Request for proposal # 2024-044

Supporting the importation and delivery of buprenorphine for research use for the HepC3P project in Vietnam
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Request for proposal number: 2024-044

For: Supporting the importation and delivery of buprenorphine for research use for the HepC3P project in Vietnam

1. Request for proposal schedule

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date and time (Hanoi time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for proposal (RFP) released</td>
<td>July 19, 2024</td>
</tr>
<tr>
<td>Confirmation of interest in submitting a proposal</td>
<td>July 24, 2024</td>
</tr>
<tr>
<td>Deadline for fact-finding questions</td>
<td>July 26, 2024, 5:30PM</td>
</tr>
<tr>
<td>PATH to respond to fact-finding questions</td>
<td>July 29, 2024</td>
</tr>
<tr>
<td>Deadline for submission of proposal in response to the RFP</td>
<td>August 9, 2024, 5:30PM</td>
</tr>
<tr>
<td>Outcome communication</td>
<td>August 12-13, 2024</td>
</tr>
<tr>
<td>Award decision (to be followed by contract negotiations)</td>
<td>August 16, 2024</td>
</tr>
</tbody>
</table>

Note: PATH may change the dates at its discretion. Changes will be communicated to those who confirmed their intent to submit a proposal.

2. PATH statement of business

PATH is a global nonprofit dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world’s most pressing health challenges. Learn more at www.path.org.

3. Contracting requirements

3.1 The contracting authority shall be PATH or any one of its affiliates either directly or on behalf of operations countries or programs.

3.2 The commercial contracting terms and conditions will be negotiated with the successful supplier toward the end of the selection process.

3.3 By submitting a proposal, the supplier confirms that they will abide by the RFP terms and PATH policies, especially our Code of Ethics (https://www.path.org/about/code-ethics/), and general good practices regarding inclusivity, diversity, fair trading, health and safety, records management, anti-fraud and corruption, and environmental policy, among others.

3.4 Duration of the contract is estimated to be 20 months.
4. Solicitation terms and conditions

4.1 Notice of nonbinding solicitation: PATH reserves the right to reject any and all bids received in response to this solicitation and is in no way bound to accept any proposal.

4.2 Confidentiality: Suppliers shall treat all information provided by PATH as part of this solicitation as confidential. If any information is inappropriately released, PATH may seek appropriate remedies as allowed under applicable law.

4.3 Conflict of interest disclosure: Suppliers bidding on PATH business (also referenced herein as “bidders”) must disclose, to the procurement contact listed in the RFP, any actual or potential conflicts of interest. Conflicts of interest could be present if there is a personal relationship with a PATH staff member that constitutes a significant financial interest, a board membership, other employment, or ownership or rights in intellectual property that may conflict with the supplier’s obligations to PATH. Suppliers and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, PATH will create a management plan that provides mitigation of potential risks presented by the disclosed conflict of interest.

4.4 Acceptance: Bidder’s submission of a proposal means the bidder accepts all terms and conditions set forth in the RFP. PATH’s acceptance of a proposal does not mean acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the RFP finalists’ proposals, as well as the option of accepting partial components of a proposal if appropriate.

4.5 Right to final negotiations: PATH reserves the option to negotiate on the final costs and final scope of work and reserves the option to limit or include third parties in such negotiations at PATH’s sole and full discretion.

4.6 Third-party limitations: PATH does not represent, warrant, or act as an agent for any third party because of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.

4.7 Proposal validity: Proposals submitted under this RFP shall be valid for at least 90 days following the date the proposal is due. The validity period shall be stated in the proposal submitted to PATH.

4.8 Limitation of liability: The terms and conditions set forth in this RFP do not exclude or limit the liability of PATH or the supplier in relation to fraud or in other circumstances giving rise to liability under any applicable law.

4.9 Tender costs and liability: Bidders are responsible for obtaining all information necessary for preparation of their proposal and for all costs and expenses incurred in preparation of the proposal. Subject to the “Limitation of liability” section in this RFP (section 4.8), the bidder accepts by their participation in response to this RFP, including without limitation the submission of the proposal, that it will not be entitled to claim from PATH any costs, expenses, or liabilities that it may incur in tendering a response to this RFP, irrespective of whether their proposal is successful.

