Frequently Asked Questions

How long will the program last?

Following country selection, donation of Janssen’s approved HIV medicines (PREZISTA® and INTELENCE®), including child-friendly formulations, will be made on behalf of each eligible child to national treatment programs and/or national Centers of Excellence in the recipient countries.

The donation program will launch officially in the first half of 2014. Eligible children and adolescents can be enrolled in the donation program until 31 December 2020. Each child enrolled will receive donated PREZISTA® and/or INTELENCE® as needed until they turn 19 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 treatment programs to ensure access to the other HIV medicines comprising a child’s full HIV treatment regimen (e.g., ritonavir).

Do children who receive donated drugs have access through adulthood?

Each child enrolled will receive our donated HIV medicines as needed until they turn 19 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 phase of the program is focused on sub-Saharan Africa, where 91% of the world’s HIV-positive children live. The donation is intended to be part of a broader collaborative effort to strengthen country-level capacity, knowledge, and action for HIV treatment-experienced children in SSA. As part of this initiative, we hope to build awareness, country capacity, knowledge, and solutions around children experiencing HIV treatment failure in sub-Saharan Africa.

However, we expect to build on this knowledge to expand to additional countries at some point in the future. Those resource-limited countries outside the African region who meet the eligibility criteria and are interested in participating in the donation program should e-mail treatmentdonation@pedaids.org for further discussion and information.
What happens if a country doesn’t meet all of the eligibility criteria or has their application rejected by the Review Committee?

Countries that do not currently meet the program criteria are still encouraged to submit an Expression of Interest. The Review Committee will review all applications, and where applicable will connect countries with technical assistance to help ramp up the programs necessary to meet the eligibility criteria. A second phase of the program is anticipated for countries that will not meet the eligibility criteria by the February 21, 2014 application deadline.

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 country eligibility to receive the donation. The committee members will be made public when the open season begins on January 15, 2014.

I am a treating clinician / organization based in SSA, can I/we apply for the donation program?

At this time, applications will be accepted from Ministries of Health, rather than individuals or organizations. If you are interested in the program, we would encourage you to review the program eligibility criteria and contact the Ministry of Health in your country.

How is this different from Janssen’s compassionate use program for PREZISTA and/or INTELENCE?

Pediatric formulations of Janssen HIV medicines, PREZISTA® and 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 Medical Affairs at Janssen to explore other means of accessing these medicines.

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

No, 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 help manage the logistics of the program. 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 in the program countries. Janssen is in the process of determining appropriate mechanisms and partners for key elements of the donation program, including how best to monitor and ensure the drugs donated reach the relevant children in need.

**Additional questions can be e-mailed to:**

treatmentdonation@pedaids.org