BID BULLETIN NO. 4
12 December 2023

PROCUREMENT OF PNEUMOCOCCAL CONJUGATE VACCINE
IB NO. 2024-003

This Bid Bulletin is being issued to announce the new schedule of the Submission and Opening of Bids set on 13 December 2023, to amend or modify the bidding documents posted in the PhilGEPS and DOH websites for the above-cited project, and to respond to Prospective Bidders (PBs) inquiries. This Bid Bulletin will form an integral part of the bidding document.

Listed below are the corresponding modifications/changes and responses:

1. **New Schedule of Activity:**

Activity	From	To	Venue
Submission and Opening of Bids	13 December 2023; 9:00 AM	**20 December 2023; 9:00 AM**	COBAC Conference Room, Ground Floor, Building No. 6, Department of Health, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila, and/or through video conferencing or webcasting via Cisco Webex

2. **Response to PBs' inquiries:**

Particular	Inquiry	End-user Unit (EUU)
GlaxoSmithKline Philippines, Inc.	Request to revise the tare weight for the Thermal packaging from 26.5kg to 25kg.	Please refer to the attached revised Technical Specification form
Faberco Life Sciences Inc.	Request to wait on the HTAC Review and pending recommendation.	The EUU retains the Technical Specifications as cited in the PR. The EUU shall revisit the technical specifications for the succeeding procurement cycle, once the HTAC Reassessment is released.

The revised Technical Specification is enclosed for the Prospective Bidders' reference and use.

All other provisions indicated in the bidding documents which are not affected by this Bid Bulletin shall remain in effect.

For guidance and information of all concerned.

NESTOR F. SANTIAGO, JR., MD, MPHC, MHSA, CESO II
Undersecretary of Health
COBAC-D Chairperson

Technical Specifications

Republic of the Philippines
Department of Health
TECHNICAL SPECIFICATIONS

Item No. 1	**Pneumococcal Conjugate Vaccine**	Quantity / Unit	**3,340,000 Doses**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP 1,204,070,000.00**			

PURCHASER'S SPECIFICATION	**STATEMENT OF COMPLIANCE**
A. Detailed Technical Specifications: 1. **Route of Administration**: Intramuscular (IM) 2. **Form and Strength**: a) Multi-dose vial preparation indicated for the following minimum serotypes: 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F 3. **With Vaccine Vial Monitor (VVM)** 4. **Additional Support:** • Thermal packaging: 300 units Packaging System Specification: o Temperature range: +2°C to +8 °C o Payload Volume: **42 liters** o Duration **100 hours** o Coolant Type: HDPE machine sealed PCM Coolant o Payload Size Imperial: **18 x 12 x 12 in** o Outer Dimension Imperial: **24.25 x 16.50 x 17.00 in** o Tare Weight Metric: **21 kg** o Validation: ISTA7D	

B. Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:

1. Valid and current Certificate Product Registration (CPR) or Valid Extension issued by Philippine Food and Drug Administration (PFDA);

   The CPR must be valid for the entire period of the award. If the CPR is about to expire, the supplier must have submitted a copy of an application of renewal to the FDA at least 3 months before the expiry date (**a copy of the expiring CPR which is stamped with an "Extension of Validity" shall be submitted as proof**); [AO 2019-0041]

2. Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA). ***Provided, that the application for renewal was made timely as per DOH AO No. 2016-003:***

   In case of expired LTO, the following copies may be submitted:
   - (i) expired LTO;
   - (ii) application for renewal with FDA document tracking number; and,
   - (iii) Official Receipt as proof of payment of renewal of LTO

3. Product Insert/Product Information or downloaded from the internet and other manufacturer's un-

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Pneumococcal Conjugate Vaccine**	Quantity / Unit	**3,340,000 Doses**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP 1,204,070,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

amended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate for cross-referencing statement of compliance to the technical specification in accordance to what is indicated in Technical Specifications;

4. Certification from the Manufacturer/Distributor/Importer/Wholesaler (as reflected in the Certificate of Product Registration of the product/s to be bid) that the Bidder is an authorized dealer or distributor of the product

5. Certificate of Compliance to the Electronic Drug Price Monitoring System (EDPMS) issued by either the Pharmaceutical Division (PD) of the DOH or DOH Regional Health Office/Centers for Health Development pursuant to DOH Administrative Order No. 2018-0020 and RA 9502 and its IRR;

   In case of expired Certificate of Compliance to the EDPMS, refer to DOH Department Circular (DC) No.2023-0001, "Interim Guidelines on the Certificate of Compliance to Electronic Drug Price Monitoring System for Government Procurement Activities for Drugs and Medicines."

6. WHO Prequalification Certificate/Listing;

7. Sworn Statement *using the prescribed form.*

8. Guarantee letter from Supplier to replace medicines with approved shorter life when returned six (6) months before expiry date.

C. Replacement Instruction:

Medicines with approved shorter shelf life, replacement for fresh stocks shall be issued when returned six (6) months before the expiry date.

D. <u>Upon delivery the following shall be complied with:</u>

1. **Shelf life:** Must be fresh commercial stock with a total shelf-life of at least twenty-four (24) months from the date of manufacture but not less than eighteen (18) months from the date of delivery.

2. **Packaging instructions:**

   a) Standard packaging of the manufacturer as approved by PFDA.

3. **Labeling instructions:**

   a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Pneumococcal Conjugate Vaccine**	Quantity / Unit	**3,340,000 Doses**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP 1,204,070,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

b) **In addition to the labelling requirements of FDA:**

i. Each **box** should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed:

Philippine Government Property – Department of Health
NOT FOR SALE

ii. Each **bigger box/corrugated carton** should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed:

Philippine Government Property – Department of Health
NOT FOR SALE

Date of Manufacture: _____
Date of Expiry: _____
Batch/Lot No.: _____

E. Product Recall & Disposal:

1. The Supplier must ensure the quality of products and if there will be problems in the quality, the Supplier will recall and replace the products distributed in the regions/hospitals/treatment hubs/RHU/HC/BHSS based on Guidelines on Product Recall, FDA Circular No. 2016-012;

2. In instances of product recalls due to failures of suppliers and manufacturers to comply with standards of safety and quality, the cost associated with proper disposal/ destruction, handling or pull out from health facilities where these products have already been distributed shall be borne by the supplier (subject to the latest policy for disposal) (DOH Administrative Order (AO) No. 2019-0041).

_____
Signature over Printed Name
[date of signing]

In the capacity of: *[title or other appropriate designation]*
Duly authorized to sign bid for and on behalf of: *[Name of Company]*
[Complete office address]
[Contact No.]
[Fax No.]
[Email Address]