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

BID BULLETIN NO. 2
23 November 2023

PROCUREMENT OF SOFOSBUVIR AND DACLATASVIR
IB NO. 2024-046

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 query of L. Meyerf Pharma Inc. (LMPI), and, to respond to the issue/concern raised during the Pre-Bidding Conference for the Procurement of Sofosbuvir and Daclatasvir under IB No. 2024-046. 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. Section VII. Technical Specification:

Particular		Concern
Item No. 2 - Daclatasvir	Shelf Life	Please refer to the revised Technical Specification Form

3. Response to the query of LMPI:

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 issue/concern raised during the Pre-Bidding Conference:

Particular	Issue/Concern	End User Unit (EUU) Response
Delivered, Calendar Days	The PB requested to change the delivery period to:	See revised Schedule of

Particular	Issue/Concern	End User Unit (EUU) Response
Sixty (60) calendar days upon receipt of approved Notice to Proceed (NTP)	Ninety (90) calendar days from receipt of approved Notice to Proceed (NTP).	Requirements Form.

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	Sofosbuvir	7,000 bottles	12,624,710.00	DOH Warehouse(s) in Metro Manila	**Ninety (90)** calendar days from receipt of the approved Notice to Proceed (NTP)
2	Daclatasvir	7,000 bottles	10,461,710.00		

_____
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. 2	**Daclatasvir**	Quantity / Unit	**7,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No.2: **PhP10,461,710.00**			

PURCHASER'S SPECIFICATION	**STATEMENT OF COMPLIANCE**
A. Detailed Technical Specifications: 1. **Route of Administration**: Oral 2. **Form and Strength**: a) 60mg 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. 2	**Daclatasvir**	Quantity / Unit	**7,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No.2: **PhP10,461,710.00**			
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. <u>Upon delivery the following shall be complied with:</u>

1. **Shelf life:** Must be fresh commercial stock with a total shelf life of **thirty-two (32) months** from the date of manufacture but not less than **twenty-four (24) months** from the date of delivery.

2. **Packaging instructions:**

   a) Primary Packaging - 28 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 and bigger box or 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. 2	**Daclatasvir**	Quantity / Unit	**7,000 bottles**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No.2: **PhP10,461,710.00**			
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]