4.10 PATH’s variation or termination rights: PATH reserves the right to vary or terminate this RFP process with written notice to all suppliers from which it has received proposals. It is intended that this solicitation process will take place in accordance with the provisions of this RFP, but PATH reserves the right to terminate, amend, or vary (to include, without limitation, in relation to any time scales or deadlines) the solicitation process by notice to all suppliers from which it has received proposals. Subject to section 4.8, “Limitation of liability,” PATH will have no liability for any losses, costs, or expenses caused by its termination, amendment, or variation to this RFP.

4.11 Joint venture or consortium or subcontractors: Any lead supplier that submits a proposal in response to this RFP takes responsibility and accountability for enforcing the RFP requirements set forth herein among the members of the joint venture or consortium, and each of their advisers, subcontractors, and staff.
4.12 **Payment and invoicing:** PATH will pay correctly addressed and undisputed invoices within 30 days. Suppliers shall ensure comparable payment provisions apply to payments to their downstream parties. **Advance payment is not preferred.** If an advance payment is envisaged and is other than industry or country known practice, such must be made clear in the financial proposal to PATH.

4.13 **PATH Values and DEI (Diversity, Equity, and Inclusion)**

4.13.1 **Supplier Diversity Statement/Commitment -** PATH works to create mutually beneficial business relationships with diverse suppliers and consultants that strengthen the communities in which we operate. We are committed to developing mutually beneficial relationships with small, minority-owned, women-owned, and other underrepresented business enterprises and consultants. The primary goal of PATH’s Supplier Diversity Program is to provide opportunities to diverse suppliers and consultants that satisfy our procurement and contractual standards and reflect the communities we serve; build resilient supply chains that drive economic growth and cost savings; and finally, advance our commitment to diversity, equity, and inclusion.

4.13.2 **Supplier Diversity at PATH -** Supplier diversity at PATH means that we seek and include small, minority-owned, women-owned, and other underrepresented businesses and consultants in our procurement policies, practices, and vendor providers. PATH recognizes that supplier diversity creates a sustainable competitive advantage for the organization, enhances our commitment to equity and has a positive impact on the communities which we serve.

4.13.3 **Planning and reporting -** Suppliers are expected to live up to PATH’s DEI vision and state how they have included diverse supplier groups in their supply chain as they aim to partner with PATH in delivery of this project. The successful supplier will report to PATH every six months what portion of the work has been delivered through an inclusive workforce and underrepresented supplier groups.

5. **Instructions for responding**

5.1 **PATH contacts:** All communications regarding this solicitation shall be directed to the contacts below. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest and could result in disqualification of the proposal. All documents required as part of the proposal must be submitted to the contacts listed by the deadline for submission:

- Procurement contact: Vietnam Procurement team ([htnguyen@path.org](mailto:htnguyen@path.org), and [vietnamprocurement@path.org](mailto:vietnamprocurement@path.org))
  - The subject line of all emails regarding the proposal should read: **RFP #2024-044 Your Company Name.**
  - Please see Annex A to this RFP, “Tips on proposal preparation and submission,” for additional details regarding the files and file types to be included in your proposal package.

5.2 **Confirmation of interest:** Please send a statement acknowledging receipt of this solicitation and your intent to respond or not respond no later than the date noted in the schedule in section 1. Send the confirmation to the contacts listed above.

5.3 **Proposal technical content:** Bidders are advised to provide only what is required in this RFP. The proposal must be clear, concise, unambiguous, and directly address the requirements stated.

5.4 **Selection of short list:** PATH reserves the right to select a short list from the bids received. PATH has the option to interview and discuss specific details with those candidates who are short-listed.
6. Specifications/Scope

6.1 Scope of work/terms of reference/specifications:

Background

The World Health Organization has set a goal to eliminate hepatitis C virus (HCV) infection as a public health threat by 2030. Despite being curable, HCV is still a global major public health concern. People who inject drugs (PWID) are profoundly and disproportionately affected by HCV.

