PROCUREMENT CONSIDERATIONS

Task

Ensure that the product is registered for importation and understand suppliers' requirements so that programs can plan the timing of shipments of LPV/r pellets.

Overview

Once the rollout of LPV/r has been planned, HIV/AIDS program supply chain personnel and/or their technical assistance providers can take initial steps to facilitate the shipment of supplies.

Procurements should adhere to all relevant drug procurement policies and national guidance, and to the policies of any external funding agency involved. These policies may indicate the specific procurement approval processes and timelines required.

As per the guidance of national drug regulatory authorities, products intended for patient use must be registered to allow their importation. Through the manufacturer is responsible for providing the documentation required by the regulatory authorities, logistics coordinators can facilitate the process by communicating these requirements to the manufacturer and inquiring about the status of the registration while the process is underway. Ensuring that dossiers are reviewed and registration is completed before the arrival of the first shipment will prevent costly delays. However, in some cases a waiver can be secured for an initial shipment, especially if the shipped products are for a pilot study.

Logistics coordinators also should communicate with the manufacturer or a relevant working group to understand current manufacturing lead times and share data used for global planning purposes.

LPV/r Pellet Considerations

- As of June 2015, the LPV/r oral pellet formulation is approved by the U.S. Food and Drug Administration (FDA).
- As of early 2018, there are concerns that global demand will continue to exceed production capacity for the near future, which has led to manufacturer lead times of up to one year. Efforts to increase production capacity are underway: if these are successful, they should reduce lead times.
- An application to secure approval to increase production capacity for LPV/r pellets was submitted by the manufacturer (Cipla) to the FDA in May 2017. As of early 2018 this approval is still pending.

- Contact the Antiretroviral (ARV) Procurement Working Group (APWG) (see the contact information listed below) for up-to-date lead times and specific questions about procurement for LPV/r pellets as well as other ARV formulations.
- Given global supply limitations, countries are encouraged to forecast requirements carefully – by identifying the specific age groups and weight bands expected to be prescribed pellets – and conduct pipeline monitoring (see the Quantification page) to delay or cancel shipments if uptake is slower than originally expected.
- Country programs are encouraged to share 12-18 month procurement plans with the APWG once quantification is completed. These procurement plans do not have a specified format, but should list quantities desired and requested delivery dates.
- Country programs are encouraged to consider managing several smaller orders per year, rather than one large order for the rollout of LPV/r pellets. Completing several smaller orders will give a country more flexibility to adjust future order quantities and ensure that the right quantity of LPV/r pellets is ordered and delivered to guard against stockouts and overstock. This approach will also allow flexibility if it is necessary to change targets or adjust the number of patients being transitioned to LPV/r pellets.

Pediatric ARVs Expected to Launch by 2020

The following timelines are tentative and can change for a number of reasons.

- LPV/r (40/10 mg) Granules: Anticipated manufacturer is Mylan.
- Use: Another heat-stable, solid formulation alternative to cold chain-dependent LPV/r oral solution.
- Expected first generic SRA approval: Second half of 2018.

ABC/3TC/LPV/r (30/15/40/10 mg) FDC ("4-in-1"). The 4-in-1 also may have the option to be AZT-3TC-LPV/r.

- Use: Provides the World Health Organization (WHO)-preferred regimen for patients under 3 years old in one formulation (granules).
- Expected first generic SRA approval: Second half of 2019.

ABC/3TC/EFV (150/75/150 mg) FDC.

- Use: Provides the WHO-preferred regimen for patients between 3 and 10 years old in one dispersible pill.
- Expected first generic SRA approval: Second half of 2019.

ARV Procurement Working Group Contacts

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Additional Resources

ARV Market Report: The state of the antiretroviral drug market in low- and middle-income countries, 2016-2021 [PDF, 2.1MB]: September 2017 issue of a Clinton Health Access Initiative (CHAI) report that provides a global perspective on the antiretroviral marketplace in low- and middle-income countries in 2016, and outlines CHAI's expectations on how the market will evolve over the next five years.