV formulary - implementation considerations

ARV treatment optimization is a key pillar in the AIDS Free agenda to reach the goal of ensuring 95% of all infants and children have access to lifesaving treatment. This policy brief outlines key considerations to facilitate the effective transition to more clinically appropriate regimens as optimal ARV medicines and dosage forms become available.

CHAI 2018 HIV market report

A clear understanding of the complex, ever-changing ARV and diagnostic markets in low- and middle-income countries is critical for all stakeholders in the HIV space. To address this need, CHAI publishes an annual HIV market report based on aggregated market intelligence from their programmatic work in over 30 countries.

Global Fund Pooled Procurement Mechanism (PPM) reference price lists

The Global Fund Pooled Procurement Mechanism (PPM) is a Global Fund strategic initiative that aggregates order volumes on behalf of participating grant recipients to negotiate prices and delivery conditions with manufacturers. The PPM produces reference price documents for global health commodities, including ARVs and other strategic medicines used in HIV programs, for use when procuring health products

Appendix

Quarterly Order Cycle Coordination

The APWG Procurement Consortium consolidates the orders of ARVs around fixed quarterly order cycle dates. These dates have been agreed upon by the AWPG and shared with suppliers and other stakeholders.

The aggregation of orders for at-risk ARVs (i.e., paediatric and low-volume adult products as well as those ARVs in transition) around this schedule allows manufacturers to plan production accordingly. Furthermore, consolidated product orders are more likely to meet the required minimum batch size and thus potentially avoid extended lead times associated with sub-batch orders.

Countries procuring ARVs independently or through non-APWG procurement agents are encouraged to use the quarterly order dates below to ensure a reliable supply of ARVs.

Deadline For Orders To Be Placed With Suppliers*	
Q4 2018	**28 December 2018**
Q1 2019	**29 March 2019**
Q2 2019	**28 June 2019**
Q3 2019	**27 September 2019**
Q4 2019	**27 December 2019**
*Orders should be submitted to procurement agents at least 6 weeks before these dates	

Scheduled ordering four times a year is especially recommended for low-volume paediatric and adult ARVs, a list of these prioritised products for coordinated procurement is provided below:

Prioritised Paediatric ARVs (2018 Optimal Formulary)	
Optimal	ABC/3TC (120 mg/60 mg) dispersible
	AZT (50/5 mg/ml) solution *(100ml)*
	LPV/r (40 mg /10 mg) solid oral dosage forms
	NVP (50 mg) dispersible
Limited-Use	3TC (50/5 mg/ml) solution (*100ml*)
	ABC (60 mg) dispersible
	ATV (200 mg) capsule
	LPV/r (80/20 mg/ml) Oral Solution
	RTV (25 mg)
Newly Non-Essential	ATV (100 mg) capsule
	AZT (60 mg) dispersible
Non-Essential	ATV (150 mg) capsule
	AZT (50/5 mg/ml) solution *(240 ml)*

Prioritised Adult ARVS
ABC (300 mg)
ATV (300 mg)
AZT (300 mg)
DRV (400 mg)
DTG (50 mg) and FDCs
EFV (400 mg) FDCs
RAL (400 mg)
RTV (100 mg)
TDF (300 mg)
3TC (150 mg)

New Product Availability

The following optimal and limited-use paediatric products as well as prioritised adult formulations have been either tentatively approved by the US FDA, received WHO Prequalification (PQ), or have been reviewed and approved by the Global Fund Expert Review Panel (GF ERP) since the publication of the last APWG Newsletter.

