THE AURUM INSTITUTE

IMPAACT4TB
PREVENTING TB TO END TB

CALL FOR EXPRESSION OF INTEREST

Early Market Access Vehicle for 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine for TB prevention.

Issue Date: December 2023
Open Call till 30 October 2024

CLINTON HEALTH ACCESS INITIATIVE

Unitaid
SAVE LIVES FASTER

1. Purpose

Children and young adolescents (aged below 15 years) represent about 12% of all people with tuberculosis (TB) globally. This means that 1.1 million children become ill with TB every year, almost half of them below five years of age. According to the Global TB report, National TB Programmes (NTPs) only notify less than half of these children, meaning that there is a large case detection gap. The reasons for this gap include challenges with specimen collection and bacteriological confirmation of TB in young children, due to the paucibacillary nature of TB disease in this age group and the lack of highly sensitive point-of-care tests. Given the complexities of diagnosis and treatment of TB in children, prevention has been shown to have a profound impact on reducing TB mortality.

TB Preventive therapy (TPT) is recommended for children with HIV disease and those who are contacts of people with TB. TPT options for children include three- month regimens which are given either as once-daily doses of dispersible 3HR or once-weekly 3HP. Without a properly formulated option for children, programmes have not been able to adopt 3HP for child household contacts (HHCs), which has impacted long-term demand. Current implementation of 3HP using Rifapentine (RPT) 150mg film coated tablets has resulted in a high rate of refusal of 3HP once caregivers see the complexity of administration for children. To succeed in achieving the UN High-Level targets for TPT in child and adult HHCs, a family-friendly, patient-centred approach is required. 3HP is well suited to be used as a single TPT regimen for all HHCs regardless of age and a newly available paediatric formulation enables 3HP to be available for use in children.

The paediatric formulation of Rifapentine is a 150 mg functionally scored (FS), dispersible tablet (DT) that is used in combination with 100mg dispersible Isoniazid (INH), (3HP). Following a Global Fund ERP approval in November 2023, the paediatric RPT 150 mg is now listed on the Global Drug Facility's catalogue under the list of paediatric TB medicines.

Unitaid has established the Early Market Access Vehicle (EMAV), to be led by the Aurum Institute NPC under the IMPAACT4TB project. The goal of the EMAV is to accelerate access to the groundbreaking paediatric dispersible formulation of Rifapentine from Lupin Limited in a wide set of countries. Unitaid and The Aurum Institute NPC hereby invite interested governments and partners to submit an expression of interest (EOI) to participate in the EMAV. The EMAV will secure approximately 85,000 patient courses from the first phase of production from the manufacturer for early product introduction). Countries are expected to couple this with in-country or externally sourced 100mg dispersible isoniazid (INH) to make up 3HP. This EMAV is expected to catalyse and increase access to a more affordable product that is easier to administer for children than what is currently available on the market to increase TPT access for children.

Weight Band	INH Weekly Dose	RPT weekly dose
10 – 15 kg	3 x 100 mg	2 x 150 mg
16 – 23 kg	5 x 100 mg	3 x 150 mg
24 – 30 kg	6 x 100 mg	4 x 150 mg
31->34 kg	7 x 100 mg	5 x 150 mg

2. Early Market Access Vehicle (EMAV) Overview

Unitaid, the Aurum Institute and CHAI have engaged with Lupin Limited to launch a Unitaid-supported, funding mechanism that will enable eligible buyers to procure Rifapentine 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation and facilitate evidence generation and user experience in a wide group of countries. Additionally, the EMAV will inform national implementation and planning, and design effective systems and processes, such as training curricula and quality assurance, to support routine use of paediatric dispersible RPT in 3HP. The provision of INH to be paired with RPT is not currently covered under the EMAV and programs are expected to use in-country or externally sourced INH for 3HP administration.

