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

BID BULLETIN NO. 2
17 March 2021

PROCUREMENT OF PNEUMOCOCCAL CONJUGATE VACCINE (PCV)
IB No. 2021-116

This Bid Bulletin is being issued to announce the new schedule of the Submission and Opening of Bids previously set on 10 March 2021, to amend or modify the posted Bidding Documents in the DOH and PhilGEPS websites, to clarify issues and concerns raised during the Pre-Bidding Conference conducted last 24 February 2021, at the COBAC Conference Room, Ground Floor, Building No. 6, Department of Health and to respond to the letters of Pfizer Inc. (PI) and Zuellig Pharma Corporation (ZPC) for the Procurement of Pneumococcal Conjugate Vaccine (PCV) under IB No. 2021-116. 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	10 March 2021; 9:00 A.M	**24 March 2021; 10:00 A.M.**	COBAC Conference Room, G/F, Bldg. 6 Department of Health San Lazaro Compound, Rizal Avenue Sta. Cruz, Manila

2. **Response to the letter of PI:**

PARTICULAR	Bidder's Inquiry	Response of End-user/ COBAC-A
Section I. Invitation to Bid 8. Bids must be duly received by the *COBAC–A Secretariat* through either (i) manual submission at the office address indicated below, (ii) online or electronic submission as indicated below, or (iii) both on or before ***10 March 2021, 9:00 AM***. Late bids shall not be accepted.	We would like to seek guidance on the interpretation of the phrase "duly received" in light of the relatively new policy of allowing electronic submission of bids in light of the ongoing State of Public Health Emergency. In the event a bidder submits through both Modes of Submission, and the manual bid is submitted before the deadline, and the electronic bid is sent before the deadline but acknowledged as received only after the deadline due to technical issues or otherwise, will the bid in such case be considered late?	Absent any statutory and administrative provisions prescribing the ground rules on the mode of service to be adopted by the movant, the Rules of Court applies suppletorily. Thus, pursuant to the Revised Rules of Civil Procedure, in case of filing through email, it is the date when the email was transmitted which is considered to be the date of filing or submission of bids. But to ensure transparency and competitiveness for all bidders, the COBAC-A through its Secretariat must be informed by the bidder who submitted their bids electronically via its official contact numbers at 8-651-7800 local 1622, 1624, 1626, 1629 to ensure that all
	Assuming only an electronic bid is sent before the deadline, but the email acknowledgement by the Secretariat mentioned under IB Clause 11 occurs after the deadline, will the submission still be	

PARTICULAR	Bidder's Inquiry	Response of End-user/ COBAC-A
	considered timely submitted? Stated otherwise, please confirm if the act of acknowledging the bid submission by the Secretariat have to occur before the deadline as well.	submitted bids will be opened at same time and on the same date. (SOURCE: Revised Rules of Civil Procedure)
Section I. Invitation to Bid 11. Electronic submission of bids must be sent via e-mail to cobaca.secretariat@gmail.com provided that it complies with the following conditions: xxx Note: xxx Further, once the GCQ is lifted or the Bidder is determined as the Single/Lowest Calculated and Responsive Bid, whichever comes first, the Bidder shall submit three (3) sets of printed copies of the eligibility documents, certified as such by the bidder or his duly authorized representative.	We understand that the National Capital Region (NCR), where the DOH Central Office is located, is still under GCQ as of date. We wish to clarify whether the imposition of a Modified GCQ will be considered lifting the GCQ. Furthermore, please confirm the exact period within which three (3) sets of the eligibility requirements are required to be submitted from the lifting of the GCQ or determination of the bidder as the Single/Lowest Calculated and Responsive Bid. Please also confirm that the printed sets refer only to "eligibility documents" and not the complete bid submission consisting of the technical and financial documents. Please confirm whether a bidder which submits a bid under both Modes of Submission will still be required to comply with the foregoing provision.	The three (3) sets of eligibility, technical and financial requirements shall be submitted within any of the following periods, whichever comes first: 1. Within three (3) calendar days from the lifting of all applicable Community Quarantine, which necessarily includes Modified or General Community Quarantine; or 2. Within five (5) calendar days from determination by the COBAC-A of the bidder as the Single / Lowest Calculated Bid, to be submitted together with the post-qualification requirements. Only those bidders which submitted its eligible, technical and financial requirements electronically will be requirement to submit three (3) hard or physical copies of eligible, technical and financial requirements within the above-period.
Section II. Instruction to Bidders Each Bidder shall submit one copy of the first and second components of its Bid. The Procuring Entity may request additional hard copies and/or electronic copies of the Bid. However, failure of the Bidders to comply with the said request shall not be a ground for disqualification. If the Procuring Entity allows the submission of bids through online submission or any other electronic	We would like to seek clarification on what kind of digital signature is acceptable for the COBAC, and the list of documents to which the requirement of digital signing applies, particularly, whether the signatures by the authorized representatives for purposes of certification on each and every page of the bid must likewise be in form of a digital signature. In the alternative, please confirm if the COBAC will accept scanned copies of documents that have been signed in wet ink.	The Rules on Electronic Evidence provides that an electronic signature includes digital signatures. For that purpose, to electronically affix the signature, using a finger (for phones) or mouse (for computers) to sign Word Documents and PDFs will suffice. But the more efficient and consistent way is to simply have an image of your signature ready for pasting. Thus, scanning a paper-based