Latest ARV Approvals (Since April Newsletter)			
Product	**Patient Type**	**Supplier**	**Approval Body**
DTG (50 mg) Tablet	Adult	Sun Pharmaceuticals	GF ERP
DTG (50 mg) Tablet	Adult	Mylan	US FDA
DTG (50 mg) Tablet	Adult	Mylan	WHO PQ
DTG (50 mg) Tablet	Adult	Hetero	WHO PQ
LPV/r (100 mg/25 mg) Tablet	Paeds	Hetero	WHO PQ
LPV/r (40 mg/10 mg) Granules	Paeds	Mylan	US FDA
LPV/r (40 mg/10 mg) Granules	Paeds	Mylan	GF ERP
TDF/3TC/DTG (300 mg/300 mg/50 mg) Tablet	Adult	Cipla	GF ERP
TDF/3TC/DTG (300 mg/300 mg/50 mg) Tablet	Adult	Hetero	US FDA
TDF/3TC/DTG (300 mg/300 mg/50 mg) Tablet	Adult	Laurus Lab	GF ERP
TDF/3TC/DTG (300 mg/300 mg/50 mg) Tablet	Adult	Macleods	GF ERP
TDF/3TC/DTG (300 mg/300 mg/50 mg) Tablet	Adult	Sun Pharmaceuticals	GF ERP
TDF/3TC/EFV (300 mg/300 mg/400 mg) Tablet	Adult	Macleods	GF ERP
TDF/3TC/EFV (300 mg/300 mg/400 mg) Tablet	Adult	Mylan	WHO PQ

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- Vineet Prabhu, Clinton Health Access Initiative

The 2018 Optimal Formulary and Limited-Use List for Paediatric ARVs

2018 Optimal Formulary			
Drug	**Formulation**	**Dose**	**Rationale for Use**
AZT	Oral Solution – 100 mL	50 mg/5 mg/mL	For postnatal prophylaxis or neonatal treatment
NVP	Tablet (Dispersible, Scored)	50 mg	For postnatal prophylaxis
NVP	Oral Solution – 100 mL	50 mg/5 mg/mL	For postnatal prophylaxis or neonatal treatment
LPV/r	Tablet (Heat Stable)	100 mg/25 mg	For alternative first-line or second-line for children 10 kg and above and able to swallow tablets whole
LPV/r	Solid Oral Dosage Form	40 mg/10 mg	For alternative first-line or second-line for infants and children below 10 kg or unable to swallow 100 mg/25 mg tablets whole.
AZT/3TC	Tablet (Dispersible, Scored)	60 mg/30 mg	For first-line in special circumstances or second-line in infants and children 4-25 kg
ABC/3TC	Tablet (Dispersible, Scored)	120 mg/60 mg	For preferred first-line or second-line in infants and children 4-25 kg
RAL	Tablet (Chewable, Scored)	25 mg	To provide alternative first-line and second-line for infants and children between 3-25 kg

2018 Limited-Use List			
Drug	**Formulation**	**Dose**	**Rationale For Use**

LPV/r	Oral Solution	80 mg/20 mg /mL	For alternative first-line or second-line for infants and children below 10 kg or unable to swallow 100 mg/25 mg tablets whole, until a suitable oral solid dosage form becomes widely available
3TC	Oral Solution – 100 mL	50 mg/5 mg/mL	For neonatal treatment only
ABC	Tablet (Dispersible, Scored)	60 mg	For provision of a triple nucleoside regimen in combination with AZT/3TC dual FDC for the duration of TB treatment
DRV	Tablet	75 mg	For third-line regimens in children 3 years and above
RTV	Tablet	25 mg	For superboosting of LPV/r during TB treatment and boosting un-coformulated protease-inhibitors
RTV	Powder	100 mg	For superboosting of LPV/r during TB cotreatment and boosting non-coformulated protease-inhibitors
ATV	Capsule	200 mg	For alternative second-line in combination with RTV 100mg
AZT/3TC/NVP	Tablet (Dispersible, Scored)	60 mg/30 mg/50 mg	For first-line in special circumstances in children below three years until suitable bPI or INSTI dosage forms become widely available
EFV	Tablet (Scored)	200 mg	For first-line in special circumstances in children above three years until suitable bPI or INSTI dosage forms become widely available
RAL	Granules for suspension	100 mg	For neonatal treatment only

For more details on the 2018 revised WHO Optimal Formulary and Limited-Use List for Paediatric ARVs, please contact Martina Penazatto (penazzatom@who.int), Nandita Sugandhi (nss14@cumc.columbia.edu), Wesley Kreft (wkreft@nl.pfscm.org), Mireille Muhimpundu (Mireille.Muhimpundu@theglobalfund.org), or Christine Malati (cmalati@usaid.gov).