IMPAAC 4HIV
IMPROVED ACCESS TO AHD CARE & TREATMENT 4 HIV

REQUEST FOR PROPOSALS

For the supply of Itraconazole Tablets/Capsules for Histoplasmosis treatment

Issued by The Aurum Institute in partnership with Market Access Africa and Unitaid

RFP NUMBER: AUR_ITR_2025

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CLOSING DATE FOR PROPOSAL SUBMISSIONS: 7 JULY 2025

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Disclaimer Notice

The distribution of this Request for Proposals (RFP) does not mean or imply that there is any commitment on the part of the Aurum Institute, Market Access Africa and/or Unitaid to fund an applicant, nor any obligation to procure any of the services or products described herein, and the issuance of this RFP shall not be construed as a commitment to enter commercial or other business relations.

Any information submitted in response to this RFP is provided voluntarily and may be shared confidentially with Unitaid and the Global Fund as part of the RFP procurement evaluation process.

Aurum Institute, Market Access Africa and Unitaid may also use the information provided by respondents to the RFP (hereinafter, "Bidders") to support strategic decisions and planning within its HIV/Advanced HIV Disease portfolio or for internal purposes, including but not limited to the design of future RFPs or other solicitations which the Aurum Institute may issue.

Background

This RFP is issued by Aurum Institute and Market Access Africa (MAA), funded partners of Unitaid, a hosted partnership of the WHO. The collaboration of Aurum Institute, Unitaid, and MAA aims to accelerate access to Advanced HIV Disease (AHD) treatment and diagnostics in LMICs, particularly histoplasmosis and other fungal infections through the Improved Access to AHD Care and Treatment for HIV (IMPAACT4HIV) project.

IMPAACT4HIV is a Unitaid-funded project led by the Aurum Institute, dedicated to enhancing access to optimal diagnosis, prevention, treatment, and innovative delivery mechanisms for AHD.

This RFP is split into **two lots (Lot I and Lot II).** Bidders must state which LOT they are bidding for. If eligible, Bidders may bid for both lots.

LOT I: Procurement

As part of this project, itraconazole tablets and/or capsules will be used to initiate and continue treatment of Histoplasmosis in seven countries in Africa as part of a study to ascertain the burden of histoplasmosis in Sub-Saharan Africa.

LOT II: Support to itraconazole manufacturer/s for submission to a Stringent Regulatory Authority (SRA[1]) and/or World Health Organization (WHO) Pre-Qualification (WHO PQ)

The second objective is to support manufacturers who are willing to submit their dossier for registration by a Stringent Regulatory Authority (SRA) or approval by the WHO Prequalification Program

About Aurum

The Aurum Institute is a proudly African organisation working to advance health, science, and innovation to create a healthier world for future generations. We partner with governments, the private sector, and civil society to design and deliver high-quality care and treatment to people in developing communities. https://www.auruminstitute.org/

About Market Access Africa

Market Access Africa is a healthcare organization dedicated to transforming healthcare delivery across the African continent. MAA works at the intersection of product introduction, public health, and policy, partnering with public, private, and third sectors to design and deliver innovative healthcare solutions. MAA's mission is to ensure equitable and affordable access to high-quality health technologies tailored to Africa's unique context. https://www.marketaccess.africa/

[1] 1 "Stringent Regulatory Authority" shall mean a regulatory authority which is: (a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or (b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

About Unitaid

Unitaid saves lives by making new health products available and affordable for people in low- and middle-income countries. Unitaid works with partners to identify innovative treatments, tests, and tools, helps tackle the market barriers that are holding them back, and gets them to the people who need them most – fast. Since it was created in 2006, Unitaid has unlocked access to more than 100 groundbreaking health products to help address the world's greatest health challenges, including HIV, TB, and malaria; women's and children's health; and pandemic prevention, preparedness, and response. Every year, these products benefit more than 170 million people. Unitaid is a hosted partnership of the World Health Organization.

Project purpose and goals

The purpose of this Request for Proposals (RFP) is twofold and divided into two lots

Lot I

a) to invite quality-assured suppliers or manufacturers of itraconazole 200mg (or 100mg) tablets or capsules to submit quotations to The Aurum Institute for the procurement of itraconazole tablets/capsules to the seven project countries in Africa, with supplies starting in Q3/Q4 2025.
b) The selected supplier(s) for LOT I will enter into a supply agreement with Aurum Institute to ensure consistent and timely delivery of the product to the seven focus countries

Lot II

c) to support manufacturers of itraconazole tablets/capsules who are willing to submit their dossier for registration by a Stringent Regulatory Authority (SRA) and/or WHO PQ and supply LMICs (as defined by the World Bank)

The selected manufacturer for **LOT II** will provide a proposal outlining the type of support that is required for them to submit a dossier that will meet SRA requirements and/or WHO PQ requirements. The Bidder is to outline the current manufacturing capabilities, including the type of support they might require to meet WHO/SRA requirements and timelines they hope to achieve the necessary standards.

