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

BID BULLETIN NO. 3
11 December 2020

PROCUREMENT OF ANTI-TB DRUGS AND MEDICINES
IB No. 2021-005

This Bid Bulletin is being issued to announce the new schedule of the Submission and Opening of Bids previously scheduled on 02 December 2020, 9:00 A.M, to amend or modify the posted Bidding Documents in the DOH and PhilGEPS website, to clarify the issues and concerns raised during the Pre-Bidding Conference held last 18 November 2020, and to respond and to the letter of Pfizer Inc. (PI) for the Procurement of Anti-TB Drugs and Medicines under IB No. 2021-005. This Bid Bulletin shall form an integral part of the bidding document. Listed below are the corresponding modifications/changes:

1. **New Schedule of Activity:**

Activity	From	To	Venue
Submission and Opening of Bids	02 December 2020; 9:00 A.M	**18 December 2020; 9:00 A.M.**	COBAC Conference Room, G/F, Bldg. 6 Department of Health San Lazaro Compound, Rizal Avenue Sta. Cruz, Manila

2. **Section I. Invitation to Bid**

FROM	TO
2. The *DOH* now invites bids for the *procurement of the above-captioned project.* Delivery of the Goods is required *within the period specified under SECTION VI. Schedule of Requirements.* Bidders should have completed, *within two (2) years from the date of submission and receipt of bids,* a contract similar to the Project, *equivalent to at least twenty five percent (25%) of the ABC.* The description of an eligible bidder is contained in the Bidding Documents, particularly, in Section II. Instructions to Bidders.	2. The *DOH* now invites bids for the *procurement of the above-captioned project.* Delivery of the Goods is required *within the period specified under SECTION VI. Schedule of Requirements.* Bidders should have completed, *within **five (5)** years from the date of submission and receipt of bids,* a contract similar to the Project, equivalent to: a) At least (2) similar contracts, and the aggregate contract amounts should be equivalent to at least twenty five percent (25%) of the (ABC) as required above. b) The largest of these similar contracts must be equivalent to at least half of the twenty five percent (25%) of the ABC as required above. xxx

3. Section II. Instruction to Bidders

FROM	TO
5.3 Pursuant to Section 23.4.1.3 of the 2016 revised IRR of RA No.9184, the Bidder shall have an SLCC that is at least one (1) contract similar to the Project the value of which, adjusted to current prices using the PSA's CPI, must be at least equivalent to: a. For the Expendable Supplies: The Bidder must have completed a single contract that is similar to this Project, equivalent to at least twenty-five percent (25%) of the ABC.	5.3 Pursuant to Section 23.4.1.3 of the 2016 revised IRR of RA No.9184, the Bidder shall have an SLCC that is at least one (1) contract similar to the Project the value of which, adjusted to current prices using the PSA's CPI, must be at least equivalent to: a. For procurement where the Procuring Entity has determined, after the conduct of market research, that imposition of either (a) or (b) will likely result to failure of bidding or monopoly that will defeat the purpose of public bidding: the Bidder should comply with the following requirements: i. Completed at least two (2) similar contracts, the aggregate amount of which should be equivalent to at least *twenty-five percent (25%)* of the ABC for this Project; and ii. The largest of these similar contracts must be equivalent to at least half of the percentage of the ABC as required above.
10.2 The Bidder's SLCC as indicated in **ITB** Clause 5.3 should have been completed within *two (2) years* prior to the deadline for the submission and receipt of bids.	10.2 Bidders should have completed as indicated in ITB Clause 5.3 within ***five (5) years*** prior to the deadline for the submission and receipt of bids, a contract similar to the Project, equivalent to: a) At least (2) similar contracts, and the aggregate contract amounts should be equivalent to at least twenty-five percent (25%) of the (ABC) as required above. b) The largest of these similar contracts must be equivalent to at least half of the twenty five percent (25%) of the ABC as required above.

4. Section III. Bid Data Sheet

ITB Clause 20.1 is included.