HCV combination prevention strategies including high coverage of needle and syringe programs, opioid agonist therapy, chronic HCV treatment and addressing underlying barriers to service access are powerful approaches to dramatically reduce incidence toward elimination of HCV among PWID. While innovative, quality-assured HCV prevention, testing, and treatment products exist, their availability and uptake among marginalized populations in low- and middle-income countries (LMICs) are limited due to cost, supply, delivery, demand, and adoption barriers.

As part of the Unitaid hepatitis C portfolio investment in prevention of hepatitis C among key populations in LMICs (HepC3P project), PATH will collaborate with its research partner to conduct a study in Ho Chi Minh City and Nghe An province in Vietnam in order to assess the values and preferences, feasibility, effectiveness and cost-effectiveness of delivering long-acting depot buprenorphine (LADB) as treatment of opioid dependence. The evidence generated through these studies will inform implementation and scale up of HCV services to accelerate micro-elimination of HCV among PWID.

The studies require the importation of buprenorphine (both long-acting depot and sublingual forms) upon obtaining the study approval granted by the Vietnam Ministry of Health (MOH).

It is expected that the study approval granted by the Vietnam Ministry of Health (MOH) in early September 2024. Since this is a study, not a non-refundable aid project for humanitarian purpose as defined by Vietnam government regulations, this study is not eligible for government approval as a non-refundable aid project according to decree No. 80/2020/NĐ-CP.

Scope of work

The agency will do the following work for PATH:

a. Provide all guidance as required by relevant laws and regulations on needed documents as well as details of documents for obtaining import permit and successfully clearing customs and importation procedures of the study products. Bidders are required to provide confirmation on whether they could successfully obtain import permits and complete the custom clearance for this study in bidder’s proposal and provide a presentation to PATH on how these processes could be succeeded.

b. On behalf of PATH, submit the import permit application of study products and to respond to any further requests from Drug Administration of Vietnam (DAV) until the import permit is granted and obtain this import permit.

c. The study products will be delivered from the warehouse of the manufacturer to the arrival port (e.g. Noi Bai port). The agency will be responsible for receiving the study products at the arrival port and handle all of the customs and importation processes to clear study products at the arrival port.

d. Store study products in accordance with the manufacturers’ recommendations from the time the study products arrive at the arrival port through the time of delivering them to study sites.

e. Affix sub-label in Vietnamese to study products to comply with the current Vietnam regulations on labeling. The information in the sub-label needs to be approved by PATH prior to printing.

f. Deliver study products to study sites multiple times throughout the study implementation period.

g. Provide the storage and inventory documentation of study products throughout the study implementation period.

h. Handle any requests (if any) from the DAV and other authorities as part of the management of study products post-importation.