Should the Bidder be selected to proceed, a due diligence exercise led by Aurum Institute will be conducted, which will impact the final decision on whether support and the type of outcome that might be provided.

Scope of Work Lot I

The IMPAACT4HIV project currently has an immediate need for the quantities of Itraconazole 200mg tablets/capsules indicated below. It is anticipated that additional quantities will be ordered in the

future, however, the exact quantities cannot be determined at this time. In recognition of this, a Firm Fixed Price Purchase Order with Options will result from this solicitation. After the initial order is placed, the project may exercise its option to purchase additional quantities of the same item. The required product is as follows:

The IMPAACT4HIV project currently has an immediate need for the quantities of itraconazole 200mg tablets/capsules indicated below. It is anticipated that additional quantities will be ordered in the future, however, the exact quantities for such future needs cannot be determined at this time. In recognition of this, a Firm Fixed Price Purchase Order with Options will result from this solicitation. After the initial order is placed, the project may exercise its option to purchase additional quantities of the same item. The required product is as follows:

Product specifications

Product Name: Itraconazole
Formulation: Tablets/Capsules
Dosage Strength: 200mg

Preference will be given to 200mg formulations meeting quality assurance requirements. In the absence of a 200mg formulation, bids will be considered for 100mg formulations. Bidders offering 100mg formulations may be engaged for the development of a 200mg formulation for future needs.

Pharmacopeial reference: Bidder to state the Pharmacopeial reference for the quoted product
Quantity: 240,422 x 200mg tablets
Delivery schedules: Distribution to comply with Good Distribution Practices (First delivery TBC; other deliveries are subject to final negotiations)
Packaging: Suitable packaging with proven stability data for zone IVb climate, e.g., blister packaging compliant, with primary and secondary labeling in English, French, and Portuguese.
Shelf Life: Minimum 18 months from the date of delivery.
Preference will be given to offers of stocks with the longest shelf life remaining at the point of delivery.
Regulatory requirement: The Product(s) offered must be WHO Prequalified or approved by an SRA. Manufacturers that are interested in supplying the project but do not have a WHO PQ or approval by SRA for the offered product/s should provide information under **LOT II.**

Bidders to include registration certificates or marketing authorization from the National Medicines Regulatory Authorities (NMRA) for countries proposed for supply, where available.

The selected supplier(s) will be responsible for the supply of itraconazole 200mg tablets/capsules to the following project study countries:

Country	Language of labeling and PIL/ package insert	Quantity required (200mg doses)
Cote d'Ivoire	French	23456
Democratic Republic of Congo	French	38702
Kenya	English	38702
Mozambique	Portuguese	38702
Nigeria	English	38702
Sierra Leone	English	23456
South Africa	English	38702
TOTAL		**240422**

Bidder responsibilities Lot I

Bidders will be responsible for:

- Stating the Pharmacopeial standard used for the product, accompanied by documentary evidence of meeting the specifications (e.g., Certificate of Analysis)
- Ensuring product compliance with international quality standards and local regulatory approvals (WHO Prequalification and/or approval from SRA)
- Providing all relevant certifications, including cGMP and quality assurance documents, i.e., Certificates of Analysis (COAs), Certificate of Origin (COO), Certificate of Pharmaceutical Product (CoPP), or others as requested.
- Timely delivery to specified locations across all seven project countries.
- Providing an ex-works pricing per 200mg dose of itraconazole, AND total price for landed delivery (DDU) for each country. Indicating Minimum Order Quantities (MOQs), if applicable.
- Stating production lead times, as well as any scheduling requirements for order placement.
- Minimum Order Quantities (MOQs), if applicable.
- Stating production lead times, as well as any scheduling requirements for order placement.