5. **Section VIII. Checklist of Technical and Financial Documents**

Particular	FROM	TO
I. f	Statement of the bidder's Single Largest Completed Contract (SLCC) similar to the contract to be bid *equivalent to at least twenty five percent (25%) of the ABC*, except under conditions provided for in Sections 23.4.1.3 and 23.4.2.4 of the 2016 revised IRR of RA No. 9184, within the relevant period as provided in the Bidding Documents; **and**	Statement of the bidder's two (2) or more completed contracts similar to the contract to be bid within ***five (5)*** years, *the aggregate amount should be equivalent to at least twenty-five percent (25%)* **of the ABC.** The largest of these similar contracts must be equivalent to at least half of the percentage of the ABC as required above.
I. h	Conformity with the Schedule of Requirements and Technical Specifications, which may include production/delivery schedule, manpower requirements, and/or after- sales/parts, if applicable;	Conformity with the Schedule of Requirements, Technical Specifications **and Framework Agreement List**, which may include production/delivery schedule, manpower requirements, and/or after- sales/parts, if applicable;

6. **Response to the Queries of Pfizer Inc. (PI) and other bidder(s):**

QUERY	COBAC/END-USER's RESPONSE
1. **Framework Agreement and Delivery Schedule** Pfizer proposes three (3) indicative delivery schedules for the Call-Offs	The quantity for each delivery will be provided to the supplier by the Disease Prevention and Control Bureau (DPCB) upon Call-Offs.
2. Apostille requirement for the Manufacturer's Authorization/Certificate of Exclusive Distributorship	The Committee already addressed this inquiry during the Pre-Bidding Conference wherein the Committee informed that the Bidding requirement does not require authenticated or Apostille Manufacturer's Certification or Certificate of Exclusive Distributorship. Refer to Bid Data Sheet ITB Clause 21.2.
3. **Digital Signature**	The Committee already addressed the cited inquiry during the Pre-Bidding conference wherein it was informed that the electronic submission of documents is accepted as long as the file to be submitted is password-protected which will be provided during the scheduled Opening of Bids pursuant to GPPB Resolution 09-2020.
4. **Certification of Copies True and Correct by the Authorized Representative**	The Committee reiterated during the Pre-Bidding Conference that Certified True Copies (CTC) of documents is still a requirement.
5. **Submission of Income and Business Tax Return** Pfizer requested for confirmation that the requirement for the submission of tax returns	Refer to the attached Revised Bid Data Sheet ITB Clause 20.1.

QUERY	COBAC/END-USER's RESPONSE
pertains to the last six (6) months immediately preceding the date of submission.	
6. **Testing by the Food and Drug Administration (FDA)** a) Whether the submission by the Supplier of a Certificate of Analysis issued by the manufacturer will be acceptable to the DOH, in lieu of FDA testing and analysis; b) Should the submission of the manufacturer's Certificate of Analysis not be acceptable as a substitute for FDA testing, please advise on the following:	Refer to General Conditions of the Contract (GCC) and Special Conditions of the Contract (SCC) No. 4.
1. On timeline and payment i. Whether the DOH has provided, and whether the FDA is bound to comply, with a period within which the laboratory testing and analysis of the TB Drugs must be completed;	Yes, under normal conditions.
ii. Within what period the Supplier should expect to receive the fifty percent (50%) balance, should the FDA fail to release the results of the laboratory analysis within thirty (30) days from receipt of delivery of the Goods; and	Refer to the GCC Clause 2.2 or you can directly raise your inquiry with the Administrative and Finance Management Team (AFMT) on the prevailing accounting and auditing rules and regulation.
iii. What is the indicative amount that will be charged to the Supplier as laboratory testing fee, and whether such fee will be based on the number of items tested, or charged on a "per batch" basis (or any other basis).	For FDA concerns 6.1.iii, and 6.2.i,ii,iii and 3.i,ii, refer to the FDA website or the bidder can submit a formal request to the Director General of the Food and Drug Administration, Dr. Rolando Enrique Domingo (FDA). For specific concerns, refer to: 1. PFDA Circular 2014-014 on the minimum samples for each tests analysis of delivered medicines. 2. PFDA Circular No. 2016-012 on guidelines of Product Recall
2. On conduct of analysis i. Can the supplier discuss with FDA, the analytical method transfer before the conduct of the actual test?	
ii. Will there be a discussion between the supplier and the FDA before disposition? Due to possible analytical testing issues that may vary between manufacturer and the FDA, is there an appeal process for the supplier before the disposition is finalized?	
iii. Will the test results be shared to the supplier before its posting in the FDA website?	