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means, the Bidder shall submit an electronic copy of its Bid, which must be digitally signed. An electronic copy that cannot be opened or is corrupted shall be considered non-responsive and, thus, automatically disqualified.		document with wet ink signature is just like a photocopy: it is not an original. What makes a signature electronic is the fact that it was electronically affixed by having a ready image of your signature for pasting to an electronic document. The act of inserting / pasting your distinctive mark is the act of electronically affixing your e-signature. Physically signing a paper-based document is not electronically affixing your distinctive mark to an electronic document. (SOURCE: UP Data Protection Office, Rules on Electronic Evidence)
Section II. Instruction to Bidders 10.2 The Bidder's SLCC as indicated in **ITB** Clause 5.3 should have been completed within *five (5) years* prior to the deadline for the submission and receipt of bids.	We respectfully request that the period be reverted back to two (2) years, instead of five (5) years, consistent with the period required in other bids. A shorter period will ensure that the bid participants have completed contracts that are recent and of the same scale, which is an indication of their experience and ability to perform and deliver under this contract, which is important for the National Immunization Program's (NIP) success.	Retain the five (5) years requirement in line with the principle of competitiveness.
Section II. Instruction to Bidders ITB Clause 5.3 For this purpose, contracts similar to the Project shall be: a. *xxx* b. completed within *five (5) years* prior to the deadline for the submission and receipt of bids.		
Section VII. Technical Specifications **Labeling Instructions** a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008. b) In addition to the labeling requirement of FDA: 1. On each vial, the	We note that this requirement was not included in the Technical Specifications for PCV in the tender for the previous year. We respectfully request reverting to accepting the FDA-approved labelling (whether with DOH-specific label or under Generic Labeling Exemption ("GLE"). Pfizer's PCV-13 multi-dose vial is currently approved by the Food and Drug Administration (FDA) Philippines under GLE on the basis	Refer to the attached revised Technical Specifications form.

