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**REQUEST FOR INFORMATION (RFI)**

**HEALTH PRODUCTS FOR MANAGING OPPORTUNISTIC INFECTIONS IN PEOPLE LIVING WITH HIV**

**Submission deadline**: 7 January 2018 at 5pm (Geneva time)

## Background

### Purpose and intent

Unitaid hereby invites manufacturers and suppliers of diagnostics and medicines for diagnosis, prevention and treatment of the key opportunistic infections for people living with HIV (PLHIV) (“Respondents”) to submit technical and product information.

This RFI is for planning purposes only and does not constitute a solicitation. It is not to be construed as a commitment by Unitaid. No Request for Proposals or other such solicitation document exists or is guaranteed to be issued as a result of this RFI. Unitaid is merely seeking information on the capabilities and willingness of Respondents to engage within the product categories listed below. In the event of any eventual solicitation by Unitaid with respect to the diagnostic and therapeutic products referred to in this RFI, Unitaid reserves the right to send solicitation documents to vendors identified by Unitaid through means other than this RFI.

Any information considered by Respondents as confidential must be clearly marked “confidential”.

### Program description

Unitaid contributes to the global response against HIV/AIDS, tuberculosis, and malaria in developing countries through time-limited catalytic investments in projects that increase access to better, more effective and more affordable health products (i.e. preventatives, medicines and diagnostics). Unitaid’s interventions span key dimensions of effective markets: innovation and availability, quality, affordability, demand and adoption, and supply and delivery. There is no standard intervention; each project is uniquely designed to address specific market challenges, and may cover one or more of the dimensions. Unitaid is hosted and administered by the World Health Organization (“WHO”).

In June 2017, the Unitaid Board approved HIV coinfections as a strategic priority for Unitaid. This enabled Unitaid to consider investing in overcoming the market shortcomings deterring access to the most optimal diagnosis, prevention and treatment tools for effectively managing opportunistic infections in HIV positive people with advanced HIV disease (defined as a CD4 cell count <200 cells/mm3 or a WHO clinical stage 3 or 4 event at presentation for care). This approval comes on the heels of the launch of the World Health Organization Guidelines for Managing Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy (the “WHO Guidelines”): <http://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/>

While the universe of diseases that affect PLHIV is vast, there are certain opportunistic infections that are more common than others, particularly in low-resource settings. These opportunistic infections include: Tuberculosis, severe bacterial infection, cryptococcal meningitis, *Pneumocytis jiroveci* pneumonia, and toxoplasmosis. For several of these opportunistic infections, optimal health products exist to optimally diagnose and manage conditions, but severe market shortcomings hamper access in lower and middle income countries. Towards that end, Unitaid is looking to address these market shortcomings in order to unlock access to these health products.

Of the products outlined by the WHO Guidelines, Unitaid has identified the following as potential priorities for targeted intervention:

Table 1

|  |  |
| --- | --- |
| **Medicines** | **Diagnostics** |
| * Amphotericin B (conventional and Liposomal)
* Flucytosine (including slow release)
* Pegylated Liposomal Doxorubicin
* Cotrimoxazole + Isoniazid + Vitamin B6 fixed dose combination
 | * CD4 semi-quantitative tests\*\*
* Cryptococcal antigen lateral flow assay
* Tuberculosis lipoarabinomannan (LAM) antigen urine test
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\*\* *Relevant to the diagnosis of advanced HIV disease in settings where current fleet of point of care and conventional CD4 devices does not reach.*

## RFI instructions

This RFI is calling on manufacturers and suppliers of the two product categories listed in Table One above to: (1) **provide pertinent information about their respective products** (commercially available and pipeline); and (2) **ascertain whether there is any interest in becoming a future supplier of these product categories**.

In addition to requests listed above, Unitaid is also: (3) **soliciting information on diagnostic and therapeutic products not listed on the product category list in table 1, but for which there is applicability for addressing the common opportunistic infections in PLHIV**. These products can either be on the market or at late-stage of the commercialization process.