QUERY	COBAC/END-USER's RESPONSE
3. In the unlikely event of batch rejection i. What are the next steps should a batch not pass testing? ii. How will the stocks delivered to the DOH be handled?	
7. **Price** Pfizer respectfully requests the DOH and the end-user to consider increasing the cost per item indicated in the Framework Agreement List by ten percent (10%), in order to address the global increase in the cost of the Goods and ensure a fair and equitable return for bidders.	No change in unit cost as cleared by the Pharmaceutical Division (PD) based on reference to the Drug Price Reference Index (DPRI).
8. **Request to Postpone Bid Submission.**	No changes in the procurement timeline as indicated in the Bidding Documents and Bid Bulletins
9. **Shelf-life Requirements:** • Shelf-life requirement should be three (3) years from the date of manufacture.	The End-user reiterates that the shelf-life of three (3) years is acceptable to the program but the minimum requirement of twenty-four (24) months from the date of manufacture but not less than eighteen months from the date of delivery will still be indicated in the bidding document.

The revised Bid Data Sheet and Checklist of Technical and Financial Documents are enclosed for the Prospective Bidder's 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
Assistant Secretary of Health
Chairperson, COBAC-A

Bid Data Sheet

<table>
<tr><th>ITB Clause</th><th></th></tr>
<tr><td>5.3</td><td>For this purpose, contracts similar to the Project shall be:

a. various drugs and medicine, vaccines, and other biological products

b. completed within two (2) years prior to the deadline for the submission and receipt of bids.</td></tr>
<tr><td>7.1</td><td>Not applicable</td></tr>
<tr><td>12</td><td>The price of the Goods shall be quoted DDP DOH warehouse or the applicable International Commercial Terms (INCOTERMS) for this Project.</td></tr>
<tr><td>14.1</td><td>The bid security shall be in the form of a Bid Securing Declaration, or any of the following forms and amounts:

a The amount of not less than PhP₱10,056,656.33, if bid security is in cash, cashier's/manager's check, bank draft/guarantee or irrevocable letter of credit; or

b The amount of not less than PhP₱25,141,640.83 if bid security is in Surety Bond.</td></tr>
<tr><td>15</td><td>Each Bidder shall submit one (1) original and two (2) copies of the first and second components of its bid: 1st copy- marked as 'ORIGINAL'; 2nd copy- marked as 'COPY 1'; 3rd copy- marked as 'COPY 2'.</td></tr>
<tr><td>19.3</td><td>The ABC is Five Hundred Two Million Eight Hundred Thirty-Two Thousand Eight Hundred Sixteen Philippine Pesos and Sixty Four Centavos (PhP502,832,816.64). Any bid with a financial component exceeding this amount shall not be accepted.
<table>
<tr><th>Lot No.</th><th>Item No.</th><th>Description</th><th>Qty.</th><th>Unit</th><th>Total ABC (PhP)</th></tr>
<tr><td rowspan="2">1</td><td>1</td><td>Rifampicin + Isoniazid</td><td>67,585,056</td><td rowspan="2">Tablet</td><td rowspan="2">502,832,816.64</td></tr>
<tr><td>2</td><td>Rifampicin + Isoniazid + Pyrazinamide + Ethambutol HCl</td><td>33,792,528</td></tr>
</table></td></tr>
<tr><td>20.1</td><td>The LCB shall submit three (3) sets of true copies of the original certified as such by the bidder or his duly authorized signatory within a <u>non-extendible period of five (5) calendar days</u> from receipt of the notification arranged, numbered and tabbed as enumerated below:

(a) Latest Annual Tax Return filed thru Electronic Filing and Payment Systems (EFPS) and must be duly validated with the tax payments made thereon for the preceding Tax Year be it on a calendar or fiscal year income (per Revenue Regulations 3-2005);