PARTICULAR	Bidder's Inquiry	Response of End-user/ COBAC-A
following shall be imprinted or stickered with non-removable or permanent sticker or label that is binding and with residue and tearing if removed: Philippine Government Property – Department of Health **NOT FOR SALE** 2. On each small/big box, the following shall be imprinted or stickered with non-removable or permanent sticker or 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.: _	that the product requires special handling at controlled temperatures between 2-8°C. This GLE approval covers the vial label, carton label and package insert. We note that Pfizer has received approval from the FDA for labels that reflect all of the information required, albeit appearing in a different sequence. These labels are currently in use for its products. To this end, please confirm whether labels that reflect all of the information required under the Technical Specifications, but in a different sequence, are acceptable to the DOH, considering that the FDA has also approved such labels pursuant to DOH Administrative Order No. 2016-0008, which issuance is cited in the Technical Specifications on the standard labeling instructions. For visualization, we can reproduce the appearance below: Philippine Government Property – Department of Health **NOT FOR SALE** Batch/Lot No.: _ Date of Expiry:_ Date of Manufacture:_	
Section VII. Technical Specifications **Additional Support:** • Biothermal Temperature of Packaging System with DOH logo-1,000 units	Please confirm the advice given during the Pre-bid Conference that the technical specifications for the temperature packaging system will be the same as those prescribed under the 2020 procurement requirement, i.e.: a. ISTA validated b. 12" x 18" x 12" internal capacity c. Tare weight 20kg d. 100 hours performance on summer profile e. 42 liters capacity f. Vacuum insulated panels 1" thick g. HDPE machine sealed refrigerants	The following are the specifications of the Bio-thermal Packaging system: a. ISTA validated b. 12" x 18" x 12" internal capacity c. Tare weight 20kg d. 100 hours performance on summer profile e. 42 liters capacity f. Vacuum insulated panels 1" thick g. HDPE machine sealed refrigerants h. Nontoxic components on refrigerant i. DOH logo on the dominant side of the box

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	h. Nontoxic components on refrigerant i. DOH logo on the dominant side of the box except for the delivery schedule which is yet to be determined based on the anticipated date of the Notice to Proceed (NTP).	j. Delivery Schedule: • 1,000 units, **120 calendar days** from receipt of approved NTP
• Advocacy Awareness Campaign	We request for the details of this requirement, specifically, the type, number of activities, target site/audience and the implementation period.	• Advocacy Awareness Campaign to be approved by the Health Promotion Bureau (HPB) for a nationwide coverage - Media placement - Social Mobilization Activities - Production/Printing of IEC materials
Section V. Special Conditions of Contract **For staggered delivery:** Terms of Payment/billing shall be made for each completed delivery and acceptance upon presentation of signed Invoices Receipt and submission of relevant documents as stipulated in the contract.	We wish to request for confirmation that the DOH can release payment for each completed batch of delivery, instead of on a per tranche basis, as has been done in accordance with the batch delivery method implemented in the previous years. In the event that payments shall be made for each delivered batch, we also respectfully request clarification on whether the supplier will need to lodge a formal request for payment with the DOH for each sub batch. If the answer to this is in the affirmative, please confirm to which division or unit of the DOH the request for payment should be submitted.	• With regards to the payment, during the contract implementation, the winning bidder will coordinate with the End-user Unit (EUU), Supply Chain Management Service (SCMS) and the Finance Division.
	In addition, we note that under SCC Clause 10.5 of the 2020 Bidding Documents for PCV (IB No. 2020-244), it was explicitly mentioned that payment using Letter of Credit (LOC) is not allowed. Please confirm that the silence of the Bid Documents for this year implies that there is now a reversion to the original rule which allows payment using LOC.	• Payment using Letter of Credit is not allowed.

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Submission and Opening of Bids	Possible postponement of the bid given that Pfizer may experience production constraints for PCV as if focuses on ramping up efforts in producing vaccine doses for COVID-19. We respectfully submit that there is prudence in deferring the 2021 PCV tender. In accordance with the COVID-19 Vaccine Plan, the Research Institute of Tropical Medicine (RITM) shall serve as the government's Centralized Vaccine Hub, before the COVID-19 vaccines are delivered to the local government units. To augment, the DOH also considers the leasing of a private warehouse which can serve as cold storage facilities. Given that the delivery of the 7.8 million doses of PCV supplies procured under the 2020 PCV tender is not yet completed, the timeline for the delivery dates in accordance with the 2021 PCV tender will likely coincide with the period where the DOH will experience a strain in its warehouse capacity, and warehouse management will become a prime concern. Having two tenders delivered within a few months of each other and in a pandemic when PCV utilization is lower than normal, may lead to eventual vaccine wastage. This may be avoided by managing the tender and delivery schedules at the onset. Bottomline, deferring the delivery dates for the 2021 PCV tender will allow the DOH to effectively plan on its priorities, especially since PCV supply for the next 12 months may still be covered by the deliveries from the 2020 tender.	The Submission and Opening of Bids is on 24 March 2021 at 10:00 A.M.

