New Horizons Advancing Pediatric HIV Care Donation Program
Frequently Asked Questions

How long will the program last?
Following country selection, donation of Janssen’s 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 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 (e.g., 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 which point they will be transitioned into adult national HIV programs for continued treatment.

My country is outside of sub-Saharan Africa, can it participate in the Donation Program?
The initial start-up phase of the Donation Program was focused on sub-Saharan Africa. Beginning in 2015 however, in addition to countries in sub-Saharan Africa, nations considered to be a Least Developed Country (LDC) as defined by the United Nations may also 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 doesn’t meet all of the eligibility criteria?
Countries that do not currently meet the eligibility criteria are still encouraged to submit an Expression of Interest. The Review Committee will review all submissions, and where applicable, will connect countries with technical assistance to support or guide programs to meet the eligibility criteria for future application rounds. Those countries which are unable to meet the eligibility criteria by the April, 2015 deadline will be encouraged to resubmit their materials for consideration in the 2016 program year.
Who are the members of the Review Committee?
The independent, third-party review committee will be convened by EGPAF and comprised of international experts in pediatric HIV. The committee will review all applications to determine countries’ eligibility to participate in the Donation Program. The committee members’ names will be made public by the submission deadline in April, 2015.

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.

How is the Donation Program different from Janssen’s compassionate use program for PREZISTA® (darunavir) and/or INTELENCE® (etravirine)?
Pediatric formulations of Janssen HIV medicines, PREZISTA® and/or INTELENCE® have received first regulatory approvals for treatment experienced pediatric patients in some sub-Saharan African countries; filings are underway across the region. For countries where pediatric formulations of Janssen’s HIV medicines have not been approved, country representatives may contact Dr. Peter Barnes, Medical Director, Janssen at PBarnes1@its.jnj.com to explore other means of accessing these medicines.

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 you ensure that donated drug reaches the intended beneficiaries?
Janssen is ultimately responsible for the success of the Donation Program, and has engaged several strategic partners to support the management of the program logistics. MAP International will manage the donation of pediatric HIV medicines to eligible countries, providing a single conduit between Janssen (and other potential industry partners) and country treatment programs. Janssen has engaged the Partnership for Supply Chain Management (PFSCM) to assist with the logistics of the donation, including receipt, warehousing, and distribution of drugs. 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.

For more information on supply chain processes, please reference New Horizons Donation Program Logistic Procedures, Roles and Responsibilities.

For application details, please visit: http://www.pedaids.org/newhorizons

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