Republic of the Philippines
Department of Health

CENTRAL OFFICE BIDS AND AWARDS COMMITTEE

BID BULLETIN NO. 3
24 November 2023

PROCUREMENT OF TENOFOVIR, LAMIVUDINE + TENOFOVIR AND ABACAVIR
IB NO. 2024-043

This Bid Bulletin is being issued to amend or modify the bidding documents posted on the PhilGEPS and DOH websites for the above-cited project, This Bid Bulletin will form an integral part of the bidding document.

Listed below are the corresponding modifications/changes and responses:

1. **Section VII. Technical Specification**

Particular	Response
Shelf-life for Item No.3: Abacavir	Please refer to the attached revised Technical Specification Form.

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

All other provisions of the bidding documents which are not affected 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. 3	**Abacavir**	Quantity / Unit	**4,980 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No.3: **PhP4,590,813.00**			

PURCHASER'S SPECIFICATION	**STATEMENT OF COMPLIANCE**
A. Detailed Technical Specifications: 1. **Route of Administration**: Oral 2. **Form and Strength**: a) 300mg b) Tablet c) as sulfate	

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-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

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
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PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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. Sworn Statement *using the prescribed form.*

7. 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. Upon delivery the following shall be complied with:

1. **Shelf life:** Must be fresh commercial stock with a total shelf life of **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) Primary Packaging – 60 tablets per bottle
   b) Secondary Packaging – 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.

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

      i. Each **bottle and 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 **small/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

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 3	**Abacavir**	Quantity / Unit	**4,980 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
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PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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]