(b) Latest Business Tax Return filed thru Electronic Filing and Payment System (EFPS) duly validated with the tax payments made thereon also refers to the Value Added Tax (VAT) or Percentage Tax Returns covering the previous</td></tr>
</table>

	six (6) months (per Revenue Regulations 3-2005); *The latest income and business tax returns are those within the last six months preceding the date of bid submission* (c) Articles of Incorporation and General Information Sheet (GIS), in case the Bidder has submitted a SEC registration as part of the Eligibility Documents, if applicable; and (d) *Valid and current Certificate of PhilGEPS Registration and Membership – Platinum (In the event the bidder opted to submit only the Class "A" Eligibility Documents (Pursuant to GPPB Circular 07-2017 dated 31 July 2017).* *Failure of the Bidder declared as LCB to duly submit the requirements stated above or a finding against the veracity of such shall be ground for forfeiture of the bid security and disqualify the Bidder for award.* ***NOTE:*** ***1) In case of a JVA, each joint venture partners shall submit the above-cited Post-qualification Documentary Requirements (GPPB NPM 006-2010 dated 04 February 2010).*** ***2) As the possible Single/Lowest Calculated Responsive Bidder (S/LCRB), please provide the COBAC – A, soft copy in "Word" and in PDF the Technical Specifications you submitted during the Submission and Opening of Bids for the above-cited procurement project.*** ***3) All submitted documents during the Submission and Opening of Bids (original and the two (2) copies) by the S/LCB must be true copies of the original certified as such by the Bidder's duly authorized signatory***
20.2	List of required licenses and permits relevant to the Project and the corresponding law requiring it:

LICENSES AND PERMITS	LAW
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]	• *RA 9711, FDA Act of 2009 & its IRR: and* • *RA 9502, Cheaper Medicines Act of 2008and its IRR*

	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. 2016-0003:*** **In case of expired LTO, the following copies may be submitted:** (i) expired LTO; (ii) application for renewal; and (iii) Official Receipt as proof of payment of renewal of LTO	• *RA 9711, FDA Act of 2009 & its IRR*
21.2	Additional required documents relevant to the Project that are required by existing laws and/or the Procuring Entity: 1. 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 2nd page of Section VII. Technical Specifications of the Bidding Documents; 2. The bidder shall submit any of the following whichever is applicable: a) If the bidder is a manufacturer, certificate that the bidder manufactures the products/item; or b) If the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items, Certificate or Contract from the manufacturer or importer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or c) If the bidder is an agent of the exclusive distributor or dealer, the following must be provided: i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and ii. Contract between the distributor/dealer and the bidder. 3. 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.; **In case of expired Certificate of Compliance to the EDPMS which expires on a quarterly basis, the following copies may be submitted:** a) Confirmation through e-mail using the official e-mail address of PD or concerned DOH Regional Health Office/ Centers for Health Development; and, b) Copy of print screen stating that the drug company is already compliant in the EDPMS pending the issuance of the Certificate. 4. Sworn Statement *using the prescribed form*	

Checklist of Technical and Financial Documents Arranged numbered and tabbed as it appears below:

I. TECHNICAL COMPONENT ENVELOPE

Class "A" Documents

Legal Documents

☐ (a) Valid PhilGEPS Registration Certificate (Platinum Membership) (all pages);
or

☐ (b) Registration certificate from Securities and Exchange Commission (SEC), Department of Trade and Industry (DTI) for sole proprietorship, or Cooperative Development Authority (CDA) for cooperatives or its equivalent document,
and

☐ (c) Mayor's or Business permit issued by the city or municipality where the principal place of business of the prospective bidder is located, or the equivalent document for Exclusive Economic Zones or Areas (together with corresponding copy of receipt(s) of payments of the said permit);

In consideration of the limited access to financial institutions, regulatory and other offices, as well as the implementation of government restrictions on transport and travel, Acceptability of the recently expired Mayor's or Business permits and the Official Receipt as proof that the Bidder has applied and paid for the renewal of the permit ; Provided that, the current and valid Mayor's or Business Permit as renewed, will be submitted by the bidder with the LCRB after the award of contract but before payment (GPPB Circular 09-2020)
and

☐ (d) Tax clearance per E.O. No. 398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue (BIR).

