

# **PHILIPPINE BIDDING DOCUMENTS**

(As Harmonized with Development Partners)

## **Procurement of Trastuzumab IB No. 2024-012**

Government of the Republic of the Philippines

**Sixth Edition  
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# *Glossary of Acronyms, Terms, and Abbreviations*

**ABC** – Approved Budget for the Contract.

**BAC** – Bids and Awards Committee.

**Bid** – A signed offer or proposal to undertake a contract submitted by a bidder in response to and in consonance with the requirements of the bidding documents. Also referred to as *Proposal* and *Tender*. (2016 revised IRR, Section 5[c])

**Bidder** – Refers to a contractor, manufacturer, supplier, distributor and/or consultant who submits a bid in response to the requirements of the Bidding Documents. (2016 revised IRR, Section 5[d])

**Bidding Documents** – The documents issued by the Procuring Entity as the bases for bids, furnishing all information necessary for a prospective bidder to prepare a bid for the Goods, Infrastructure Projects, and/or Consulting Services required by the Procuring Entity. (2016 revised IRR, Section 5[e])

**BIR** – Bureau of Internal Revenue.

**BSP** – Bangko Sentral ng Pilipinas.

**Consulting Services** – Refer to services for Infrastructure Projects and other types of projects or activities of the GOP requiring adequate external technical and professional expertise that are beyond the capability and/or capacity of the GOP to undertake such as, but not limited to: (i) advisory and review services; (ii) pre-investment or feasibility studies; (iii) design; (iv) construction supervision; (v) management and related services; and (vi) other technical services or special studies. (2016 revised IRR, Section 5[i])

**CDA** - Cooperative Development Authority.

**Contract** – Refers to the agreement entered into between the Procuring Entity and the Supplier or Manufacturer or Distributor or Service Provider for procurement of Goods and Services; Contractor for Procurement of Infrastructure Projects; or Consultant or Consulting Firm for Procurement of Consulting Services; as the case may be, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

**CIF** – Cost Insurance and Freight.

**CIP** – Carriage and Insurance Paid.

**CPI** – Consumer Price Index.

**DDP** – Refers to the quoted price of the Goods, which means “delivered duty paid.”

**DTI** – Department of Trade and Industry.

**EXW** – Ex works.

**FCA** – “Free Carrier” shipping point.

**FOB** – “Free on Board” shipping point.

**Foreign-funded Procurement or Foreign-Assisted Project**– Refers to procurement whose funding source is from a foreign government, foreign or international financing institution as specified in the Treaty or International or Executive Agreement. (2016 revised IRR, Section 5[b]).

**Framework Agreement** – Refers to a written agreement between a procuring entity and a supplier or service provider that identifies the terms and conditions, under which specific purchases, otherwise known as “Call-Offs,” are made for the duration of the agreement. It is in the nature of an option contract between the procuring entity and the bidder(s) granting the procuring entity the option to either place an order for any of the goods or services identified in the Framework Agreement List or not buy at all, within a minimum period of one (1) year to a maximum period of three (3) years. (GPPB Resolution No. 27-2019)

**GFI** – Government Financial Institution.

**GOCC** – Government-owned and/or –controlled corporation.

**Goods** – Refer to all items, supplies, materials and general support services, except Consulting Services and Infrastructure Projects, which may be needed in the transaction of public businesses or in the pursuit of any government undertaking, project or activity, whether in the nature of equipment, furniture, stationery, materials for construction, or personal property of any kind, including non-personal or contractual services such as the repair and maintenance of equipment and furniture, as well as trucking, hauling, janitorial, security, and related or analogous services, as well as procurement of materials and supplies provided by the Procuring Entity for such services. The term “related” or “analogous services” shall include, but is not limited to, lease or purchase of office space, media advertisements, health maintenance services, and other services essential to the operation of the Procuring Entity. (2016 revised IRR, Section 5[r])

**GOP** – Government of the Philippines.

**GPPB** – Government Procurement Policy Board.

**INCOTERMS** – International Commercial Terms.

**Infrastructure Projects** – Include the construction, improvement, rehabilitation, demolition, repair, restoration or maintenance of roads and bridges, railways, airports, seaports, communication facilities, civil works components of information technology projects, irrigation, flood control and drainage, water supply, sanitation, sewerage and solid waste management systems, shore protection, energy/power and electrification facilities, national

buildings, school buildings, hospital buildings, and other related construction projects of the government. Also referred to as *civil works or works*. (2016 revised IRR, Section 5[u])

**LGUs** – Local Government Units.

**NFCC** – Net Financial Contracting Capacity.

**NGA** – National Government Agency.

**PhilGEPS** - Philippine Government Electronic Procurement System.

**Procurement Project** – refers to a specific or identified procurement covering goods, infrastructure project or consulting services. A Procurement Project shall be described, detailed, and scheduled in the Project Procurement Management Plan prepared by the agency which shall be consolidated in the procuring entity's Annual Procurement Plan. (GPPB Circular No. 06-2019 dated 17 July 2019)

**PSA** – Philippine Statistics Authority.

**SEC** – Securities and Exchange Commission.

**SLCC** – Single Largest Completed Contract.

**Supplier** – refers to a citizen, or any corporate body or commercial company duly organized and registered under the laws where it is established, habitually established in business and engaged in the manufacture or sale of the merchandise or performance of the general services covered by his bid. (Item 3.8 of GPPB Resolution No. 13-2019, dated 23 May 2019). Supplier as used in these Bidding Documents may likewise refer to a distributor, manufacturer, contractor, or consultant.