Summary features of the EMAV:

Global access ceiling price[2]	US$ 0,138/tablet Ex works
Unitaid's total commitment[3]	3,000,000 tablets (~85,000 patient courses)
Maximum number of patient courses per implementer	360,000 tablets (~10,000 patient courses)/ 6 months of stock based on historical/ projected consumption
Validity of the EMAV	December 2023 – October 2024
Coordinating team secretariat	Aurum Institute, as part of the Unitaid / Aurum Institute led IMPAACT4TB led consortium, will serve as the secretariat for the EMAV. The EMAV secretariat will be responsible for the review and approval of all submissions, as well as coordination of order fulfillment with the manufacturer.

[2]Eligible countries for access price presented in Appendix A.
[3]Unitaid will finance up to a maximum of 3,000,000 tablets that have been approved during the eligibility period Unitaid will only cover EXW cost of the product. Eligible countries or buyers/USAID will be responsible for PSA fees, freight, and other procurement costs as well as taking ownership of securing waivers and covering in-country distribution costs.
[4]This requirement may not apply if there is a government/partner entity coordinating EMAV activities at country level. Preference will be given to models with a coordination government or partner entity in countries.
[5]Offer is limited to the maximum commitment of 10,000 patient courses and subject to availability of a quality assured product through WHO prequalification or Expert Review Panel (ERP) renewal. Requests for additional volumes will be considered on a case-by-case basis

3. EMAV Participation

a. The EMAV is open to all high-burden TB countries (Annex A).
b. The Applicant must meet the following eligibility criteria:
   i. Availability of TB guidelines or rapid advice including 3HP/1HP as a TPT option for children
   ii. Evidence of strategy for contact tracing in TB households including an implementation plan that clearly outlines process for linkage to TPT.
   iii. Visibility into existing and expected stocks of paediatric INH (100mg DT) and 3HR and historic consumption patterns.
   iv. Pathway/commitment to importation waiver and/or in-country registration. Product registration or relevant import waiver will be required before products can be delivered.
   v. Commitment to sustain paediatric TPT using Rifapentine based formulations.
   vi. A proven track record in successful implementation of public health projects in resource limited settings.

c. EMAV Procurement approach
   i. EMAV procurement will be channeled through the Global Drug Facility (GDF) purchasing mechanism (as with other routine TB medicines procurement) and the respective procurement services agents. Required in-country approvals should be sought by the applicant in this regard. PEPFAR programs can access the EMAV through GHSC-PSM channels. USAID TB programs will access through the normal GDF channels. The link for GDF procurement can be found here.
   ii. Other eligible buyers including Ministries of Health or implementing partners who are not supported through PEPFAR or GF funding should consult directly with the EMAV secretariat to establish an appropriate procurement approach. GDF can support countries/MOHs with procurement via GDF regardless of funding source as long as it is within their laws.
   iii. The Applicant will be requested to specify the preferred procurement channel on the Expression of Interest (EOI) form.

d. GDF procurement fee, freight and other PSM Costs
   i. The IMPAACT4TB project through the Global Drug Facility (GDF) will only fund the ex-works costs of the product and shipping to the warehouse . This EMAV will not fund in-country distribution.
   ii. Unitaid requires the eligible buyer/implementing partner to be responsible for in-country distribution, healthcare worker capacitation and implementation.

e. EMAV Reporting
   i. EMAV Implementers will be required to provide monthly reports on paediatric TPT implementation to the EMAV secretariat using a standardized reporting form (see example questions in Annex B).

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4. EOI Process

a. Submission of EOI
   Beginning on 1 December 2023, the Aurum Institute will accept Expressions of Interest (EOI) to the EMAV on a rolling basis through 30 October 2024 (or when total volume commitment is approved, whichever comes first). Parties interested in participation in the EMAV may submit an EOI using the response form (see below) during this time. Following submission of an EOI, the EMAV secretariat will assess the application and notify the applicant of the decision reached within 3 weeks. Please note that incomplete applications will not be processed.
   i. All Applicants should submit the completed EOI form to: impaact4tb@auruminstitute.org.
   ii. PEPFAR and the Global Fund partners should copy their respective focal point when submitting the EOI.

