Background

With the release of the 2014 UNAIDS 90-90-90 treatment target, programs are expected to scale-up efforts to significantly increase the number of HIV-infected children and adolescents identified and initiated on antiretroviral therapy (ART). Diagnosing HIV infection and initiating treatment are critical steps toward addressing gaps in ART coverage between adults and pediatric patients, and are highly prioritized in the fight to eradicate HIV. Greater awareness and increased programmatic focus will also be necessary to reach the third “90” of the 2014 UNAIDS target – 90% of all people receiving ART will have viral suppression by 2020. The issues of adherence, retention in care, and advanced (second- and third-line) treatment for children and adolescents living with HIV must be prioritized in order to achieve and maintain viral suppression as well as prevent drug resistance.

Today, a growing number of children and adolescents are experiencing first- and second-line HIV treatment failure in resource-limited settings. The absence of systematic data on viral load and treatment failure among children on ART likely leads to underestimates of the need for pediatric second- and third-line HIV treatment, and with the rapid scale-up of first-line, the need for these drugs is expected to grow in the coming years.

Janssen, the Pharmaceutical Companies of Johnson & Johnson, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), and Partnership for Supply Chain Management are collaborating on a first-of-its-kind initiative to improve access to pediatric HIV medicines for children experiencing HIV treatment failure in sub-Saharan Africa and/or least developed countries (LDCs). ¹

Janssen will donate its HIV medicines PREZISTA™ (darunavir) and/or INTELENCE™ (etravirine) to national HIV programs in eligible countries in sub-Saharan Africa and/or LDCs for use in children and adolescents up to 19 years of age. Upon turning 19 years, patients are to be transitioned into the countries’ HIV treatment programs for adults as designated by the participating countries’ ministries of health. The donation will be made free of charge to countries meeting the eligibility criteria including the clinical capacity and willingness to address second- and third-line pediatric HIV treatment. Please note that eligible countries are not required to accept both PREZISTA™ (darunavir) and INTELENCE™ (etravirine) to qualify for participation in this program.

EGPAF will manage the application process, convening an independent Review Committee for country selection based on a predetermined set of criteria. EGPAF also will also provide technical assistance for the program and opportunities for sharing best practices. PFSCM and Imperial Health Sciences will work together to manage the logistics of drug donation, including forecasting support, receipt of product, warehousing, and distribution of drugs to appropriate countries.

Expression of Interest Process and Instructions

Timeline

- **February 22 to April 17, 2016** – Submission period for Expression of Interest by countries
- **April 17 to May 16, 2016** – Application review by independent, third-party review committee
- **June, 2016** – Announcement of country selections

Who May Apply
Applications to the program may be submitted by Ministries of Health or their designee. Individuals and non-governmental organizations, not designated by a Ministry of Health may not submit independent applications.

To Submit Expression of Interest
Please submit your national program’s completed Expression of Interest Application Form (below) and supporting documents to newhorizons@pedaids.org between February 22 and April 17, 2016. Please note that incomplete applications may not be reviewed or else returned to applicants for revision.

Country Selection and Engagement
Countries identified as eligible and invited for participation in the Donation Program will be asked to sign a letter of mutual intent acknowledging the roles and responsibilities of participating parties.

Questions
For immediate questions or comments regarding the Expression of Interest, country eligibility, or the Donation Program, please reference the Frequently Asked Questions (FAQ) page or email newhorizons@pedaids.org
I. Applicant Contact Information

Country:

Include the names and contact information for the following individuals:

National HIV/AIDS Program Director/Primary Programmatic Point of Contact
- Name:
- Title:
- Department within MOH or MOH-Designated Organization:
- Phone:
- Email:

National Drug Donation Regulatory Point of Contact
- Name:
- Title:
- Department within MOH or MOH-Designated Organization:
- Phone:
- Email:

National Medical Store Procurement Point of Contact
- Name:
- Title:
- Department within MOH or MOH-Designated Organization:
- Phone:
- Email:

Other Key Personnel
- Name:
- Title:
- Organization and Department:
- Phone:
- Email:

II. Letter of Support

Please provide a letter of support, on behalf of the National HIV/AIDS program, as part of a complete Expression of Interest submission. Letters should confirm the national program’s endorsement of application submission to the Donation Program and include the signature of a representing authority within the program (e.g., Director, etc.).
III. Applicant Country Eligibility Criteria Verification

*Complete the table below by indicating *Yes* or *No* for each question with an “X.”*

<table>
<thead>
<tr>
<th>Eligibility Criteria</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>1. Is the applicant country either located in either: a) sub-Saharan Africa [OR] b)</td>
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<td>considered to be a Least Developed Country as defined by the United Nations?</td>
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<td>2. Is medicine donation legal in the applicant country?</td>
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<td>3. Is there a demonstrated need within the applicant country for third line ARVS</td>
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<td>for children and adolescents?</td>
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<td>4. Does the applicant country have national guidelines for third-line pediatric</td>
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<td>HIV treatment?</td>
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<td>5. Does the applicant country have the necessary laboratory and facility</td>
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<td>infrastructure and resources (including viral load monitoring and genotyping)</td>
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<td>to support the provision and management of third-line treatment for children and</td>
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<td>adolescents?</td>
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<td>6. Does the applicant country have necessary clinical expertise to identify</td>
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<td>children experiencing HIV treatment failure and manage children and adolescents on</td>
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<td>third-line treatment?</td>
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<td>7. Are other ARVs necessary to create an active regimen with darunavir and/or</td>
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<td>etravirine, such as raltegravir and an optimized backbone (based on patient’s ART</td>
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<td>history) available in country?</td>
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<td>8. Is standalone ritonavir (i.e., ritonavir not coformulated with other drugs such</td>
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<td>as lopinavir) for boosting darunavir, available in-country?</td>
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<td>9. Is adult third-line HIV treatment currently part of the national HIV program</td>
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<td>(or will it be in place within 6 months of the applicant country’s acceptance into</td>
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<td>the donation program)?</td>
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2 If this criterion will not be met within 6 months of country selection, please explain in the following sections and describe the effect that this criterion may, or may not, have on the provision of third-line treatment.
IV. Applicant Background Information

Please justify responses to the eligibility criteria by completing each of the following sections. Responses should not exceed 2 paragraphs per question.

Eligibility Criterion 1

1) Is the applicant country located within sub-Saharan Africa or identified as a least developed country by the United Nations? Indicate which.

Eligibility Criterion 2

2) Provide a description of the drug regulatory requirements which direct the importation, and use, of donated medicines within the applicant country. Within the description, please indicate which of 3 scenarios applies to the applicant country by responding to the following relevant questions:
   a. Is it a prerequisite that donated medicines first be approved in country by the local/national regulatory authority? If yes, please indicate estimated approval timeline from submission to approval.
   b. If it is not a prerequisite that donated medicines must be approved before donation, is it a prerequisite that they must be submitted for approval and/or must be submitted within a certain time frame? If yes, please indicate the terms and timeline.
   c. If it is not a prerequisite that donated medicines must be approved or submitted before donation please indicate any specific requirements that may need to be met prior to the importation of unregistered donated medicines (note all donated medicines from Janssen are approved by the United States Food and Drug Administration (FDA) and are WHO pre-qualified³).

3) Provide a description of any additional official processes and/or required documentation needed to direct the importation and use of donated medicines (e.g., formal endorsement from the MOH, formal permission from the regulatory authority, etc.).

Eligibility Criterion 3

4) Provide current national level HIV/AIDS epidemiological data including, but not limited to, estimated HIV prevalence for adults as well as children and adolescents.