**UN** – United Nations.

## ***Section I. Invitation to Bid***



Republic of the Philippines  
Department of Health

## CENTRAL OFFICE BIDS AND AWARDS COMMITTEE

### INVITATION TO BID FOR THE PROCUREMENT OF TRASTUZUMAB IB No. 2024-012

1. The *Department of Health (DOH)*, through the *General Appropriations Act (GAA)* of 2024 intends to apply the sum of *Three Hundred Fourteen Million One Hundred Eighty-Four Thousand Three Hundred Twenty-Three Philippine Pesos (PhP314,184,323.00)* being the Approved Budget for the Contract (ABC) to payments under the contract for the *Procurement of Trastuzumab under IB No. 2024-012*. Bids received in excess of the ABC shall be automatically rejected at bid opening.
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.
3. Bidding will be conducted through open competitive bidding procedures using a non-discretionary “pass/fail” criterion as specified in the 2016 revised Implementing Rules and Regulations (IRR) of Republic Act (RA) No. 9184.

Bidding is restricted to Filipino citizens/sole proprietorships, partnerships, or organizations with at least sixty percent (60%) interest or outstanding capital stock belonging to citizens of the Philippines, and to citizens or organizations of a country the laws or regulations of which grant similar rights or privileges to Filipino citizens, pursuant to RA 5183.

4. Prospective bidders may obtain further information from the *COBAC Secretariat, Ground Floor, Building No. 6, DOH, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila* and inspect the Bidding Documents at the address given above during *8:00 AM – 5:00 PM, Monday to Friday*.
5. A complete set of Bidding Documents may be acquired by interested Bidders on **09 January – 31 January 2024** from the given address and website below and upon payment of the applicable fee for the Bidding Documents, pursuant to the latest Guidelines issued by the GPPB, in the amount of **Fifty Thousand Philippine Pesos (PhP50,000.00)**. *The Procuring Entity shall allow the bidder to present its proof of payment for the fees be presented in person.*

It may also be downloaded free of charge from the website of the Philippine Government Electronic Procurement System (PhilGEPS) and the website of the Procuring Entity, provided that Bidders shall pay the applicable fee for the Bidding Documents not later than the submission of their bids.

6. The *DOH* will hold a Pre-Bid Conference on **17 January 2024; 10:00 AM** at the *COBAC Conference Room, Ground Floor, Building No. 6, DOH, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila*, and/or through video conferencing or webcasting *via Cisco Webex*, which

shall be open to prospective bidders. Interested bidders may contact the COBAC-D Secretariat at this electronic mail (e-mail) address, [cobacdsecretariat@doh.gov.ph](mailto:cobacdsecretariat@doh.gov.ph) for details.

7. Bids must be duly received by the *COBAC-D 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 **31 January 2024 at 09:00 A.M.** Late bids shall not be accepted.
8. All Bids must be accompanied by a bid security in any of the acceptable forms and in the amount stated in **ITB** Clause 14.
9. Bid opening shall be on **31 January 2024 at 9:00 A.M.** at the given address below and or through video conferencing or webcasting *via Cisco Webex*. Bids will be opened in the presence of the bidders' representatives who choose to attend the activity.
10. Electronic submission of bids must be sent via e-mail to [cobacdsecretariat@doh.gov.ph](mailto:cobacdsecretariat@doh.gov.ph) provided that it complies with the following conditions:
  - i. It should be in a clear .PDF/.IMG/.JPG/.TIFF/.GIF/.PNG format, and shall be in two (2) password protected Bidding Documents in compressed archive folders *pursuant to GPPB Resolution No. 09-2020 and Section 25.1 of the 2016 IRR of RA 9184*;
  - ii. A generated bid receipt page or email acknowledgement indicating the time of submission must be secured and printed as a reference;
  - iii. The documentary requirements are arranged accordingly based on the Eligibility Checklist using the standard file name indicated therein.
  - iv. *For electronic bid submission, the passwords for accessing the Bidding Documents will be disclosed by the Bidders only during the actual bid opening which may be done in person or face-to-face through videoconferencing, webcasting or similar technology. (GPPB Resolution No. 09-2020 and Section 29 of the 2016 IRR of RA 9184)*

Note:

The BAC shall open the bid envelopes using a non-discretionary “pass/fail” criterion. *In case of electronic bid submission, Bidding Documents not in compressed archive folders and are not password protected, shall be rejected. However, bid envelopes that are not properly sealed and marked or not properly compressed and password-protected, as required in the Bidding Documents, shall be accepted, provided that the bidder or its duly authorized representative shall acknowledge such condition of the bid as submitted. The BAC shall assume no responsibility for the misplacement of the contents of the improperly sealed or marked bid, or improperly compressed or password-protected folder, or for its premature opening. (GPPB Resolution No. 09-2020 and Section 25.9 of the 2016 IRR of RA 9184)*

Further, once the Bidder is determined as the Single/Lowest Calculated and Responsive Bid, 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.