Eligibility Criteria Lot I

Qualified suppliers must meet the following criteria:

- The company has marketing authorization or product approval for the offered products from WHO PQ or SRA; AND
- The Company's production facility operates under current Good Manufacturing Practice (cGMP), and the manufacturing site/unit has been inspected and has a valid Public Inspection Report by WHO PQ or a GMP certificate from an SRA;
- Demonstrated experience in supplying pharmaceutical products to global health organizations, including non-profit and governmental entities, with established supply chains in all project countries
- Flexibility in terms of delivery schedules to meet project requirements
- All medicines procured under Unitaid-funded projects are required to comply with Unitaid's quality assurance policy see more here

Evaluation Criteria Lot I

Bidders should quote Ex-Works prices for the requested goods as well as Delivery Duty Paid (DDP) to the capital city of the countries listed, and should include all local taxes, discounts, or extra fees.

It will be assumed that all quotes are inclusive of all applicable fees if the bidder fails to separate out these costs. Prices quoted by the Bidder shall be firm and fixed during the timeline of the final contract and not subject to variation on any account.

Interested suppliers are requested to submit a proposal that includes:

- **Company Profile:** Background, including relevant experience in itraconazole manufacturing and distribution as well as a list of countries where the product is currently registered (included in cover letter, see Annex A for template)
- **Product Description:** Detailed description of the itraconazole tablets/capsules being offered, including dosage strength, pharmacopeia reference, formulation, packaging type, packaging language, shelf life, etc, as per excel sheet
- **Compliance and Certifications:** Documentation of cGMP compliance for the facility where the finished product is manufactured, sample CoA, CoPP as per WHO format
- **Quality Assurance: Product must be** WHO Prequalified or SRA approved.
- **Manufacturing license:** Manufacturing license for a production facility in which products offered will be made
- **Pricing:** Detailed breakdown of pricing per unit,
- **Delivery Timeline:** Outline of manufacturing schedule, lead-time for new orders, and MOQ.
- **Distributor:** List of in-country distributors/partners in the focal countries and across the continent.
- **Proposed countries for supply: Bidders are to specify if they are quoting for all of the project countries or quoting for select countries.**
- **References:** Contact details for at least two previous clients, ideally NGOs or the public sector.

Scope of Work Lot II

Support for non-SRA/WHO PQ manufacturers of itraconazole who are interested in supplying LMICs and are committed to applying for either WHO PQ or SRA approval.

- Timelines for submission of the dossier, including bioequivalence testing if required, to WHO PQ/SRA should be provided
- Commitment to supplying at an affordable and sustainable price and in sufficient quantities to cover the needs in LMICs as defined by the World Bank
- The Manufacturer may be required to establish a project team that may include representatives from one or more of the collaborating institutions (Aurum, MAA, and Unitaid) and host regular meetings (in person and/or via teleconference) as required.
- Outline of current itraconazole supply experience, manufacturing capacity, and regulatory approvals.

Submission Information LOT I & LOT II

All RFPs should be submitted in English and signed by an authorized representative of the company. Responses will not be considered if any of the following are missing from the submission:

Required documents (broken down into the following categories):

a. RFP documentation

1. Cover letter (refer to **Annex A** for information to be included) (**Lot I & Lot II**)
2. Completed Excel response sheet **(LOT I TAB 2 and Lot II TAB 2)**
3. Bidders Declaration (refer to **Annex B** for information to be included)

Soft copies of the documents listed are to be submitted. The Aurum Institute reserves the right to request notarized copies of any submitted documents. Please provide an English translation of certificates if the original certificates are not in English.

b. Company documents

4. Company profile
5. Copy of business license
6. Copy of audited accounts for the last 3 financial years.
7. Copies of tax compliance documentation in the country of operation
8. Proposal outlining support required (i.e., BE study, GMP support, CMC support) to comply with SRA/WHO PQ standards **(Lot II)**

c. Regulatory documentation

9. Copy of Manufacturing licenses
10. Copy of current GMP certificate (**for LOT I,** please only include GMP for the factory that will be supplying the WHO PQ/SRA approved products).
11. Copies of product registration/ market authorization for itraconazole in the countries proposed for supply **(LOT I)** and current global marketing authorizations **(LOT II)**
12. Copy of valid COPP as per WHO format (* does not have to be in the name of one of the supply countries)

Proposals should be submitted via e-mail with the subject line Request for Proposals – **Itraconazole Procurement** to impaact4hiv@auruminstitute.org

Timelines

The timeline for the RFP process is described below. Responses received after the deadline will not be considered

RFP released	9 June 2025
RFP questions submitted by the Bidders	23rd June 2025 17:00 SAST
Response to questions by Aurum	27th June 2025
*RFP due date	7th July 2025; 17:00 SAST
Final decision made Lot I	21 July 2025
Final decision made Lot II	14 August 2025

*Late submissions will not be accepted

Delivery dates to be discussed as part of contracting

Failure to provide any of the above submission requirements may be considered non-responsive and disqualify the applicant from final selection

Questions and answers

Questions regarding this RFP will be answered by email only within the 2 weeks following the posting of the RFP. It will not be possible to engage in telephone enquiries.