b. Selection Criteria
   In the event that eligible application requests exceed the total funding available for the EMAV or the maximum implementer positions per country is surpassed, the Aurum Institute and Unitaid will agree to a set of evaluation criteria and a selection methodology to assess which of the eligible proposals should be selected.
c. Confidentiality
   Information which the Applicant considers to be proprietary or confidential should be clearly marked as such. All such information will be treated as confidential and used for EMAV internal purposes only.
d. Disclosure
   Information relating to the examination, clarification, and evaluation of responses shall not be disclosed to Applicant or any other persons not officially concerned with such process.
e. Questions

For immediate questions or comments regarding the EOI process or the EMAV, please email: impaact4tb@auruminstitute.org

The Aurum Institute NPC. Company Information

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/

The Aurum Institute leads the Unitaid funded Increasing Market and Public Health Outcomes Through Scaling Up Affordable Access Models of Short Course Preventive Therapy For TB (IMPAACT4TB) consortium which is comprised of the Clinton Health Access Initiative (CHAI), Johns Hopkins University, KNCV the Dutch TB Foundation and the Treatment Action Group (TAG) for the scale-up of short course rifapentine-based TB preventive therapy (TPT) among high-risk groups: People living with HIV (PLHIV) and child contacts of persons with active TB infection. The project was initially focused on 3HP (a three-month, once-weekly oral treatment of rifapentine 900mg and isoniazid 900mg for 12 weeks).

5. About Unitaid

We save lives by making new health products available and affordable for people in low- and middle-income countries. We work with partners to identify innovative treatments, tests and tools, help tackle the market barriers that are holding them back, and get them to the people who need them most – fast. Since we were created in 2006, we have unlocked access to more than 100 groundbreaking health products to help address the world's biggest health challenges, including HIV, TB, and malaria; women's and children's health; and pandemic prevention, preparedness and response. Every year, more than 170 million people benefit from the products we've helped roll out.

150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine Early Market Access Vehicle

EARLY MARKET ACCESS VEHICLE APPLICATION FORM

Please complete this form and return to impaact4tb@auruminstitute.org. The information in this form is necessary to process your request for participation in the 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine Early Market Access Vehicle (EMAV).

Name of requesting entity: _____ *(please print)*

PART A – Application details

1. Preliminary Details

EMAV FOCAL POINT FOR RESPONDING ENTITY ("Applicant"):

Name: _____ Title: _____

Organization: _____ Country: _____

Phone #: _____ Email: _____

Country / Countries of Interest:

2. Applicant Information

A. Source of implementing partner funding for TB-related activities: PEPFAR/GF/ Government/ Others, specify:

B. Number of sites covered by partner for TB services:

C. Number of sites being proposed for the EMAV from the above:

D. Prior or current experience implementing TB interventions (please include specifics regarding sizes and types of interventions):

3. Country TB Program

A. TB Burden: ☐ B. Prevalence of TB in Country: ☐ C. Number of TB notifications: ☐

C. Does the host country have existing guidance on 3HP or 1HP for children? ☐ Yes ☐ No

If no, is this in development? ☐ Yes ☐ No

(Attach existing TB/TPT guidelines where available)

4. Plans for introduction of 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine

A. In a sentence or two, please provide a narrative on the objective and intended approach for deploying the 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine.

B. Quantity of 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine is required by the applicant asking for through the EMAV:

C. Stocks of 100mg INH DT in country or planned for procurement that will be available for dispensing with rifapentine for 3HP:

D. What other options of TPT do you have at the be available at the facilities that will receive 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine and what quantities?

E. Please explain how the catalytic procurement of 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine through the EMAV will inform implementation planning, including timeline and future plans for national scale up of paediatric TPT (500 words):

F. Please select the facility types at which the applicant intends to introduce 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine: (Select All that apply)

- ☐ Facilities with 6H
- ☐ Facilities with 6H and 3HR
- ☐ Facilities without any TPT option
- ☐ Other, please specify:

G. What are your plans to continue paediatric 3HP procurement after this initial catalytic procurement?

☐ Yes ☐ No

H. What are the potential funding sources for continuity of the paediatric 3HP beyond EMAV?

I. Is the country/implementing partner committed to share monthly summary data/information on implementation progress and lessons learned with Unitaid, Aurum Institute and the relevant Ministry of Health?

