Republic of the Philippines
Department of Health
CENTRAL OFFICE BIDS AND AWARDS COMMITTEE

BID BULLETIN NO. 2
23 November 2023

PROCUREMENT OF DOLUTEGRAVIR
IB NO. 2024-045

This Bid Bulletin is being issued to announce the new schedule of the Submission and Opening of Bids, to amend or modify the Bidding Documents posted in DOH and PhilGEPS websites, to respond to queries of Prospective Bidders (PBs), and, to respond to the issue/concern raised during the Pre-Bidding Conference for the Procurement of Dolutegravir under IB No. 2024-045. This Bid Bulletin will form an integral part of the bidding documents. Listed below are the corresponding modifications/changes:

1. New Schedule of Activities:

Activity	From	To	Venue
	Date/Time	Date/time	
Submission and Opening of Bids	08 November 2023, 9:00 AM	**01 December 2023, 9:00 AM**	COBAC Conference Room, Ground Floor, Bldg. No. 6, Department of Health, Sta. Cruz, Manila, and/or through video conferencing or webcasting via Cisco Webex

2. Response to the query of L. Meyerf Pharma Inc.:

Particular	Issue/Concern	End User Unit (EUU) Response
Schedule of Requirements	To extend the delivery period to: Ninety (90) calendar days upon receipt of approved NTP	Please refer to the revised Schedule of Requirements Form.
Technical Specification	Request for the shelf life of **twenty-four (24) months** from the date of manufacture but not less than **eighteen (18) months** from the date of delivery based on the valid Certificate of Product Registration	Please refer to the revised Technical Specification Form.

3. Response to the query of MedEthix Inc.:

Particular	Issue/Concern	End User Unit (EUU) Response
Schedule of Requirements	To extend the delivery period to: Ninety (90) calendar days upon receipt of approved NTP	Please refer to the revised Schedule of Requirements Form.

4. Response to the query of Faberco Life Sciences Inc.:

Particular	Issue/Concern	Response
Schedule of the Submission and Opening of Bids	Request for a 7-day extension of the Submission and Opening of Bids due to nultiple holidays, both national and international which leaves the PBs 10-days to prepare and may put insufficient time to ready the requirements specially those documents needs to be apostilled and/or documents needs approval from other country/ies.	Please refer to the new schedule of activities stated above.

5. Response to the issue/concern raised during the Pre-Bidding Conference:

Particular	Issue/Concern	End User Unit (EUU) Response
Delivered, Calendar Days **Sixty (60)** calendar days upon receipt of approved Notice to Proceed (NTP)	The PB requested to change the delivery period to: Ninety (90) calendar days from receipt of approved Notice to Proceed (NTP).	Please refer to the revised Schedule of Requirements Form.
Guarantee Letter and Replacement Instruction	PBs are requesting for a standard template/form for the said requirement and if the reckoning date of the guarantee letter should be upon receipt of delivery. Further, PBs requested to consider replacement *three (3) months* before expiry date when returned same in the commercial setting rather than six (6) months as stated in the requirements.	Regarding the format of the Guarantee Letter, the Pharmaceutical Division (PD) responded that there is no predefined template available. Instead, a letter from the supplier, affirming their commitment to replace the product, will be acceptable. The guarantee letter will be subject to approval by the end-user.

The revised Schedule of Requirements Form and Technical Specification are enclosed for the Prospective Bidders' reference and use.

All other provisions of the bidding documents which are not affected shall remain in force and in effect.

For guidance and information of all concerned.

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

Section VI. Schedule of Requirements

The delivery schedule expressed as calendar days stipulates hereafter a delivery date which is the date of delivery to the project site.

Item Number	Description	Quantity/ Unit	Total ABC (PhP)	Delivery Site	Delivered, Calendar Days
1	Dolutegravir	100,707 bottles	14,750,554.29	DOH Warehouse(s) in Metro Manila	**Ninety (90)** calendar days from receipt of the approved Notice to Proceed (NTP)

_____
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]

Technical Specifications

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Dolutegravir**	Quantity / Unit	**100,707 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP14,750,554.29**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
A. Detailed Technical Specifications: 1. **Route of Administration**: Oral 2. **Form and Strength**: a) 50mg b) Tablet			

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 IRR;

   In case of expired Certificate of Compliance to the EDPMS, refer to DOH Department

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Dolutegravir**	Quantity / Unit	**100,707 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP14,750,554.29**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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: 30 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
      NOT FOR SALE

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

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Dolutegravir**	Quantity / Unit	**100,707 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP14,750,554.29**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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]