Assumptions
a. Study approval granted by the Vietnam Ministry of Health (MOH) is expected in early September 2024.
b. Estimated timing for obtaining the export permit upon the availability of import permit: 5 working days.
c. Study sites are as follow:
   • District 4 and Binh Thanh District Health Centers in Ho Chi Minh City, and
   • Quy Chau and Que Phong District Health Centers in Nghe An province
d. Duration for study implementation: 18 months
e. Detailed information on study products:
<table>
<thead>
<tr>
<th>Name of study product</th>
<th>Buvidal</th>
<th>Option 1: Addnok</th>
<th>Option 2: Buprenorphine sublingual tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration/strength</td>
<td>Buvida© Weekly: 8 mg/0.16 mL; 16 mg/0.32 mL; 24 mg/0.48 mL; 32 mg/0.64 mL; Buvida© Monthly: 64 mg/0.18 mL; 96 mg/0.27 mL; 128 mg/0.36 mL; 160 mg/0.45 mL</td>
<td>2 mg, 8 mg</td>
<td>2 mg, 8 mg</td>
</tr>
<tr>
<td>Pharmaceutical form</td>
<td>Prolonged-release solution for injection</td>
<td>Sublingual tablet</td>
<td>Sublingual tablet</td>
</tr>
<tr>
<td>Special precautions for storage</td>
<td>Store below 25°C. Do not refrigerate or freeze.</td>
<td>Store below 30°C. Protect from light and moisture.</td>
<td>Store below 30°C. Protect from light and moisture.</td>
</tr>
<tr>
<td>Name and address of the manufacturer</td>
<td>Rechon Life Science AB Soldattorpsvägen 5 Limhamn 216 13 Sweden</td>
<td>Rusan Pharma Limited Plot No. 59 to 62 and 64 to 65, Sector II, Kandla Special Economic Zone, Gandhidham, Kutch - 370 230, Gujarat, India</td>
<td>Alkaloida Chemical Company Kabay János út 29 4440 Tiszavasvári Hungary</td>
</tr>
<tr>
<td>Exportation country</td>
<td>Malmo or Stokholm, Sweden</td>
<td>Mumbai, India</td>
<td>London, United Kingdom</td>
</tr>
<tr>
<td>Pack type and size</td>
<td>Box of 1 pre-filled syringe with safety device and 1 plunger rod</td>
<td>Box of 10 blisters x 10 tablets/blister</td>
<td>Box of 1 blister x 7 tablets/blister</td>
</tr>
<tr>
<td>Imported quantity</td>
<td>5,190 (boxes)</td>
<td>11,311 (tablets)</td>
<td>11,311 (tablets)</td>
</tr>
<tr>
<td>Ex works price</td>
<td>USD 357,210</td>
<td>USD 20,000</td>
<td>USD 20,000</td>
</tr>
<tr>
<td>Number of shipment(s)</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
6.2 Deliverables:

<table>
<thead>
<tr>
<th>Detailed Deliverables</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The import permit application of study products is submitted.</td>
<td>30 September 2024</td>
</tr>
<tr>
<td>2 Import permit is granted.</td>
<td>31 October 2024</td>
</tr>
<tr>
<td>3 Study products are cleared at the imported port.</td>
<td>No later than 5 days after study products arriving at importation port.</td>
</tr>
<tr>
<td>4 Sub-label in Vietnamese is affixed on study products.</td>
<td>Within 3 days after study products are cleared at importation port</td>
</tr>
<tr>
<td>5 Study products are delivered at the study sites per requests and instructions from PATH.</td>
<td>First delivery: no later than 3 days after study products are cleared at importation port. Other deliveries: per requests and instructions from PATH throughout the study implementation period.</td>
</tr>
<tr>
<td>6 Storage and inventory documentation of study products is provided to PATH.</td>
<td>Per requests and instructions from PATH throughout the study implementation period.</td>
</tr>
</tbody>
</table>

7. Fact-finding questions

7.1 Fact-finding questions should be sent to the contacts listed in Section 5.1 by the date in the RFP schedule (section 1). Fact-finding questions received after this deadline cannot be accommodated.

7.2 It is advisable that any fact-finding questions refer to a specific section of the RFP; and to the extent possible, be aggregated rather than sent individually.

7.3 In line with transparency principles, all fact-finding questions and all of PATH’s responses to these questions will be shared with all those who confirmed their intent to bid. Questions will be anonymized and answered if PATH reasonably determines that such fact-finding questions do not disadvantage any potential supplier and are not commercially in confidence. If such are commercially in confidence, they shall be handled in line with PATH’s policy on information and data.

7.4 PATH may request from a bidder additional information at any time ahead of award, and the bidder will be expected to provide the requested information within the time frame given. Failure by a bidder to provide supplementary information to PATH in a timely manner may lead to the proposal being rejected in full or disqualification from the procurement process.

8. Qualifications, evaluation criteria, and selection

8.1 Supplier qualifications: In relation to the scope, provide information on your overall qualifications, including:

- Profile of relevant corporate qualifications.
- Profile of relevant experience and examples of related work.
- Qualifications of key members of the proposed project team (attach CVs/resumes and provide details of backup/standby teams).
• Number of years in business.

