EXPRESSION OF INTEREST
New Horizons Advancing Pediatric HIV Care Donation Program

Program 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 subsequently 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 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 highlighted 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 limited availability of systematic data on viral load and treatment failure among children on antiretroviral therapy (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), Partnership for Supply Chain Management (PFSCM), and others 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, DRV) and/or INTELENCE™ (etravirine, ETR) to national HIV programs 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 (MOH). The donation will be made free of charge to countries identified as ready to manage donated product. Countries are not required to accept both PREZISTA™ (DRV) and INTELENCE™ (ETR) to qualify for participation in this program. The pharmacokinetic booster, ritonavir (RTV) must be provided by countries and will not be supplied by the New Horizons Collaborative at this time.

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) will manage the Expression of Interest (EOI) process, convening an independent Review Committee to assess country readiness and capacity building needs. EGPAF also will also provide technical assistance. 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.

EOI Process and Instructions

Process

Material Submission and Review
Beginning in 2018, EOIs to the New Horizons Advancing Pediatric HIV Care Donation Program will now be accepted on a quarterly basis throughout the calendar year. Countries may submit materials for consideration in 2018 prior to the following quarterly deadlines: February 21st, May 21st, August 21st, and November 21st. Materials submitted after the quarterly deadline will receive a response during the application round of the following quarter.

Following submission of materials for review, an expert Review Committee convened by EGPAF will assess and document the readiness of countries to manage donated product (i.e., DRV and/or ETR) at the point in time of submission. Countries will be notified of the Committee’s decision within four to six weeks of receiving a submission.

Readiness to Manage Donated Product
• **Countries determined to be ready** to manage donated product will be connected to Janssen and PFSCM for next steps related to donation regulation, forecasting, and procurement. Countries may also be asked to sign a letter of mutual intent acknowledging the roles and responsibilities of participating parties.

• **Countries determined not ready** for management of donated product at the time of EOI submission, are welcome to address recommendations made by the Review Committee and resubmit materials for review during the following quarter.

Capacity Building and Health Systems Strengthening
Recommendations for capacity building and health systems strengthening will be provided to all national HIV/AIDS programs which submit an EOI. Areas of potential collaboration with the New Horizons Collaborative on capacity building and technical assistance (TA) will be highlighted and next steps for this collaboration will be detailed.

Who May Submit an EOI?
National HIV/AIDS programs of countries in Sub-Saharan Africa, or else countries considered to be Least Developed as defined by the United Nations.

Materials for review may be submitted by the MOH or their designee. Individuals and non-governmental organizations, not designated by an MOH may not submit independently.

Submit an EOI
Interested National HIV/AIDS programs may complete and submit an EOI Form (below) and supporting documents to newhorizons@pedaids.org. Please note that incomplete applications may not be reviewed or returned to submitting entities for revision. Kindly complete and answer all questions in the application form.

Questions
For immediate questions or comments regarding the EOI process, the Donation Program, or the New Horizons Collaborative, please email newhorizons@pedaids.org
2018 EXPRESSION OF INTEREST FORM
New Horizons Advancing Pediatric HIV Care Donation Program

I. Points of Contact

Country of Interest:

National HIV and 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 and AIDS program, as part of a complete EOI submission. Letters should confirm the national program’s endorsement of material submission to the donation program and include the signature of a representing authority within the program.
III. Service Delivery Checklist and Needs Assessment

Patients with treatment-experienced HIV and AIDS who are challenged by treatment failure and require second-and third-generation protease inhibitor- (PI), non-nucleoside reverse transcriptase inhibitor- (NNRTI), or integrase strand transfer inhibitor- (INSTI) based regimens, also require careful clinical monitoring and focused services to reduce morbidity and mortality.

Issues are further compounded for higher at-risk pediatric populations (i.e., children and adolescents). Children and adolescents also require the provision of enhanced services regarding disclosure of HIV status, retention in care, adherence support, psychosocial support, and others.

The World Health Organization (WHO) recommends that HIV and AIDS programs with a standardized public health approach towards initiation and provision of first- and even second-line therapy consider the integration of a differentiated model of care to account for variance between stable patients and those requiring intensified clinical care. Programs must have the flexibility in service delivery to recognize and respond to the needs of patients with treatment failure.²

Four basic components of a differentiated framework for HIV and AIDS care and treatment are:

1) Service Provision
   - What types of resources and services are provided at facilities (e.g., ART, clinical monitoring, adolescent support, management of opportunistic infections, etc.)?

2) Service Frequency
   - How often do patients receive services (i.e., stable patients may require less frequent visits)?

