**New Horizons Collaborative: Advancing Pediatric HIV Care**

***Donation Program Frequently Asked Questions***

**How long will the program last?**

The Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) will donate its approved HIV medicines, PREZISTA® (darunavir, DRV, TMC114) and/or INTELENCE® (etravirine, ETR, TMC125), (including child-friendly formulations) on behalf of each eligible child/adolescent/young person to national HIV treatment programs in the recipient countries. Eligible countries may be enrolled until December 2020. Donated PREZISTA® and/or INTELENCE® will be made available, as needed until each recipient young person turns 25 years of age, at which point the recipient country is responsible for transitioning patients into the adult national HIV programs for continued treatment. The Donation Program may run as long as 31st December 2045. It is the responsibility of participating national HIV and AIDS programs to ensure access to the other HIV medicines comprising a pediatric or adolescent patient’s complete HIV treatment regimen (including ritonavir).

**Do children who receive donated medicines have access through adulthood?**

Each child/adolescent enrolled will receive donated PREZISTA® and/or INTELENCE®, as needed until they turn 19 years of age. At this point, access to these medicines will be required to transition from donation to sustainable procurement (under the adult national HIV and AIDS program).

**Which countries are invited to submit expressions of interest to the donation program?**

Any country in sub-Saharan Africa is permitted to submit an expression of interest (EOI) application. In addition, nations considered to be a Least Developed Country (LDC) as defined by the United Nations are also invited to apply. For a list of LDCs, click [here](https://www.un.org/development/desa/dpad/least-developed-country-category/ldcs-at-a-glance.html).

The donation program is one activity under a broad collaborative effort to strengthen national level capacity, knowledge, and action for HIV treatment-experienced children and adolescents. Additional opportunities for capacity building and health systems strengthening for countries, in and beyond the donation program will be made available in 2019.

**What happens after a country’s expression of interest is reviewed?**

Following each EOI submission, based on the materials provided for review, the independent review committee, will conduct two assessments to: **a)** determine a country’s readiness to manage donated product (DRV and/or ETR) and, **b)** assess a country’s capacity building and technical assistance needs regarding management of treatment failure and advanced antiretroviral therapy (ART) for children and adolescents.

Notification of the review committee’s determination will be provided to each country within 4-6 weeks times following submission.

All countries, including those determined not yet ready to manage donated product (i.e., DRV and/or ETR) by the independent review committee, will be provided with a capacity building assessment and recommendations. This review will also include areas for potential engagement with the New Horizons Collaborative for training, mentorship, and other resources.

**Can individual clinicians or organizations based in sub-Saharan Africa and/or in a LDC submit materials for review to the donation program?**

Materials will only be accepted from Ministries of Health, or their designee, and not from individuals or organizations. If you are interested in the program, you are encouraged to review the submission materials and contact the Ministry of Health in your country.

**Is there a plan to make other pediatric HIV medicines available for free through this mechanism?**

Not at this time. However, we will use the information gleaned from this program to help inform decisions about potential additional donation programs in the future.

**How will donated medicines reach the intended beneficiaries?**

Janssen and the recipient country programs are ultimately responsible for the success of the donation program. Janssen is collaborating with the Partnership for Supply Chain Management (PFSCM) and Imperial Health Sciences to assist with the logistics of the donation, including receipt, warehousing, and distribution of the donated HIV medicines to appropriate countries.

**Should a country apply if it has very limited number of pediatric and youth patients needing third-line treatment?**

Countries that have limited, but immediate, need for third-line treatment (i.e., < five pediatric and youth patients) or those countries that do not current meet the eligibility criteria but have immediate need, may contact Dr. Perry Mohammed, Medical Director, Janssen at PMohamme@its.jnj.com to explore other means of accessing PREZISTA® and INTELENCE®.

**What is the regulatory status of PREZISTA® and/or INTELENCE® in each country?**

There are several formulations of PREZISTA® and INTELENCE® donated, and the registration process is at various stages for each. For specific country information on filing and approval status, country representatives may contact Usheema Maraj De Villiers at umarajde@ITS.JNJ.com

***Additional questions can be e-mailed to:*** ***newhorizons@pedaids.org***