5) Provide the total number of children and adolescents (i.e., < 19 years of age) currently initiated on/receiving ART. If possible, stratify these data to indicate the total number of children and adolescents currently on first- and second-, and third-line ART, respectively.

6) Describe the current estimated need for third line pediatric and adolescent ART in-country.

³ Please note one formulation is still pending.
Eligibility Criterion 4

7) Summarize the current country guidelines for pediatric first-, second-, and third-line treatment. If guidelines do not currently exist, provide a summary of guidelines planned for release by November, 2016.

8) Provide a description of the first-, second-, and third-line ART regimen(s) most commonly used for children and adolescents.

Eligibility Criterion 5

9) Provide a description of the current laboratory infrastructure and capacity to provide routine viral load testing in country, as well as the current recommended frequency of viral load testing for children and adolescents.

10) How is viral load monitoring currently funded? Are patients requested to pay for this service?

11) Is there access to, and provision of, genotyping for children experiencing second-line HIV treatment failure in the applicant country? Please describe.

12) How is genotyping currently funded? Are patients requested to pay for this service?

13) Describe the system of supply chain and storage capacity for ARVs from the national level to the facility level. Include details as to how donated drugs (i.e., darunavir and/or etravirine) will integrate within the existing system.

14) Provide a description of the current national level data management processes for pediatric and adolescent care and treatment. Include in your description, relevant indicators that are routinely collected and reported.

Eligibility Criterion 6

1) Provide the estimated number of facilities expected to participate in the Donation Program in 2016.

2) If available, for each facility provide the following information (required for at least one):
   a. Facility name
   b. Primary point of contact at facility (name and email)
   c. Facility type (i.e., public, private, etc.) and level of facility (i.e., primary, secondary,
d. Does the facility also manage adult third-line ART?
e. Describe the number and types of providers managing pediatric and adolescent ART at facility (i.e., doctors, nurses, clinical officers, etc.)
g. Provide the number of children and adolescents currently on third-line managed at the facility.
h. Describe the types of adolescent focused or adolescent friendly, services provided at facility.
i. Describe the types of adherence support for children and adolescents provided at the facility.

**Eligibility Criterion 7**

15) Are other ARVs necessary to create an active regimen with darunavir and/or etravirine, such as raltegravir and an optimized backbone readily available in country? Please list the available drugs and their formulations. In the response please also indicate the mechanism by which these drugs are procured (funding source, supply chain, etc.).

**Eligibility Criterion 8**

16) Is standalone ritonavir (i.e., ritonavir not coformulated with other drugs such as lopinavir) available in-country for boosting darunavir? If so, please list the formulations of ritonavir currently procured. In the response please indicate the mechanism by which these drugs are procured (funding source, supply chain, etc.).

**Eligibility Criterion 9**

17) Summarize the current country guidelines for adult first-, second-, and third-line treatment. If guidelines do not currently exist, provide a summary of guidelines planned for release by November, 2016.

18) Describe the current system for adult third-line management in the applicant countries (i.e., what facilities, reimbursement mechanism, etc.).

19) Provide the total number of adults (i.e., ≥ 19 years of age) currently initiated on/receiving ART. If possible, stratify these data to indicate the total number of adults on first- and second-, and third-line treatment, respectively.

20) Describe the national approach to transition patients from pediatric to adult care and treatment to ensure continued access to ART, and the average age of transition.
IV. Supporting Documents

Along with the completed Expression of Interest Application Form, please submit the following documentation (electronic versions only):

1. Adult and pediatric treatment guidelines.

2. Relevant documentation related to drug donation regulatory processes.

3. Letter of support (reference Section II).

4. Signed acknowledgement page indicating understanding of, and compliance with the New Horizons Logistic Procedures, Roles and Responsibilities document. Download the document, read, sign and return along with the complete Expression of Interest Application package.

Note: Additional documentation may be requested throughout the process of EOI review

For questions regarding eligibility criteria or this Expression of Interest Application Form, please contact newhorizons@pedaids.org