3) Service Location
   - What type of facility is providing services? Are services decentralized or at a single center? Can some services be provided in the home or community?

4) Healthcare Workers
   - Who provides these services? May some tasks be shifted to others?³

Informed by differentiated models of care, the New Horizons Collaborative has developed a checklist of recommended elements for the implementation of pediatric (children and adolescents) third-line care and treatment. The following sections will help direct a readiness assessment for receipt of donated drugs through the donation program and also a needs assessment for capacity building and TA.

Please complete the following sections, providing as much detail as possible. Simple reference to guidelines will not be accepted in lieu of narrative explanations. Responses should not exceed 3 paragraphs per question, if possible.

### A. Supply Chain Management

#### Checklist: Recommended Service Delivery Components

- Medication donation is legal in the applicant country, and drugs of interest are appropriately registered.
- A stable supply chain is in place to direct the receipt, and management, of needed medications.
- The national HIV and AIDS program currently procures, or has the documented capacity to procure, separate (i.e., not co-formulated) RTV for pharmacokinetic boosting with DRV.
- The national HIV and AIDS program currently procures, or has the documented capacity to procure, other ARVs needed for active regimens with DRV and/or ETR such as raltegravir and optimized backbones.

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<td>1) Provide a description of any drug regulatory requirements which direct the importation, and use, of donated medicines within the country. Within the description, please respond to the following relevant questions:</td>
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<td>- Is it a prerequisite that donated medicines first be approved in country by the local/national regulatory authority? If yes, indicate estimated approval timeline from submission to approval.</td>
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<td>- If it is not a prerequisite that donated medicines be approved before donation, is it a prerequisite that they be submitted for approval and/or must be submitted within a certain time frame? If yes, indicate the terms and timeline.</td>
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<td>- If it is not a prerequisite that donated medicines be approved or submitted before donation, indicate any requirements that must be met prior to the importation of unregistered donations (note all donated medicines from Janssen are approved by the United States Food and Drug Administration (FDA) and are WHO pre-qualified³).</td>
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<td>2) Provide a description of additional official processes and/or required documentation needed prior to the importation and use of donated medicines (e.g., endorsement from the MOH, permission from the regulatory authority, etc.).</td>
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<td>3) Describe the system of supply chain and storage for ARVs from the national level to the facility level. Include details as to how donated drugs (i.e., DRV and/or ETR) will integrate within the existing system.</td>
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<td>4) Is standalone RTV (i.e., RTV not coformulated with other drugs such as lopinavir) available in-country for boosting DRV? If so, list the formulations of RTV currently procured. Indicate the procurement mechanisms for RTV (i.e., funding source, supply chain, etc.)</td>
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<td>5) Are other ARVs necessary to create an active regimen with DRV and/or ETR, such as raltegravir and an optimized backbone readily available in country? List the available drugs and their formulations. Also, indicate the procurement mechanisms (i.e., funding source, supply chain, etc.),</td>
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³ Please note one formulation is still pending.
B. Epidemiology and Background

Checklist: Recommended Service Delivery Components

✓ There is a need for advanced pediatric therapy in the applicant country as evidenced by documented treatment failure in those populations (children and adolescents).

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

2) Provide the total number of children and adolescents (i.e., < 19 years of age) currently initiated on/receiving [any] 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.

3) Describe the current estimated need for second- and third-line pediatric and adolescent ART in-country (differentiate in number between children/adolescents currently initiated on third-line, and those anticipated to switch regimens in the coming year).

4) 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.
C. Service Provision and Frequency

Checklist: Recommended Service Delivery Components

✓ National HIV and AIDS guidelines are inclusive of recommendations for adult and adolescent third-line sequencing.
✓ National HIV and AIDS guidelines are inclusive of recommendations for pediatric (i.e., children and adolescent) third-line sequencing.
✓ The national HIV and AIDS program has a second- and third-line program for adults incorporated into the existing care and treatment model.
✓ The national HIV and AIDS program has an approach for transitioning patients who have graduated from adolescent, into adult, care and treatment.
✓ The national HIV and AIDS program provides services for adolescent support including, but not limited to, youth friendly corners, dedicated facilities or clinic days, psychosocial support services, adherence support, disclosure support, and others.
✓ The national HIV and AIDS program has the capacity to provide routine annual viral load monitoring for patients, especially those initiated on second- and third-line therapies.
✓ The national HIV and AIDS program has the capacity to provide genotype testing for patients switching from second- to third-line regimens.

1) 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 2018.