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Surveillance as Recommended by the HTAC	Please confirm the COBAC's advice during the Pre-bidding Conference that support for the foregoing surveillance and monitoring activities will not be included in the tender as part of the additional support under the Technical Specifications, but will nevertheless be conducted by the DOH through the RITM using its own resources. Please confirm that the COBAC's advice also covers the conduct of research studies at indicated in item (iv) of the HTA report as recommended by the HTAC in case of an open tender for PCV: "Studies should be commissioned to determine the clinical and economic burden of pneumococcal diseases in the Philippines". We respectfully emphasize that the HTAC recommendation for the product specifications includes surveillance and research.	As discussed during the Pre-bidding Conference, the DOH will require the surveillance but it is not included in this bidding. The DOH will do the sub allotment to the RITM to do the surveillance.
Total Approved Budget for the Contract (ABC) **PhP2,730,000,000.00**	We note that for this year, the COBAC intends to procure 6,500,000 doses of PCV, with an ABC of PhP2,730,000,000.00 which results to a PhP420 price per dose. Given the 17% reduction in the number of doses compared to last year (i.e. 7,800,000 doses), please confirm it is possible to increase the price per dose taking into account increased costs of production and lesser number of doses for this year.	As discussed during the Pre-bidding Conference, there will be no changes in the Total ABC of the project.
Section VII. Technical Specifications Pneumococcal Conjugate Vaccine (PCV) (indicated for the following minimum Serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F)	Request to review the current minimum serotypes required in the Technical Specifications, which we understand, is based on the recommendation of the HTAC and is as approved by the Secretary of Health last 15 October 2020. We kindly emphasize that in its report, the HTAC recommends not just the coverage of the minimum serotypes 1,4,5,6B,7F,9V,14,18C,19A, 19F and 23F, but also the conduct of	No changes in the Technical Specifications.

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	surveillance and research initiatives, including the instructions to start the high-quality surveillance "within the year" or within the year 2020 for impact of monitoring and assessment. In order to meet the full recommendation of HTAC and not just the product specification, we request that the Technical Specifications retain the existing coverage of Serotypes **1,4,5,6B,7F,9V,14,18C,19A,19F, 23F plus 3 and 6A,** at least until such time that the surveillance and research initiatives are in place. In addition to the adhering to the full recommendation, this also allows the program to completely assess the impact of its current vaccination program.	
HTAC Recommendation	Reassessment of the recommendation from the HTAC to open the tender to pneumococcal conjugate vaccines that meet the minimum serotypes prescribed (i.e. 1, 4, 5, 6B, 7F, 9V, 14, 18C,19A, 19F and 23F for the following reasons: 1. Change in result of the Budget Impact Analysis based on 2020 bid price 2. The minimum serotypes do not represent the serotypes with the highest disease burden. 3. Programmatic impact of possible switch from PCV-13 to PCV-10 4. New evidence in support of HTA Reassessment	No changes in the Technical Specifications.