### Information sought

For each product, interested Respondents are encouraged to provide a product dossier, responding in so far as possible to the fields set out in Table 2 below. The dossier should cover the following areas:

* Manufacturer overview
* Product specification
* Regulatory status and plans
* Pricing information (including price points for various volume thresholds as relevant)

Table 2

|  |  |
| --- | --- |
| **Information category**  | **Responses** |
| **Manufacturer overview**  |
| Name of Manufacturer |  |
| Contact details of manufacturer (Name, address, email and telephone number) |  |
| Number of functional manufacturing sites and accreditation achieved for each site |  |
| Is the manufacturing site manual, semi-automated, or fully automated |  |
| Please describe the capabilities and capacity of your organization toprovide with after sale support, such as maintenance, replenishment,and quality control (Directly and/or through third party channels) |  |
| Please describe your distributorship footprint in LMICs |  |
| Other relevant information |  |
| **Product specification (Diagnostics)** |
| Product name |  |
| Commercial name |  |
| Product reference |  |
| Is the product commercially available? |  |
| If not commercially available, what is the stage of development and projected launch date? |  |
| What are the priority countries for launch?  |  |
| Type of technology  |  |
| Sensitivity and specificity |  |
| Specimen/sample required |  |
| Volume of specimen/sample required |  |
| Time to result |  |
| Read window |  |
| Protocol complexity |  |
| Shelf life |  |
| Storage requirements |  |
| Test components |  |
| What is the expected lead time for deliveries after orders are placed (please specify separately in cases of equipment and reagents)? |  |
| Current production volumes (annual) |  |
| Maximum annual production capacity |  |
| Other relevant information |  |
| **Product specification (Medicines)** |
| International Nonproprietary Names, |  |
| Commercial name(s) |  |
| Product reference |  |
| Is the product commercially available? |  |
| If not commercially available, what is the stage of development and projected launch date? |  |
| What are the priority countries for launch?  |  |
| Dosage form(s) |  |
| Strength per dosage unit |  |
| Route of administration (e.g. oral, I.M, I.V etc.) |  |
| Pack size (quantity of dosage-form units per pack) |  |
| Shelf life |  |
| Storage requirements |  |
| What is the expected lead time for deliveries after orders are placed |  |
| Current production volumes (annual) |  |
| Maximum annual production capacity |  |
| Other relevant information |  |
| **Regulatory status and plans** |
| Market authorization/regulatory approvals (global, regional and country) |  |
| Regulatory plans: regulatory authority, target date of dossier submission, estimated target date of approval |  |
| Please describe the capabilities of your organization to initiate and/or manage the regulatory aspects of country approval |  |
| Please describe relevant commercial strategic options, that in your opinion could further fast track registration in resource limited settings |  |
| Other relevant information |  |
| **Pricing information**  |
| Pricing (US$/unit) – *Please specify incoterms e.g. Ex works, DDP etc.* |  |
| Discounted pricing based on volume (US$/volume) |  |
| Please describe relevant commercial strategic options, that in your opinion could further reduce price in resource limited settings |  |
| Other relevant information |  |

## Submission instructions

Please submit Table 2 together with a completed and signed Information Form, as set out in Annex 1 in this RFI to unitaid-proc@who.int . The title of the email subject line should read “Request for information for opportunistic infection products”

Deadline for submission is **7 January 2018** at **17:00pm** (Geneva time).

If you have any additional question about the RFI, please contact Ademola Osigbesan: osigbesana@unitaid.who.int

**Annex 1 – Information Form**

|  |  |
| --- | --- |
| **Respondent Name:** |  |
| **Contact person:** |  |
| **Address:** |  |
| **Telephone Number:** |  |
| **Email Address:** |  |
| **Fax Number:** |  |
| **Company Website:** |  |

The Respondent hereby confirms that the information provided in response to this RFI is true and accurate as of the date of submission.

|  |  |
| --- | --- |
| **Name and Title of duly authorized representative:** | **……………………………………………** |
| **Signature:** |  |
| **Date:** | **……………………………………………** |