Technical Documents

☐ (e) Statement of the prospective bidder of all its ongoing government and private contracts, including contracts awarded but not yet started, if any, whether similar or not similar in nature and complexity to the contract to be bid; **and**

☐ (f) Statement of the bidder's two (2) or more completed contracts similar to the contract to be bid within ***five (5)*** years, *the aggregate amount should be equivalent to at least twenty five percent (25%)* **of the ABC.**

The largest of these similar contracts must be equivalent to at least half of the percentage of the ABC as required above; **and**

☐ (g) Original copy of Bid Security. If in the form of a Surety Bond, submit also a certification issued by the Insurance Commission;

or
Original copy of Notarized Bid Securing Declaration; **and**

☐ (h) Conformity with the Schedule of Requirements, Technical Specifications and Framework Agreement List, which may include production/delivery schedule, manpower requirements, and/or after- sales/parts, if applicable; **and**

☐ (i) Original duly signed Omnibus Sworn Statement (OSS);

and if applicable, Original Notarized Secretary's Certificate in case of a corporation, partnership, or cooperative; or Original Special Power of Attorney of all members of the joint venture giving full power and authority to its officer to sign the OSS and do acts to represent the Bidder.

Financial Documents

☐ (j) The Supplier's audited financial statements, showing, among others, the Supplier's total and current assets and liabilities, stamped "received" by the BIR or its duly accredited and authorized institutions, for the preceding calendar year which should not be earlier than two (2) years from the date of bid submission; **and**

☐ (k) The prospective bidder's computation of Net Financial Contracting Capacity (NFCC);
or
A committed Line of Credit from a Universal or Commercial Bank in lieu of its NFCC computation.

Class "B" Documents

☐ (l) If applicable, a duly signed joint venture agreement (JVA) in case the joint venture is already in existence;
or

duly notarized statements from all the potential joint venture partners stating that they will enter into and abide by the provisions of the JVA in the instance that the bid is successful.

Other documentary requirements under RA No. 9184 (as applicable)

☐ (m) *[For foreign bidders claiming by reason of their country's extension of reciprocal rights to Filipinos]* Certification from the relevant government office of their country stating that Filipinos are allowed to participate in government procurement activities for the same item or product.

☐ (n) Certification from the DTI if the Bidder claims preference as a Domestic Bidder or Domestic Entity.

II. FINANCIAL COMPONENT ENVELOPE

☐ (a) Original of duly signed and accomplished Financial Bid Form; **and**
☐ (b) Original of duly signed and accomplished Price Schedule(s).

III. REQUIRED DOCUMENTS in BDS SECTIONS 20.2 and 21.2

☐ (a) 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]

☐ (b) 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; and,
(iii) Official Receipt as proof of payment of renewal of LTO

☐ (c) 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

☐ (d) The bidder shall submit any of the following whichever is applicable:

a) If the bidder is a manufacturer, certificate that the bidder manufactures the products/item; or
b) If the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items, Certificate or Contract from the manufacturer or importer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or
c) If the bidder is an agent of the exclusive distributor or dealer, the following must be provided:

i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and
ii. Contract between the distributor/dealer and the bidder.

☐ (e) 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 which expires on a quarterly basis, the following copies may be submitted:

a) Confirmation through e-mail using the official e-mail address of PD or concerned DOH Regional Health Office/ Centers for Health Development; and,
b) Copy of print screen stating that the drug company is already compliant in the EDPMS pending the issuance of the Certificate.

☐ (f) Guarantee letter from Supplier to replace medicines with approved shorter life when returned three (3) months before expiry date.

☐ (g) Sworn Statement *using the prescribed form*

Note:

1) Please refer to https://doh.gov.ph/sites/default/files/basic-page/COBAC-Prescribed-Forms.pdf for the following requirements:

a) Sworn Statement;
b) Computation of NFCC;
c) Manufacturer's Authorization;
d) Secretary's Certificate;
e) Special Power of Attorney;
f) Statement of Ongoing Contracts; and
g) Statement of SLCC.

2) For the following requirements, please refer to **GPPB Resolution No. 16-2020:**

a) Bid Form;
b) Price Schedule;
c) Bid Securing Declaration; and
d) Omnibus Sworn Statement