11. The *DOH* reserves the right to reject any and all bids, declare a failure of bidding, or not award the contract at any time prior to contract award in accordance with Sections 35.6 and 41 of RA 9184 and its IRR, without thereby incurring any liability to the affected bidder or bidders.

12. For further information, please refer to:

*COBAC-D Secretariat*

*Department of Health*

*San Lazaro Compound*

*Sta. Cruz, Manila*

*Tel. Nos. 8651-7800 local 1624 to 1627; 1650 to 52*

*Facsimile No.: 8711-6061; 8740-6830*

*Official email address: [cobacdsecretariat@doh.gov.ph](mailto:cobacdsecretariat@doh.gov.ph)*

13. You may visit the website listed below:

For downloading of Bidding Documents: <https://www.doh.gov.ph/procurement>

For Online Bidding Documents Payment System: <https://obdps.doh.gov.ph/>

**NESTOR F. SANTIAGO, JR., MD, MPHC, MHSA, CESO II**

Undersecretary of Health

COBAC-D Chairperson

## ***Section II. Instructions to Bidders***

## **1. Scope of Bid**

The Procuring Entity, *DOH* wishes to receive Bids for the *Procurement of Trastuzumab under IB No. 2024-012*.

The Procurement Project (referred to herein as “Project”) is composed of *two (2) items*, the details of which are described in Section VII (Technical Specifications).

## **2. Funding Information**

2.1. The GOP through the source of funding as indicated below for *2024* in the amount of Three Hundred Fourteen Million One Hundred Eighty-Four Thousand Three Hundred Twenty-Three Philippine Pesos (PhP314,184,323.00).

2.2. The source of funding is:

a. NGA, the *General Appropriations Act*

## **3. Bidding Requirements**

The Bidding for the Project shall be governed by all the provisions of RA No. 9184 and its 2016 revised IRR, including its Generic Procurement Manuals and associated policies, rules and regulations as the primary source thereof, while the herein clauses shall serve as the secondary source thereof.

Any amendments made to the IRR and other GPPB issuances shall be applicable only to the ongoing posting, advertisement, or **IB** by the BAC through the issuance of a supplemental or bid bulletin.

The Bidder, by the act of submitting its Bid, shall be deemed to have verified and accepted the general requirements of this Project, including other factors that may affect the cost, duration and execution or implementation of the contract, project, or work and examine all instructions, forms, terms, and project requirements in the Bidding Documents.

## **4. Corrupt, Fraudulent, Collusive, and Coercive Practices**

The Procuring Entity, as well as the Bidders and Suppliers, shall observe the highest standard of ethics during the procurement and execution of the contract. They or through an agent shall not engage in corrupt, fraudulent, collusive, coercive, and obstructive practices defined under Annex “I” of the 2016 revised IRR of RA No. 9184 or other integrity violations in competing for the Project.

## **5. Eligible Bidders**

5.1. Only Bids of Bidders found to be legally, technically, and financially capable will be evaluated.

5.2. *Foreign bidders may be eligible to participate when any of the following*

*circumstances exist:*

- a. Foreign ownership exceeding those allowed under the rules may participate pursuant to:
    - i. When a Treaty or International or Executive Agreement as provided in Section 4 of the RA No. 9184 and its 2016 revised IRR allow foreign bidders to participate;
    - ii. Citizens, corporations, or associations of a country, included in the list issued by the GPPB, the laws or regulations of which grant reciprocal rights or privileges to citizens, corporations, or associations of the Philippines;
    - iii. When the Goods sought to be procured are not available from local suppliers; or
    - iv. When there is a need to prevent situations that defeat competition or restrain trade.
- 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 procurement of 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.
- 5.4. The Bidders shall comply with the eligibility criteria under Section 23.4.1 of the 2016 IRR of RA No. 9184.

## **6. Origin of Goods**

There is no restriction on the origin of goods other than those prohibited by a decision of the UN Security Council taken under Chapter VII of the Charter of the UN, subject to Domestic Preference requirements under **ITB** Clause 18.

## **7. Subcontracts**

- 7.1. The Bidder may subcontract portions of the Project to the extent allowed by the Procuring Entity as stated herein, but in no case more than twenty percent (20%) of the Project.

The Procuring Entity has prescribed that:

- a. Subcontracting is not allowed.
- 7.2. Subcontracting of any portion of the Project does not relieve the Supplier of any liability or obligation under the Contract. The Supplier will be responsible for

the acts, defaults, and negligence of any subcontractor, its agents, servants, or workmen as fully as if these were the Supplier's own acts, defaults, or negligence, or those of its agents, servants, or workmen.