☐ Yes ☐ No

5. Supply Chain

A. Is 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine registered in the country or is an importation waiver available? (If yes skip next question)

☐ Yes ☐ No

B. If no, will the applicant/supporting donor process the importation waiver to enable receipt of commodities and their use in clinical management?

☐ Yes ☐ No

C. Estimated time duration to receive waiver approval ☐

D. Will the applicant/supporting donor cover costs for procurement services agent fees, freight, insurance, waivers, warehousing and distribution to implementation sites?

☐ Yes ☐ No

E. If a Ministry of Health or Global Fund Principal Recipient (PR), will the respondent prefer to order the commodity directly via GDF/ PEPFAR GHSC-PSM?

☐ Direct GDF platform ☐ Aurum order placement ☐ PEPFAR GHSC-PSM

Please state consignee details below:

Name:		Title:	
Organization:		Country:	
Phone #:		Email:	

PART B– DECLARATION

This form is being submitted on behalf of [REQUESTING ENTITY] , to provide a non-binding expression of interest for participation in the EMAV for 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine, an initiative of the Unitaid-IMPAACT4TB project.

As part of the EMAV, we understand that the catalytic procurement of the 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine aims to generate country experience with and use case for on the 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine. This experience should also help expand the knowledge of paediatric TPT and inform potential national roll-out of the supply chain management and TPT initiation of 3HP for children. Participation in the EMAV is not a commitment to continue to procure the 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine; however, should relevant government stakeholders, including the Ministry of Health find a valid use case, we would support continuous use of the 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine.

We also acknowledge that we understand the basic terms of the EMAV to be that:

i. The Aurum Institute will coordinate the various mechanisms to procure the 150 mg functionally scored (FS), dispersible tablet (DT) paediatric formulation of Rifapentine for country use, as part of the Unitaid-Aurum Institute IMPAACT4TB;
ii. The Aurum Institute will serve as a secretariat of, the EMAV, including, but not limited to, activities relating to the (1) general advisory, introduction, and oversight of the EMAV activities in-country, and (2) the coordination of other partners who will be leveraging the EMAV in-country.

iii. Approved applicants commit to share EMAV summary data on implementation progress and lessons learned with Unitaid, the Aurum Institute and the relevant Ministry of Health and shall provide reports, in such timely and accurate manner as is practicable, on distribution, consumption, utilization, and/or loss of the rifapentine product, upon the reasonable request of the Aurum Institute.

This submission constitutes only an expression of interest for a possible participation in the EMAV. By submitting this expression of interest, we acknowledge that we meet the basic eligibility criteria for EMAV participation, as outlined above.

We understand that after submission of this expression of interest, if the Unitaid-Aurum Institute IMPAACT4TB deems that the criteria for participation has been met, and accepts the application, it will make arrangements to finalize our participation in the EMAV and notify us of the next steps required. In the event that the Unitaid-Aurum Institute IMPAACT4TB does not approve our application to participate in EMAV, the secretariat will notify us of the decision.

By submitting this expression of interest, we confirm that we have verified that there are no legal or regulatory barriers that would prevent us from meeting the basic terms outlined above. Where necessary, we confirm that we will obtain any waivers and/or exemptions required under applicable laws or regulations to enable the initiation of the EMAV activities in country.

We understand that issue of the expression of interest by the Aurum Institute and submission of our response is not a commitment by either party to enter into such discussions or such collaboration. We further understand that Unitaid and the Aurum Institute reserve the right to enter into collaboration discussions and a resulting collaboration with one or multiple parties, with no parties, or to cancel this expression of interest at their sole discretion.

Finally, we acknowledge that our relationship with Unitaid and Aurum Institute is that of independent parties, and that the EMAV will act as means of procurement, rollout, monitoring and evaluation, and potential scale-up planning for paediatric rifapentine program. We confirm that all the information provided here is true.