Questions should be sent via email to impaact4hiv@auruminstitute.org

Costs of preparing documents

All costs associated with preparing and submitting an RFP will be borne by the Bidder.

Disclosure

Information relating to the examination, clarification, and evaluation of responses shall not be disclosed to other Bidders or any other persons not officially concerned with such processes.

We thank you for your interest and look forward to receiving your proposal

Annex A: COVER LETTER

The cover letter should be on company-headed paper showing the full registered and trading name(s), trading and registered office address, and business number of the agency.

The letter must be signed by a person of suitable authority to commit the agency to a binding contract.

Guidance:
Cover letter to include:

- RFP number and the Lot that the Bidder is responding to
- Statements of capacity covering production capacity for each product offered **(Lot I)**
- History of supply for similar supply contracts with national or international organizations (Lot I)
- Statement of commitment to provide certificates of analysis for supplied batches **(Lot I).**
- A commitment to submit dossiers to WHO PQ and/or SRA and/ or undergo quality assurance due diligence **(Lot II)**
- If applicable, to indicate interest in the exploration of product development/ market shaping opportunities for the products offered.

ANNEX B: DECLARATION BY BIDDER

This declaration must be completed, signed, and returned to The Aurum Institute as part of the Bid proposal.

[To be on company letterhead]

We, the undersigned, have examined the information provided in your Request for Proposal (RFP) and offer to undertake the work described by the requirements as set out in the RFP. This proposal is valid for acceptance for 120 days after submission, and we confirm that this proposal will remain binding upon us and may be accepted by you at any time before this expiry date.

We accept that any contract that may result from this RFP will be based upon the documents and information that have been submitted as part of our proposal.

Our proposal (technical and financial) has been arrived at independently and without consultation, communication, agreement, or understanding (for the purpose of restricting competition) with any other Respondent to or recipient of this RFP from the Aurum Institute.

All statements and responses to this RFP are true and accurate.

We understand the obligations regarding the disclosure to and the potential sharing of our submission with our partners on a confidential basis as described in the RFP.

We agree to bear all costs incurred by us in connection with the preparation and submission of this proposal and to bear any further pre-contract costs.

We agree to follow Unitaid's quality assurance policy for all products supplied.

I *[name of signatory]* confirm that I have the authority of *[insert name of company]* to submit this proposal and to clarify any details on its behalf.

- **If bidding for LOT II, please also include the below:**

I [name of signatory] confirm that the company commits to an affordable selling price and to making the product accessible to low and middle-income countries (LMICs) (as defined by the World Bank) as part of the development and commercialisation contract that follows, should an award be granted.

The following clauses are only applicable for submissions for products that do not have WHO prequalification or stringent regulatory approval: (Lot II)

We agree that if selected for further due diligence under the RFP award, permission will be given to the Aurum Institute and/ or their designated representatives to conduct a GMP audit to assess support required to meet WHO PQ/SRA requirements.

We fully commit to submitting a dossier and any other required documentation to facilitate quality assurance evaluation of offered products.

Name of authorized representative: _____

Title: _____

Signature: _____

Date: _____

Company name: _____
(please provide full registered and trading name(s))

Postal Address: _____
(please provide full trading and registered office address)

Telephone No.: _____

Email Address: _____

Attachments checklist:

Attachment to be submitted	Applicable LOT	Attached (Yes/No)
Company documents		
Cover Letter (Annex A)	Lot I & Lot II	
Declaration (Annex B)	Lot I & Lot II	
Completed Excel response spreadsheet	Lot I	
COMPANY DOCUMENTS		
Company profile	Lot I & Lot II	
Company registration documents, i.e., business license	Lot I & Lot II	
Audited financial statements for the last 3 years	Lot I & Lot II	
Copies of tax compliance documentation in the country of operation	Lot I & Lot II	
Proposal for support to meet WHO/SRA requirements	Lot II	
REGULATORY DOCUMENTS		
Manufacturing license	Lot I & Lot II	
cGMP certificates of the itraconazole manufacturing site(s)	Lot I & Lot II	
Product registration certificates/Global regulatory approvals	Lot I & Lot II	
Product COPPs	Lot I & Lot II	