## **8. Pre-Bid Conference**

The Procuring Entity will hold a pre-bid conference for this Project on the specified date and time and either at its physical address *COBAC Conference Room, Ground Floor, Building No. 6, DOH, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila*, and/or through video conferencing or webcasting *via Cisco Webex*, which shall be open to prospective bidders as indicated in paragraph 6 of the **IB**.

## **9. Clarification and Amendment of Bidding Documents**

Prospective bidders may request for clarification on and/or interpretation of any part of the Bidding Documents. Such requests must be in writing and received by the Procuring Entity, either at its given address or through electronic mail indicated in the **IB**, at least ten (10) calendar days before the deadline set for the submission and receipt of Bids.

## **10. Documents comprising the Bid: Eligibility and Technical Components**

- 10.1. The first envelope shall contain the eligibility and technical documents of the Bid as specified in **Section VIII (Checklist of Technical and Financial Documents)**.
- 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.
- 10.3. If the eligibility requirements or statements, the bids, and all other documents for submission to the BAC are in foreign language other than English, it must be accompanied by a translation in English, which shall be authenticated by the appropriate Philippine foreign service establishment, post, or the equivalent office having jurisdiction over the foreign bidder's affairs in the Philippines.

Parties to the Apostille Convention, only the translated documents shall be authenticated through an apostille pursuant to GPPB Resolution No. 13-2019 dated 23 May 2019. The English translation shall govern, for purposes of interpretation of the bid. Similar to the required authentication above, for Contracting

## **11. Documents comprising the Bid: Financial Component**

- 11.1. The second bid envelope shall contain the financial documents for the Bid as specified in **Section VIII (Checklist of Technical and Financial Documents)**.
- 11.2. If the Bidder claims preference as a Domestic Bidder or Domestic Entity, a certification issued by DTI shall be provided by the Bidder in accordance with Section 43.1.3 of the 2016 revised IRR of RA No. 9184.
- 11.3. Any bid exceeding the ABC indicated in paragraph 1 of the **IB** shall not be

accepted.

- 11.4. For Foreign-funded Procurement, a ceiling may be applied to bid prices provided the conditions are met under Section 31.2 of the 2016 revised IRR of RA No. 9184.

## 12. Bid Prices

- 12.1. Prices indicated on the Price Schedule shall be entered separately in the following manner:

- a. For Goods offered from within the Procuring Entity's country:
  - i. The price of the Goods quoted EXW (ex-works, ex-factory, ex-warehouse, ex-showroom, or off-the-shelf, as applicable);
  - ii. The cost of all customs duties and sales and other taxes already paid or payable;
  - iii. The cost of transportation, insurance, and other costs incidental to delivery of the Goods to their final destination; and
  - iv. The price of other (incidental) services, if any, listed in e.
- b. For Goods offered from abroad:
  - i. Unless otherwise stated in the **BDS**, the price of the Goods shall be quoted delivered duty paid (DDP) with the place of destination in the Philippines as specified in the **BDS**. In quoting the price, the Bidder shall be free to use transportation through carriers registered in any eligible country. Similarly, the Bidder may obtain insurance services from any eligible source country.
  - ii. The price of other (incidental) services, if any, as listed in **Section VII (Technical Specifications)**.

## 13. Bid and Payment Currencies

- 13.1. For Goods that the Bidder will supply from outside the Philippines, the bid prices may be quoted in the local currency or tradeable currency accepted by the BSP at the discretion of the Bidder. However, for purposes of bid evaluation, Bids denominated in foreign currencies, shall be converted to Philippine currency based on the exchange rate as published in the BSP reference rate bulletin on the day of the bid opening.
- 13.2. Payment of the contract price shall be made in:
  - a. Philippine Pesos.

## **14. Bid Security**

- 14.1. The Bidder shall submit a Bid Securing Declaration<sup>2</sup> or any form of Bid Security in the amount indicated in the **BDS**, which shall be not less than the percentage of the ABC in accordance with the schedule in the **BDS**.
- 14.2. The Bid and bid security shall be valid until *One Hundred Twenty (120) days from the submission and opening of bids*. Any Bid not accompanied by an acceptable bid security shall be rejected by the Procuring Entity as non-responsive.

## **15. Sealing and Marking of Bids**

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 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.

## **16. Deadline for Submission of Bids**

- 16.1. The Bidders shall submit on the specified date and time and either at its physical address or through online submission as indicated in paragraph 7 of the **IB**.

## **17. Opening and Preliminary Examination of Bids**

- 17.1. The BAC shall open the Bids in public at the time, on the date, and at the place specified in paragraph 9 of the **IB**. The Bidders' representatives who are present shall sign a register evidencing their attendance. In case videoconferencing, webcasting or other similar technologies will be used, attendance of participants shall likewise be recorded by the BAC Secretariat.

In case the Bids cannot be opened as scheduled due to justifiable reasons, the rescheduling requirements under Section 29 of the 2016 revised IRR of RA No. 9184 shall prevail.