SIGNATURE

_____ _____

Authorized Representative Name Authorized Representative Signature

Title: _____ Date: _____

Company Name: _____

Company Address: _____

Telephone No.: Email:

Annex A: List of Countries Eligible for the EMAV /Ceiling Price

Low-Income Countries		
Afghanistan	Guinea-Bissau	Sierra Leone
Benin	Haiti	Somalia
Burkina Faso	Korea, Dem. People's Rep.	South Sudan
Burundi	Liberia	Syrian Arab Republic
Central African Republic	Madagascar	Tajikistan
Chad	Malawi	Tanzania
Congo, Dem. Rep	Mali	Togo
Eritrea	Mozambique	Uganda
Ethiopia	Nepal	Yemen, Rep.
Gambia, The	Niger	
Guinea	Rwanda	

Lower-Middle Income Countries		
Angola	India	Papua New Guinea
Bangladesh	Indonesia	Philippines
Bhutan	Kenya	Sao Tome and Principe
Bolivia	Kiribati	Senegal
Cabo Verde	Kyrgyz Republic	Solomon Islands
Cambodia	Lao PDR	Sudan
Cameroon	Lesotho	Timor-Leste
Comoros	Mauritania	Tunisia
Congo, Rep.	Micronesia, Fed. Sts.	Ukraine
Cote d'Ivoire	Moldova	Uzbekistan
Djibouti	Mongolia	Vanuatu
Egypt, Arab Rep.	Morocco	Vietnam
El Salvador	Myanmar	West Bank and Gaza
Eswatini	Nicaragua	Zambia
Ghana	Nigeria	Zimbabwe
Honduras	Pakistan	

Upper-Middle Income Countries[1]		
Albania	Fiji	Namibia
Algeria	Gabon	Nauru
American Samoa	Georgia	North Macedonia
Argentina	Grenada	Paraguay
Armenia	Guatemala	Peru
Azerbaijan	Guyana	Romania
Belarus	Iran, Islamic Rep.	Russian Federation
Belize	Iraq	Samoa
Bosnia and Herzegovina	Jamaica	Serbia
Botswana	Jordan	South Africa
Brazil	Kazakhstan	Sri Lanka
Bulgaria	Kosovo	St. Lucia
China	Lebanon	St. Vincent and the Grenadines
Colombia	Libya	Surinam e
Costa Rica	Malaysia	Thailand
Cuba	Maldives	Tonga
Dominica	Marshall Islands	Turkey
Dominican Republic	Mauritius	Turkmenistan
Ecuador	Mexico	Tuvalu
Equatorial Guinea	Montenegro	Venezuela, RB

Notes:
Upper middle-income countries will be eligible to access the Ceiling Price for procurements through United Nations-related organization, non-governmental organizations and not-for-profit organizations, development and/or public health financing mechanisms, or a procurement agent appointed by any of these entities. South Africa is the exception to this stipulation and will be eligible to access the Ceiling Price through all Eligible Buyers defined above.

Eligibility for accessing the ceiling price extends to public sector buyers and funders such as:

i. Governments of Eligible Countries.
ii. United Nations-related organizations, non-governmental organizations and not-for-profit organizations.
iii. Development and/or public health financing mechanisms, or a procurement agent appointed by any of the entities above.

The ceiling price does not apply to product sales to “for-profit” private sector entities.

Annex 2: Proposed indicators to be collected quarterly

Eligibility for accessing the ceiling price extends to public sector buyers and funders such as:

i. Governments of Eligible Countries.
ii. United Nations-related organizations, non-governmental organizations and not-for-profit organizations.
iii. Development and/or public health financing mechanisms, or a procurement agent appointed by any of the entities above.

The ceiling price does not apply to product sales to “for-profit” private sector entities.

Annex 2: Proposed indicators to be collected quarterly

#	Variable
1	# household contacts <15 initiating 3HP
1.1	# household contacts <15 completing 3HP
1.2	# household contacts <15 reporting AEs associated with 3HP
2	# children living with HIV <15 initiating 3HP
2.1	# children living with HIV <15 completing 3HP
2.2	# children living with HIV <15 reporting AEs associated with 3HP