3. Response to the letter of PI:

PARTICULAR	Bidder's Inquiry	Response of End-user/ COBAC-A
Section VII. Technical Specifications **Labeling Instructions** a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008. b) In addition to the labeling requirement of FDA: 1. On each vial, the following shall be imprinted or stickered with non-removable or permanent sticker or label that is binding and with residue and tearing if removed: Philippine Government Property – Department of Health **NOT FOR SALE** 2. On each small/big box, the following shall be imprinted or stickered with non-removable or permanent sticker or 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.: _	We would kindly request for consideration that the labeling requirement follow the previous DOH PCV tenders and other vaccine tender requirements where the label is printed in the outer box since the proposed DOH sticker would cover pertinent information including product label & expiration date that is written in the actual vial. There are physical limitations on the vial itself considering its size, manufacturing complexities on adding additional texts to the label and potential substantial regulatory challenges. Moreover, the outer box of GSK's Synflorix 4DV has already a temper proof seal that extends beyond the flag. The only way for redressing the vial would mean destroying the label and therefore the pack would be deemed as "tampered". There may be significant patient safety and quality related risks with the new requirement if we try to redress post manufacturing. The vaccines come with the secondary boxes sealed to ensure their integrity. By putting a label in the vial, there is significant risk for cracking and exposure to physical stresses since we are opening the secondary packaging and exposing the primary pack during redressing activity. Likewise, putting the DOH sticker at the vial may also lead to quality assurance related concerns that will put the quality and integrity of the product at risk. Any manipulation is a potential risk for the integrity of the primary packaging i.e. risk for the sterility, as well as for the stability of the product due to the fact that vaccines are temperature sensitive products.	Refer to the attached revised Technical Specifications form.
Section VII. Technical Specifications	Request for details on the technical specification for the Bio Thermal Packaging System (approximate	The following are the specifications of the Bio-

PARTICULAR	Bidder's Inquiry	Response of End-user/ COBAC-A
Additional Support: • Biothermal Temperature of Packaging System with DOH logo- 1,000 units • Advocacy Awareness Campaign	dimensions and delivery timelines) & Advocacy Awareness Campaign	thermal Packaging system: a. ISTA validated b. 12" x 18" x 12" internal capacity c. Tare weight 20kg d. 100 hours performance on summer profile e. 42 liters capacity f. Vacuum insulated panels 1" thick g. HDPE machine sealed refrigerants h. Nontoxic components on refrigerant i. DOH logo on the dominant side of the box j. Delivery Schedule: • 1,000 units, **120 calendar days** from receipt of approved NTP • Advocacy Awareness Campaign to be approved by the Health Promotion Bureau (HPB) for a nationwide coverage - Media placement - Social Mobilization Activities - Production/Printing of IEC materials
Section VI. Schedule of Requirements and Section VII. Technical Specifications under item (h) of the Technical Component Envelope, Section VIII. Checklist of Technical and Financial Documents of the Philippine Bidding Documents	We would like to request for clarification that it is not mandatory for the bidders to provide information on the production/delivery schedule, manpower requirements, and/or after-sales/parts.	Please refer to Section VIII. Checklist of Technical and Financial Documents, to wit: (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; and** xxx
Section VIII. Checklist of Technical and Financial Documents of the Philippine Bidding Documents	In case the bidder is an unincorporated joint venture, we would like to request for clarification that only one of the joint venture partners need to comply	Pursuant to Section 23.1 (b) of the 2016 Revised IRR of RA 9184, only one member of the Joint Venture (JV) partners is

PARTICULAR	Bidder's Inquiry	Response of End-user/ COBAC-A
(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.	with this requirement.	required to submit the NFCC. Provided, that the JV partner responsible to submit the NFCC shall likewise submit the Statement of all of its Ongoing Contracts and Audited Financial Statements.
Prescribed Forms	We would like to request for confirmation that all prescribed forms may be retyped to properly reflect the required information.	There is no prohibition in re-typing the prescribed forms provided they reflect all terms and conditions specified therein.

4. Section V. Special Conditions of the Contract

FROM	TO
GCC Clause 1 xxx **DR. NAPOLEON L. AREVALO** Director IV Disease Prevention and Control Bureau Building 14, Department of Health Tel No.: 651-7800 local 1700 to 1701 Fax No.: 8711-0380	**GCC Clause 1** xxx **DR. BEVERLY LORRAINE C. HO** Director IV Disease Prevention and Control Bureau Building 14, Department of Health Tel No.: 651-7800 local 1700 to 1701 Fax No.: 8711-0380
GCC Clause Based on the General Provisions of the NEP/GAA of 2021, Section 60: Cash Budgeting System, all appropriations shall be made available for release and disbursement for the purpose specified and under the same general and special provisions applicable until December 31, 2021. xxx	**GCC Clause 2.2** Based on the General Provisions of the NEP/GAA of 2021, Section **62**: Cash Budgeting System, all appropriations shall be made available for release and disbursement for the purpose specified and under the same general and special provisions applicable until December 31, 2021. xxx