- 17.2. The preliminary examination of bids shall be governed by Section 30 of the 2016 revised IRR of RA No. 9184.

## **18. Domestic Preference**

- 18.1. The Procuring Entity will grant a margin of preference for the purpose of comparison of Bids in accordance with Section 43.1.2 of the 2016 revised IRR of RA No. 9184.

## 19. Detailed Evaluation and Comparison of Bids

- 19.1. The Procuring BAC shall immediately conduct a detailed evaluation of all Bids rated “*passed*,” using non-discretionary pass/fail criteria. The BAC shall consider the conditions in the evaluation of Bids under Section 32.2 of the 2016 revised IRR of RA No. 9184.
- 19.2. If the Project allows partial bids, bidders may submit a proposal on any of the lots or items, and evaluation will be undertaken on a per lot or item basis, as the case maybe. In this case, the Bid Security as required by **ITB** Clause 15 shall be submitted for each lot or item separately.
- 19.3. The descriptions of the lots or items shall be indicated in **Section VII (Technical Specifications)**, although the ABCs of these lots or items are indicated in the **BDS** for purposes of the NFCC computation pursuant to Section 23.4.2.6 of the 2016 revised IRR of RA No. 9184. The NFCC must be sufficient for the total of the ABCs for all the lots or items participated in by the prospective Bidder.
- 19.4. The Project shall be awarded as follows:

One Project having several items, which shall be awarded as separate contracts per item.
- 19.5. Except for bidders submitting a committed Line of Credit from a Universal or Commercial Bank in lieu of its NFCC computation, all Bids must include the NFCC computation pursuant to Section 23.4.1.4 of the 2016 revised IRR of RA No. 9184, which must be sufficient for the total of the ABCs for all the lots or items participated in by the prospective Bidder. For bidders submitting the committed Line of Credit, it must be at least equal to ten percent (10%) of the ABCs for all the lots or items participated in by the prospective Bidder.

## 20. Post-Qualification

- 20.1. Within a non-extendible period of five (5) calendar days from receipt by the Bidder of the notice from the BAC that it submitted the Lowest Calculated Bid, the Bidder shall submit its latest income and business tax returns filed and paid through the BIR Electronic Filing and Payment System (eFPS) and other appropriate licenses and permits required by law and stated in the **BDS**.

## 21. Signing of the Contract

- 21.1. The documents required in Section 37.2 of the 2016 revised IRR of RA No. 9184 shall form part of the Contract. Additional Contract documents are indicated in the **BDS**.



## ***Section III. Bid Data Sheet***

# Bid Data Sheet

ITB Clause																							
5.3	For this purpose, contracts similar to the Project shall be: <ul style="list-style-type: none"> <li>a. <i>various drugs and medicines, vaccines and other biological products.</i></li> <li>b. completed within two (2) years prior to the deadline for the submission and receipt of bids.</li> </ul>																						
7.1	Subcontracting is not allowed.																						
12	The price of the Goods shall be quoted DDP to <b>DOH Warehouse(s) within Metro Manila</b> or the applicable International Commercial Terms (INCOTERMS) for this Project.																						
14.1	The bid security shall be in the form of a Bid Securing Declaration, or any of the following forms and amounts: <ul style="list-style-type: none"> <li>a. The amount of not less than <b>PhP6,283,686.46</b> or equivalent to two percent (2%) of ABC, if bid security is in cash, cashier's/manager's check, bank draft/guarantee or irrevocable letter of credit; or</li> <li>b. The amount of not less than <b>PhP15,709,216.15</b> or equivalent to five percent (5%) of ABC if bid security is in Surety Bond.</li> </ul> <p>For purposes of determining the amount of the bid security in biddings with lots or items, whereby a bidder submits a bid for more than one lot or item, the bid security shall be based upon the sum of the ABC for each of the lots or items for which bids are submitted.</p>																						
15	Each Bidder shall submit <i>one (1)</i> original and <i>two (2)</i> copies of the first and second components of its bid: 1 <sup>st</sup> copy- marked as 'ORIGINAL'; 2 <sup>nd</sup> copy- marked as 'COPY 1'; 3 <sup>rd</sup> copy- marked as 'COPY 2'.																						
19.3	The ABC is <b>Three Hundred Fourteen Million One Hundred Eighty-Four Thousand Three Hundred Twenty-Three Philippine Pesos (PhP314,184,323.00)</b> . Any bid with a financial component exceeding each amount shall not be accepted: <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="text-align: center;">Item No.</th> <th style="text-align: center;">Description</th> <th style="text-align: center;">Qty.</th> <th style="text-align: center;">Unit</th> <th style="text-align: center;">Total ABC (PhP)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">Trastuzumab 150 mg</td> <td style="text-align: center;">25,000</td> <td rowspan="2" style="text-align: center; vertical-align: middle;">vial</td> <td style="text-align: right;">112,220,000.00</td> </tr> <tr> <td style="text-align: center;">2</td> <td style="text-align: center;">Trastuzumab 600 mg</td> <td style="text-align: center;">8,700</td> <td style="text-align: right;">201,964,323.00</td> </tr> <tr> <td colspan="4" style="text-align: center;"><b>TOTAL</b></td> <td style="text-align: right;"><b>314,184,323.00</b></td> </tr> </tbody> </table> <p><i>Note: The above items are included in the list of Vat Exempt Products. Please refer to Bureau of Internal Revenue (BIR) Revenue Memorandum Circular No. 81-2021 on the "List of VAT-Exempt Products" pursuant to RA No. 11534 otherwise known as the Corporate Recovery and Tax Incentives for Enterprises (CREATE) Act.</i></p>				Item No.	Description	Qty.	Unit	Total ABC (PhP)	1	Trastuzumab 150 mg	25,000	vial	112,220,000.00	2	Trastuzumab 600 mg	8,700	201,964,323.00	<b>TOTAL</b>				<b>314,184,323.00</b>
Item No.	Description	Qty.	Unit	Total ABC (PhP)																			
1	Trastuzumab 150 mg	25,000	vial	112,220,000.00																			
2	Trastuzumab 600 mg	8,700		201,964,323.00																			
<b>TOTAL</b>				<b>314,184,323.00</b>																			