• If your company has more than one location, please indicate these qualifications for the site that is responding.

Suppliers that do not meet reasonable qualifications shall not be short-listed and therefore not technically evaluated.

8.2 **Selection and evaluation criteria:** The proposal will be expected to address all the requirements.

- **Stage 1:** Proposals will be checked for completeness in terms of submission on time, technical proposal, financial proposal, and all required information. Proposals that are correctly completed will proceed to Stage 2. Any proposals submitted late, incomplete, or with omissions may be rejected at this point. If a proposal is rejected at this stage, it will automatically be disqualified from further review.

- **Stage 2:** If a proposal passes the Stage 1 evaluation, it will be evaluated in detail in line with the evaluation methodology below. Information provided as part of the qualification may be verified at this stage, and as part of the evaluation process.

8.3 **Evaluation criteria:** Proposals will be assessed to determine the most economically advantageous using the criteria and weightings in Table 1 and will be assessed strictly based on the proposal submitted.

<table>
<thead>
<tr>
<th>Evaluation criteria</th>
<th>Weight (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suitable methodology and approach with clear presentation on procedures to successfully obtain import permits and complete the custom clearance for this study as required by relevant laws and regulations, including provide list of documents for import permit and clearing customs of the study products.</td>
<td>40%</td>
</tr>
<tr>
<td>Suitable timeline for importation of the study products</td>
<td>15%</td>
</tr>
<tr>
<td>Relevant experience in importation and custom clearance, especially for the study products</td>
<td>10%</td>
</tr>
<tr>
<td>Relevant experience in storage, delivery and inventory management</td>
<td>5%</td>
</tr>
<tr>
<td>Experts (proposed personnel, including CVs/resumes highlighting experience)</td>
<td>5%</td>
</tr>
<tr>
<td>Financial approach</td>
<td>25%</td>
</tr>
</tbody>
</table>

8.4 **Scoring model:** Proposals that are subjected to technical/detail evaluation will be scored based on the model in Table 2 below for all the technical components. The financial proposal will be evaluated separately, as highlighted in section 8.4.1 below and Annex B.
Table 2. Proposal scoring model.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Score</th>
<th>Summary</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>5</td>
<td>Very strong evidence of appropriate knowledge, skills, and experience to meet the scope. Demonstrated innovation in better delivery of the scope.</td>
<td>As well as addressing all or the vast majority of bullet points under each criterion heading, proposal demonstrates a deep understanding of the project. All solutions offered are linked directly to project requirements and show how they will be delivered and the impact they will have on other areas and stakeholders.</td>
</tr>
<tr>
<td>Good</td>
<td>4</td>
<td>Sufficient evidence provided of adequate knowledge, skills, and experience to meet the scope. May demonstrate some innovation though it may be less robust. Meets all requirements with some minimal gaps.</td>
<td>Reflects that the bidder has addressed, in some detail, all or most of the bullet points listed under each criterion heading. Evidence is included that shows not only what will be provided but also gives some detail of how this will be achieved. Bidders should make clear how their proposals relate directly to the aims of the project and be specific, rather than general, in the way proposed solutions will deliver the desired outcomes.</td>
</tr>
<tr>
<td>Acceptable</td>
<td>3</td>
<td>Reasonable evidence of appropriate knowledge, skills, and experience for the scope. Meets requirements in many areas but not all areas.</td>
<td>Addresses the majority of the bullet points under each criterion heading, but lacks some clarity or detail on how the proposed solutions will be achieved. Evidence is included that shows not only what will be provided but also gives some detail of how this will be achieved. Evidence provided is considered weak or inappropriate and is unclear on how this relates to the desired outcomes.</td>
</tr>
<tr>
<td>Minor reservations</td>
<td>2</td>
<td>There is some evidence of appropriate knowledge, skills, and experience for the scope. Meets requirements in some areas but has important omissions.</td>
<td>Reflects that the bidder has not provided evidence to suggest how they will address several bullet points under the evaluation criteria headings. Tender is, in part, sketchy, with little or no detail given of how the project requirements will be met. Evidence provided is considered weak or inappropriate and is unclear on how this relates to the desired outcomes.</td>
</tr>
<tr>
<td>Serious reservations</td>
<td>1</td>
<td>Limited evidence of appropriate knowledge, skills, and experience for the scope.</td>
<td>Reflects major weaknesses or gaps in the information provided. The bidder displays poor understanding and there are major doubts about fitness for purpose.</td>
</tr>
<tr>
<td>Unacceptable</td>
<td>0</td>
<td>No evidence of knowledge, skills, and experience for the scope.</td>
<td>Results if no response is given and/or if the response is not acceptable and/or does not cover the required criteria.</td>
</tr>
</tbody>
</table>
8.4.1 **Financial evaluation:** The “total cost” will be evaluated for the purposes of financial evaluation and prices are not subject to any pricing assumptions, qualifications, or indexation other than that stated in the financial proposal. A maximum score of 25 (financial score/points allocated in the evaluation criteria) will be awarded to the proposal offering the lowest “overall cost.” Other proposals will be awarded a mark by application of the following formula: \((\text{lowest overall cost} / \text{overall cost being evaluated}) \times x\) (rounded to one decimal place) = financial score. Annex B provides detailed guidelines on inclusions and exclusions for your consideration in preparation of the financial proposal. Applicable currency: Vietnam Dong is acceptable for financial proposal.

