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. Though 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 2020, the manufacturers of both pellets and granules have increased production capacity to reduce supply constraints experienced earlier in these products' introduction.

- 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.

LPV/R Pellet Timeline

- May 2015: Cipla received FDA approval for pellets after many years of development.
- Mid-2016: After manufacturing pellets only for clinical trial uses, Cipla began to commercialize the product.
- Early 2017: Following low-volume orders for pellets during the first few months of commercial availability, demand began to exceed production capacity.
- 2018-2020: Production capacity increases for LPV/r pellets and introduction of LPV/r granules from Mylan have allowed more countries to introduce these products into their regimens. As of 2019 over 30 countries have ordered and imported one of these formulations.
- Active monitoring will continue through the APWG until there is sufficient stability in the market.

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.

ARV Working Group Site: The ARV Working Group maintains a site which includes up-to-date global procurement guidance for LPV/r pellets, granules, and DTG.