20.1	<p>The S/LCB shall submit <b>three (3) sets of true copies of the original certified as such by the bidder or his duly authorized signatory</b> within a <b><u>non-extendible period of five (5) calendar days</u></b> from receipt of the notification <b>arranged, numbered and tabbed as enumerated below:</b></p> <p>(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);</p> <p>(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 <b>six (6) months</b> (per Revenue Regulations 3-2005);</p> <p><i>The latest income and business tax returns are those within the last six months preceding the date of bid submission.</i></p> <p>(c) Articles of Incorporation and General Information Sheet (GIS), in case the Bidder has submitted a SEC registration in its PhilGEPS Certificate Platinum Membership, if applicable; and</p> <p><i>Failure of the Bidder declared as S/LCB to duly submit the requirements stated above or a finding against the veracity of such shall be ground for <u>forfeiture of the bid security and disqualify the Bidder for award.</u></i></p> <p><b>NOTE:</b></p> <p><b>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).</b></p> <p><b>2) As the possible Single/Lowest Calculated Responsive Bidder (S/LCRB), please provide the COBAC-D, 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.</b></p> <p><b>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.</b></p>
20.2	<i>Not Applicable.</i>
21.2	<i>Not Applicable.</i>

## ***Section IV. General Conditions of Contract***

## 1. Scope of Contract

This Contract shall include all such items, although not specifically mentioned, that can be reasonably inferred as being required for its completion as if such items were expressly mentioned herein. All the provisions of RA No. 9184 and its 2016 revised IRR, including the Generic Procurement Manual, and associated issuances, constitute the primary source for the terms and conditions of the Contract, and thus, applicable in contract implementation. Herein clauses shall serve as the secondary source for the terms and conditions of the Contract.

This is without prejudice to Sections 74.1 and 74.2 of the 2016 revised IRR of RA No. 9184 allowing the GPPB to amend the IRR, which shall be applied to all procurement activities, the advertisement, posting, or invitation of which were issued after the effectivity of the said amendment.

Additional requirements for the completion of this Contract shall be provided in the **Special Conditions of Contract (SCC)**.

## 2. Advance Payment and Terms of Payment

- 2.1. Advance payment of the contract amount is provided under Annex “D” of the revised 2016 IRR of RA No. 9184.
- 2.2. The Procuring Entity is allowed to determine the terms of payment on the partial or staggered delivery of the Goods procured, provided such partial payment shall correspond to the value of the goods delivered and accepted in accordance with prevailing accounting and auditing rules and regulations. The terms of payment are indicated in the **SCC**.

## 3. Performance Security

Within ten (10) calendar days from receipt of the Notice of Award by the Bidder from the Procuring Entity but in no case later than prior to the signing of the Contract by both parties, the successful Bidder shall furnish the performance security in any of the forms prescribed in Section 39 of the 2016 revised IRR of RA No. 9184.

## 4. Inspection and Tests

The Procuring Entity or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Project specifications at no extra cost to the Procuring Entity in accordance with the Generic Procurement Manual. In addition to tests in the **SCC, Section IV (Technical Specifications)** shall specify what inspections and/or tests the Procuring Entity requires, and where they are to be conducted. The Procuring Entity shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

All reasonable facilities and assistance for the inspection and testing of Goods, including access to drawings and production data, shall be provided by the Supplier to the authorized inspectors at no charge to the Procuring Entity.

## **5. Warranty**

- 5.1. In order to assure that manufacturing defects shall be corrected by the Supplier, a warranty shall be required from the Supplier as provided under Section 62.1 of the 2016 revised IRR of RA No. 9184.
- 5.2. The Procuring Entity shall promptly notify the Supplier in writing of any claims arising under this warranty. Upon receipt of such notice, the Supplier shall, repair or replace the defective Goods or parts thereof without cost to the Procuring Entity, pursuant to the Generic Procurement Manual.