5. Section VII. Technical Specifications

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

FROM	TO
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; and (iii) Official Receipt as proof of payment of renewal of LTO xxx	1) Valid and current Certificate Product Registration (CPR) or Expired CPR with Extension of Validity issued by Philippine Food and Drug Administration (PFDA); 2) Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA). **Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 July 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]** xxx

6. Query raised during the Pre-bidding Conference:

PARTICULAR	Bidder's Inquiry	Response of End-user/ COBAC-A
Delivered Calendar Days **1st Tranche:** 2,000,000 doses- Ninety (90) calendar days from receipt of approved Notice to Proceed (NTP). **2nd Tranche:** 4,000,000 doses- One Hundred Fifty (150) calendar days from receipt of approved NTP. **3rd Tranche:** 2,000,000 doses- Two Hundred Ten (210) calendar days from receipt of approved NTP.	The representative of PI asked the indicative schedule of the 1st tranche of the delivery for their company's planning purposes.	As discussed during the Pre-bidding Conference, the End-user will follow the delivery schedule as required upon release of the approved NTP.

The revised Schedule of Requirements, Technical Specifications 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

Technical Specifications

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Pneumococcal Conjugate Vaccine (PCV)**	Quantity / Unit	**6,500,000 doses**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP2,730,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
A. Detailed Technical Specifications: 1. **Route of Administration**: Suspension for IM Injection 2. **Form and Strength**: a) Pneumococcal Conjugate Vaccine (PCV) (indicated for the following minimum Serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) b) Multidose vial c) With Vaccine Vial Monitor 3. **Additional Support:** • Biothermal Temperature of Packaging System with DOH logo- 1,000 units • Advocacy Awareness Campaign			

B. Additional Requirements to be attached to Technical Specifications form arranges, 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);

2. Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA).

   Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 July 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]

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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

4. 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

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Pneumococcal Conjugate Vaccine (PCV)**	Quantity / Unit	**6,500,000 doses**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP2,730,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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.

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 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.

6. WHO Prequalification Certificate/Dossier/Listing;

7. Sworn Statement *using the prescribed form.*

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 24 months from the date of manufacture but not less than 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.

   b) In addition to the labeling requirement of FDA:

      1. On each **small box**, the following shall be imprinted or stickered with non-removable or permanent sticker or label that is binding and with residue and tearing if removed:

         Philippine Government Property – Department of Health
         NOT FOR SALE

      2. On each small/big box, the following shall be imprinted or stickered with non-removable or permanent sticker or label that is binding and with residue and tearing if removed:

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Pneumococcal Conjugate Vaccine (PCV)**	Quantity / Unit	**6,500,000 doses**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP2,730,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

Philippine Government Property – Department of Health
NOT FOR SALE

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

D. Product Recall & Disposal:

1. In instances of product recall due to failures of the suppliers and manufacturers to comply with the standards of safety and quality, the cost associated with the 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 FDA Circular No. 2016-012 or the latest policy for disposal);
2. In cases of expired drugs, the health facility shall bear the cost for disposal. The disposal of the expired goods shall be coordinated through a third-party accredited by the Department of Environment and Natural Resources (DENR), engaged by Administrative Services (AS) of the DOH health facility, subject to compliance to applicable laws.

_____
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]

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 and Technical Specifications, 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. ADDITIONAL DOCUMENTARY REQUIREMENTS TO BE ATTACHED IN THE TECHNICAL SPECIFICATIONS FORM:

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

☐ (b) Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA).

Note: Existing Licenses to Operate (LTO) and Certificates of Product Registration/Notification (CPR/Ns) issued by the Food and Drugs Administration (FDA) that have a validity expiring on *01 January to 30 July 2021*, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given. [FDA Circular No. 2020-024-A]

☐ (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) WHO Prequalification Certificate/Dossier/Listing;

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

Note:

1) Please refer to **https://doh.gov.ph/sites/default/files/basic-page/COBAC-Sample-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