8.4.2 **Moderation and application of weightings:** The evaluation panel will moderate criteria that have substantial divergence among the individual scores and agree on the final score (as opposed to averaging scores). The score for each award criterion will be amalgamated to give a percentage score out of 100.

8.4.3 **The recommended winning supplier:** The recommended award winner will be the proposal that receives the highest score out of 100 (combined technical and financial scores) when applying the above evaluation methodology. **PATH reserves the right to:**

- PATH has the right to eliminate bids for technical or other reasons throughout the evaluation/selection process. PATH shall not in any way be obliged to reveal, or discuss with any bidder, how a proposal was assessed, or to provide any other information relating to the evaluation/selection process or to state the reasons for elimination to any bidder.

- Award the contract to a bidder of its choice, even if its financial proposal is not the lowest.
Annex A: RFP#2024-002 Tips on Proposal Preparation and Submission

To ensure your proposal is submitted and accepted for review by PATH:

- Please send the proposal on time to avoid any last-minute technology issues.
- The technical proposal and the financial proposal should be clearly separated in different sections or files.
- No additional supporting documentation is to be submitted other than what the RFP has requested. PDF, JPG, PPT, Word, and Excel formats can be used for any additional information (other formats should be avoided and may not be operationally supported).
- For ease of review, any supporting documents must be attached separately to your main proposal and clearly labeled as to which part of your proposal each relates.
- Any generic policy document submitted needs to clearly indicate the section that is relevant to your proposal.
- Deliberate alteration of a PATH requirement as part of your proposal will invalidate your proposal; and for evaluation purposes, you may be deemed not to have responded to the requirement.

Your proposal (technical and financial) may be incorporated into the contract as appropriately determined at the contract negotiation stage.
Annex B. Financial proposal

The financial proposal should comply with the following guidelines.

Itemized costs

Provide itemized costs for the total scope of this project, based on the scope of work and deliverables outlined in section 6. The final scope of work may be subject to negotiation; however, bidder selection will be made against the original scope of work. Bids should include itemized costs for key elements of the scope of work, as follows:

- Itemization of import permit application and custom clearance cost.
- Roles and rates of key staff, estimated total level of effort and associated costs (if any).
- Itemization of all other costs (storage, delivery, e.g., service tax, etc. (if any).
- Reimbursable costs (e.g., transportation/flights, accommodations, internet, agency costs, agency fees, subcontracted resources, administrative costs, supplies, taxes).

The bidder must provide a VAT invoice for all the listed costs to be paid by PATH.