## **6. Liability of the Supplier**

The Supplier's liability under this Contract shall be as provided by the laws of the Republic of the Philippines.

If the Supplier is a joint venture, all partners to the joint venture shall be jointly and severally liable to the Procuring Entity.

## ***Section V. Special Conditions of Contract***

## Special Conditions of Contract

GCC Clause	
1	<p><b>Delivery and Documents –</b></p> <p>For purposes of the Contract, “EXW,” “FOB,” “FCA,” “CIF,” “CIP,” “DDP” and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of INCOTERMS published by the International Chamber of Commerce, Paris. The Delivery terms of this Contract shall be as follows:</p> <p><i>[For Goods supplied from abroad, state:]</i> “The delivery terms applicable to the Contract are DDP delivered <i>[indicate place of destination]</i>. In accordance with INCOTERMS.”</p> <p><i>[For Goods supplied from within the Philippines, state:]</i> “The delivery terms applicable to this Contract are delivered <i>[indicate place of destination]</i>. Risk and title will pass from the Supplier to the Procuring Entity upon receipt and final acceptance of the Goods at their final destination.”</p> <p>Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in Section VI (Schedule of Requirements).</p> <p>For purposes of this Clause the Procuring Entity’s Representative at the Project Site is/are:</p> <p><b>DR. ANNA MARIE CELINA G. GARFIN</b>            Director IV            Disease Prevention and Control Bureau            Building 14, Department of Health            Tel No.: 651-7800 local 1700 to 1701            Fax No.: 8711-0380</p> <p><b>MS. MARITES B. ESTRELLA</b>            OIC-Division Chief, Financial and Supply Chain Management Division            Disease Prevention and Control Bureau            Building 14, Department of Health            Tel No.: 8651-7800 local 2363-64            Fax No.: 8711-0380</p> <p>The Contract price for the Goods shall include the prices charged by the Supplier for incidental services and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.</p> <p><b>Packaging –</b></p>



The Supplier shall provide such packaging of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in this Contract. The packaging shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packaging case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.

The packaging, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified below, and in any subsequent instructions ordered by the Procuring Entity.

The outer packaging must be clearly marked on at least four (4) sides as follows:

Name of the Procuring Entity

Name of the Supplier

Contract Description

Final Destination

Gross weight

Any special lifting instructions

Any special handling instructions

Any relevant HAZCHEM classifications

A packaging list identifying the contents and quantities of the package is to be placed on an accessible point of the outer packaging if practical. If not practical the packaging list is to be placed inside the outer packaging but outside the secondary packaging.

**Insurance –**

The Goods supplied under this Contract shall be fully insured by the Supplier in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery. The Goods remain at the risk and title of the Supplier until their final acceptance by the Procuring Entity.

**Transportation –**

Where the Supplier is required under Contract to deliver the Goods CIF, CIP, or DDP, transport of the Goods to the port of destination or such other named place of destination in the Philippines, as shall be specified in this Contract, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

Where the Supplier is required under this Contract to transport the Goods to a specified place of destination within the Philippines, defined as the Project Site, transport to such place of destination in the Philippines, including insurance and storage, as shall be specified in this Contract, shall be arranged by the Supplier, and related costs shall be included in the contract price.

	<p>Where the Supplier is required under Contract to deliver the Goods CIF, CIP or DDP, Goods are to be transported on carriers of Philippine registry. In the event that no carrier of Philippine registry is available, Goods may be shipped by a carrier which is not of Philippine registry provided that the Supplier obtains and presents to the Procuring Entity certification to this effect from the nearest Philippine consulate to the port of dispatch. In the event that carriers of Philippine registry are available but their schedule delays the Supplier in its performance of this Contract the period from when the Goods were first ready for shipment and the actual date of shipment the period of delay will be considered force majeure.</p> <p>The Procuring Entity accepts no liability for the damage of Goods during transit other than those prescribed by INCOTERMS for DDP deliveries. In the case of Goods supplied from within the Philippines or supplied by domestic Suppliers risk and title will not be deemed to have passed to the Procuring Entity until their receipt and final acceptance at the final destination.</p> <p><b>Intellectual Property Rights –</b></p> <p>The Supplier shall indemnify the Procuring Entity against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof.</p>
2.2	<p>Based on the General Provisions of the GAA of 2024, Section 70: Cash Budgeting System, all appropriations authorized in this Act shall be available for release and obligation for the purpose specified, and under the same general and special provisions applicable thereto, until December 31, 2025.</p> <p>The construction of infrastructure projects, delivery of goods and services, inspection, and payment of infrastructure capital outlays, MOOE and other capital outlays, shall be made not later than December 31, 2025.</p> <p>After the end of validity period, all unreleased appropriations and unobligated allotment shall lapse, while unexpended or undisbursed funds shall revert to the unappropriated surplus of the General Fund in accordance with Section 28, Chapter 4, Book VI of E.O. No. 292 and shall not thereafter be available for expenditure except by subsequent legislative enactment. Departments, bureaus, and offices of the National Government, including Constitutional Offices enjoying fiscal autonomy, and SUCs shall strictly observe the validity of appropriations and the reversion of funds.</p> <p><b>For staggered delivery:</b> 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.</p>
4	<p>The inspections and tests that will be conducted are:</p> <ol style="list-style-type: none"> <li>1) Upon delivery, the Goods shall undergo preliminary physical inspection by the Inspection Team of the PROCURING ENTITY to ascertain the physical condition and acceptability of the Goods.</li> </ol>

