**Donation Program Frequently Asked Questions**

**How long will the program last?**
Following country selection, Janssen will donate its approved HIV medicines, PREZISTA™ (darunavir) and/or INTELENCE™ (etravirine), including child-friendly formulations, will be made on behalf of each eligible child/adolescent to national HIV treatment programs in the recipient countries. Eligible children and adolescents can be enrolled in the Donation Program until 31, December 2020. Each child enrolled will receive donated PREZISTA™ (darunavir) and/or INTELENCE™ (etravirine) as needed until they turn 19 years of age, at which point they will be transitioned into adult national HIV programs for continued treatment. The Donation Program may run as long as 31, December 2039, depending on the age and time of the last patient enrolled. It is the responsibility of participating national HIV/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 drugs have access through adulthood?**
Each child/adolescent enrolled will receive donated PREZISTA™ (darunavir) and/or INTELENCE™ (etravirine), 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 program).

**Which countries are invited to submit expressions of interest to the Donation Program?**
Any country in sub-Saharan Africa is permitted to submit expressions of interest. 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.

The Donation Program is one activity under a broader collaborative initiative to strengthen country-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 2015 and on.

For questions or clarification regarding the Donation Program or this eligibility criteria, please e-mail newhorizons@pedaids.org.

**What happens if a country does not meet all of the eligibility criteria?**
Countries that do not currently meet the eligibility criteria are still encouraged to submit an Expression of Interest, especially if they are in the process of adopting measures that would mean they would expect to meet the criteria within 2016. The Review Committee will review all submissions, and where applicable, will connect countries with technical assistance to help support or guide programs to meet the eligibility criteria for future application in the 2017 program year.
Can individual clinicians or organization based in sub-Saharan Africa and/or a Least Developed Country apply for the Donation Program?
Applications will only be accepted from Ministries of Health, or their designee, rather than individuals or organizations. If you are interested in the program, you are encouraged to review the program eligibility criteria and contact the Ministry of Health in your country.

Is there a plan to make other pediatric HIV drugs 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 drug reach the intended beneficiaries?
Janssen and the recipient country programs are ultimately responsible for the success of the Donation Program. Janssen has engaged 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 drugs to appropriate countries. Due to the complexities of treating children experiencing HIV treatment failure, we anticipate that most of the donated medicines will be used at a small number of Centers of Excellence or tertiary centers in the program countries.

Should a country apply if it has very limited number of pediatric patients needing third-line treatment?
Countries that have limited, but immediate, need for third-line treatment (i.e., < 5 pediatric patients) or those countries that do not current meet the eligibility criteria but have immediate need, may contact Dr. Peter Barnes, Medical Director, Janssen at PBarnes1@its.jnj.com to explore other means of accessing PREZISTA™ and INTELENCE™.

What is the registration status of PREZISTA™ (darunavir) and/or INTELENCE™ (etravirine) in each country?
There are several formulations of PREZISTA™ and INTELENCE™ that will be donated, and the registration process is at various stages for each. For specific country information on filing and approval status, country representatives may contact Kanusha van Tonder, Technical Affairs Manager, Janssen at kmurathl@ITS.JNJ.com.

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