2) Describe the process of treatment failure identification and determination to switch regimens from first- to second-line and from second- to third-line for pediatric (i.e., children and adolescent) patients. In your answer please address the following (if applicable):
   a. Does a second- and/or third-line committee exist in-country to manage regimen switching and sequencing? If so, describe the expertise represented on this committee and indicate if individuals with pediatric expertise are represented.
   b. If a second- and/or third-line committee exists, please describe the frequency of meetings and the structure/process for submission of cases. How fast (approximately) is the turnaround time for responses to facilities? Describe the process of follow-up and continued management of cases between the third-line committee and facilities.

3) Describe the first-, second-, and third-line ART regimen(s) most commonly used for children and adolescents.

4) Describe the frequency of recommended clinic visits for patients experiencing treatment failure as well as those switched to third-line regimens.

5) Summarize the availability of adolescent support services nationally (inclusive of adherence, disclosure, psychosocial, and other support services).
6) Describe 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. In your description, please indicate approximate turnaround time of results from lab to facility.

7) Describe how viral load monitoring is currently funded. Are patients requested to pay for this service?

8) Describe the current laboratory infrastructure and capacity to provide genotype testing for children experiencing second-line HIV treatment failure. In your description, please indicate approximate turnaround time of results from lab to facility.

9) Describe how genotype testing is currently funded. Are patients requested to pay for this service?

10) 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 2018.

11) Describe the national approach to transition patients from pediatric (i.e., children and adolescents) to adult care and treatment to ensure continued access to ART. Provide the average age of transition.

Checklist: Recommended Service Delivery Components

✓ All facilities managing third-line regimens have the capacity to respond to the specific needs of patients experiencing treatment failure. This is especially important in systems where third-line care has been decentralized. All facilities should have access to routine viral load monitoring and genotyping; have a stable supply chain; provide, or link patients to, adherence support services and other adolescent support services; and employ healthcare providers with expertise in pediatric (i.e., children and adolescent) treatment failure and management of advanced regimens.

D. Service Location

1) Are second- and third-line centrally managed at one or more select location(s) or decentralized? Indicate if separate clinics or dedicated days exist for pediatric (i.e., children and adolescent) second- and third-line care.
2) Provide the estimated number of facilities providing second- and third-line treatment for adults and pediatrics (children and adolescents), respectively. Emphasize the number of facilities requested to participate in the New Horizons donation program.

3) For each facility anticipated to participate in the Donation Program, provide:
   a. Facility name
   b. Primary point of contact at facility (name and email)
   c. Facility type (i.e., public, private, etc.) and facility level (i.e., primary, secondary, tertiary, etc.)
   d. Does the facility also manage adult third-line ART?
   e. Facility’s experience with managing third-line ART treatment for children and adolescents
   f. Number of children and adolescents currently on third-line managed at the facility
   g. Description of adolescent services provided at facility
   h. Description of adherence support for children and adolescents provided at the facility.

E. Healthcare Workforce

Checklist: Recommended Service Delivery Components

✓ National HIV and AIDS program has dedicated healthcare providers with expertise in third-line management, especially for pediatric patients (i.e., capacity to order and interpret necessary therapeutic monitoring tests, follow a treatment failure cascade, appropriately time regimen switching, and more).

✓ National HIV and AIDS program has ongoing training and capacity building opportunities for healthcare providers regarding issues related to pediatric care and treatment, treatment failure, and management of advanced therapies.

1) Describe the availability of pediatric (i.e., children and adolescents) HIV and AIDS healthcare providers nationally and at facilities managing second- and third-line. Include specifics such as numbers and types of providers, qualifications, trainings, years of experience, and expertise managing HIV and AIDS treatment failure and advanced therapy management of healthcare providers.

2) Describe opportunities for ongoing training and capacity building of healthcare providers, especially those providing pediatric care and those managing treatment failure and advanced therapies.
F. **Data Management**

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**Checklist: Recommended Service Delivery Components**

✓ *The national HIV and AIDS health management information system, or other standard monitoring and evaluation and reporting system, is inclusive of routine pediatric (children and adolescent) HIV and AIDS epidemiological indicators, as well as indicators regarding treatment failure and outcomes of advanced therapies. All data should have the capacity for stratification by age group, including the adolescent sub-population.*

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1) Provide a description of the current national level data management processes for pediatric and adolescent care and treatment.

2) Provide a list of the relevant indicators that are routinely collected and reported.
IV. Supporting Documents

Along with the completed Expression of Interest Form, please submit the following documentation:

1. National adult and pediatric HIV and AIDS 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 (available at www.pedaids.org/newhorizons). 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 EOI Application Form, please contact:
newhorizons@pedaids.org