

Request for quotation (RFQ) number: 2025-HEPC3P-01

For: Importation of medical needle and syringe for research use

1.	Summarv	of deadlines
	Gammary	

Activity	Deadline (Hanoi time)	
Release of RFQ	May 29, 2025	
Quotations due	June 10, 2025 at 5:00PM	
Shorlist interview (if any)	June 12-13, 2025	
Bidders notified of decision	Week June 16-20, 2025	

Note: PATH reserves the right to modify this schedule as needed. All parties will be notified simultaneously by email of any changes.

2. PATH statement of business

PATH is a global nonprofit dedicated to a mission to advance health equity through innovation and partnerships. 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 <u>www.path.org</u>.

3. Purpose of the request for quotations

Briefly describe the purpose of the RFQ here.

• Deliverables:

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 1) obtaining the numbers of declarations of applied standards for Class-A or Class-B medical devices on the portal on the management of medical devices (https://imda.moh.gov.vn/) and 2) successfully clearing customs and importation procedures of the

study products. Bidders are required to provide confirmation on whether they could successfully obtain the numbers of declarations of applied standards for Class-A or Class-B medical devices 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. Under the agreement between PATH and the product owner, work closely with the physical manufacturers to obtain all of the documents needed for the applications for declarations of applied standards for Class-A or Class-B medical devices for the study products.

c. Submit the applications for declarations of applied standards for Class-A or Class-B medical devices for the study products and respond to any further requests from the local Department of Health until the numbers of declarations of applied standards for Class-A or Class-B medical devices for the study products are obtained.

d. 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.

e. 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.

f. 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.

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

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

i. Handle any requests (if any) from the local Department of Health and other authorities as part of the management of study products post-importation.

Required experience

Experience in 1) obtaining the numbers of declarations of applied standards for Class-A or Class-B medical devices, and 2) successfully clearing customs and importation procedures for needles and syringes products produced by Chinese manufacturers within 3 years is required.

Assumptions

- a. Study sites: Quy Chau and Que Phong District Health Centers in Nghe An province
- b. Duration for study implementation: 12 months
- c. Number of shipment: 01
- d. Estimated value of the shipment (for reference only): USD 40,000
- Specifications: Detailed information on study products:

No.	Medical device name	Model/code	Name of physical manufacturer & country of origin	Name of product owner & country	Quantity*
1	Hypodermic needle, single- use, sterile	16 mm 25G 0.5mm 5/8 inch orange, total dose, disposable needles (Low dead space) (TO16)	Zhejiang Kindly Medical Devices Co., Ltd, China	Exchange Supplies, United Kingdom	500,000 Units

No.	Medical device name	Model/code	Name of physical manufacturer & country of origin	Name of product owner & country	Quantity*
		(https://www.exchangesupplies.org/ product/orange_total_dose_16mm_1 ow_dead_space_needle)			
2	Hypodermic needle, single- use, sterile	25 mm 25G 0.5mm 1 inch orange, total dose, disposable needles (Low dead space) (TO25) (https://www.exchangesupplies.org/ product/orange total dose 25mm 1 ow_dead_space_needle)	Zhejiang Kindly Medical Devices Co., Ltd, China	Exchange Supplies, United Kingdom	500,000 Units
3	Syringe, general- purpose	unifix 3mL Luer slip syringe (UX3) (https://www.exchangesupplies.org/ product/UX3)	Shanghai Kindly Enterprise Development Group Co., Ltd. China	Exchange Supplies, United Kingdom	500,000 Units

*According to the approved protocol. The actual quantity may be less.

- Estimated dimensions: 29 cartons (490 mm x 445 mm x 455 mm) and 80 cartons (580 mm x 440 mm x 530 mm)
- Estimated timeline:

	Detailed Deliverables	Timeline	
1	The applications for declarations of applied standards for Class-A or Class-B medical devices for the study products are submitted.	1 July 2025	
2	The numbers of declarations of applied standards for Class-A or Class-B medical devices for the study products are posted on the portal on the management of medical devices (https://imda.moh.gov.vn/).	15 August 2025	
3	Study products are cleared at the imported port.	No later than 5 days after study products arriving at importation port.	
4	Sub-label in Vietnamese is affixed on study products.	Within 3 days after study products are cleared at importation port	
5	Study products are delivered at the study sites per requests and instructions from PATH.	 First delivery: no later than 3 days after study products are cleared at importation port. Other deliveries (quarterly, maximum 4 times): per requests and instructions from PATH throughout the study implementation period. 	

h	Storage and inventory documentation of study	Per requests and instructions from PATH throughout the study implementation period.
	h	

4. Quotation requirements, pricing, and costs

Please insert your costs in the table below. The costs should be broken down into components and include a full description of each component and its associated time and costs.

Line item no.	Component/Item [insert name]	Component/Item description	Delivery date [by when?]	Unit cost [VND]	Total line item cost [VND]
	Net price				
	VAT %				
	Total price				

Note:

- Indicate associated services for delivery of the supply, as applicable, including any cost of deliverables/commodities, shipping/freight, insurance, import taxes, any other associated costs, payment terms (if not standard; that is, payment after delivery), or any other costs not listed.
- The supplier is expected to submit a profile of corporate qualification, a summary of experience in similar/related work carried out in the past 24 to 36 months, number of years in business, annual revenue for the last three financial periods, clarification regarding which specific company legal entity is bidding, and any other relevant justification for qualification.
- By submitting a quotation, the supplier consents for PATH to carry out further due diligence, responsibly and in line with relevant General Data Protection Regulation provisions.
- Applicable currency: Vietnam Dong (VND)

5. Instructions for responding

A. PATH contacts

Technical/Program contact: <u>ango@path.org</u> Procurement contact: Vietnam Procurement Team (<u>vietnam.procurement@path.org</u>; <u>htnguyen@path.org</u>)

B. Quotations due: June 10, 2025, 5:00PM Hanoi time

Completed quotations should be submitted by email to the contacts listed above. The subject line of the email should read: RFQ #2025-HEPC3P-01 Your Company Name.

C. Conclusion of process

Applicants will be notified of PATH's decision by the week of June 16-20, 2025. Final award is subject to the terms and conditions included in this solicitation, as well as successful final negotiations of all applicable terms and conditions affecting this work.

6. Terms and conditions of the solicitation

A. 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.

B. Confidentiality

All information provided by PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed. Proposals, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

C. Conflict of interest disclosure

Suppliers bidding on PATH business must disclose, to the procurement contact listed in the RFP, any actual or potential conflicts of interest. Conflicts of interest could include a personal relationship with a PATH staff member that constitutes a significant financial interest; board memberships or other employment; and/or ownership or rights in intellectual property that may be in 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. 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 communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section 5 A.

D. Acceptance

Acceptance of a proposal does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We also reserve the right to negotiate the substance of finalists' proposals, as well as the option of accepting partial components of a proposal if appropriate.

E. Proposal validity

Proposals submitted under this request shall be valid for 90 days from the date the proposal is due. The validity period shall be stated in the proposal submitted to PATH.