	<p>2) The supplier shall promptly replace the equivalent quantity of Goods taken as samples without cost to the PROCURING ENTITY.</p> <p>3) Failure to comply within the prescribed time shall compel the SCMS to have the subject commodities pulled out by the third party logistics service provider of the DOH with <b>the hauling and freight fees chargeable against the concerned supplier/company</b>. In observance of the above-mentioned timeline, coordinate with the SCMS of the DOH.</p>
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## *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	Total ABC (PhP)	Delivery Site	Delivered, Calendar Days
1	Trastuzumab 150 mg	25,000 vials	112,220,000.00	DOH Warehouse(s) in Metro Manila	<p><b>1<sup>st</sup> Tranche:</b> 12,500 vials – Sixty (60) calendar days from receipt of approved Notice to Proceed (NTP).</p> <p><b>2<sup>nd</sup> Tranche:</b> 12,500 vials – Ninety (90) calendar days from receipt of approved NTP.</p>
2	Trastuzumab 600 mg	8,700 vials	201,964,323.00		<p><b>1<sup>st</sup> Tranche:</b> 4,350 vials – Sixty (60) calendar days from receipt of approved NTP.</p> <p><b>2<sup>nd</sup> Tranche:</b> 4,350 vials – Ninety (90) calendar days from receipt of approved NTP.</p>

\_\_\_\_\_  
Signature over Printed Name  
*[date of signing]*

In the capacity of:

Duly authorized to sign bid for and on behalf of:

*[title or other appropriate designation]*

*[Name of Company]*

*[Complete office address]*

*[Contact No.]*

*[Fax No.]*

*[Email Address]*

## ***Section VII. Technical Specifications***

# Technical Specifications

Item	Specification	Statement of Compliance
		<p><i>Bidders must state here either “<b>Comply</b>” or “<b>Not Comply</b>” against each of the individual parameters of each Specification stating the corresponding performance parameter of the equipment offered. Statements of “Comply” or “Not Comply” must be supported by evidence in a Bidders Bid and cross-referenced to that evidence. Evidence shall be in the form of manufacturer’s un-amended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate. A statement that is not supported by evidence or is subsequently found to be contradicted by the evidence presented will render the Bid under evaluation liable for rejection. A statement either in the Bidder's statement of compliance or the supporting evidence that is found to be false either during Bid evaluation, post-qualification or the execution of the Contract may be regarded as fraudulent and render the Bidder or supplier liable for prosecution subject to the applicable laws and issuances.</i></p>

# Technical Specifications

Republic of the Philippines Department of Health <b>TECHNICAL SPECIFICATIONS</b>			
Item No. 1	<b>Trastuzumab 150 mg</b>	Quantity / Unit	<b>25,000 vials</b>
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No. 1: <b>PhP112,220,000.00</b>			
<b>PURCHASER'S SPECIFICATION</b>		<b>STATEMENT OF COMPLIANCE</b>	
<b>A. Detailed Technical Specifications:</b>  1. <b>Route of Administration:</b> IV infusion 2. <b>Form and Strength:</b> a) 150 mg lyophilized powder			
<b>B. Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</b>  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 ( <b>a copy of the expiring CPR which is stamped with an “Extension of Validity” shall be submitted as proof</b> ); [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). <b>Provided, that the application for renewal was made timely as per DOH AO No. 2016-003:</b>  <b>In case of expired LTO, the following copies may be submitted:</b> (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;  <b><i>In case of expired Certificate of Compliance to the EDPMS, refer to DOH Department Circular</i></b>			

Republic of the Philippines  
Department of Health  
TECHNICAL SPECIFICATIONS

Item No. 1	<b>Trastuzumab 150 mg</b>	Quantity / Unit	<b>25,000 vials</b>
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No. 1: <b>PhP112,220,000.00</b>			
<b>PURCHASER'S SPECIFICATION</b>		<b>STATEMENT OF COMPLIANCE</b>	
<i>(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."</i>			
6. Declaration or equivalent document from prospective bidders affirming the existence of a comprehensive pharmacovigilance system within their organizations;			
7. Sworn Statement <i>using the prescribed form</i> ;			
8. Guarantee letter from Supplier to replace medicines with approved shorter shelf-life six (6) months before expiry date.			
<b>C. <u>Replacement Instructions</u></b>			
Medicines with approved shorter shelf-life, replacement for fresh stocks shall be issued six (6) months before expiry date.			
<b>D. <u>Upon delivery the following shall be complied with:</u></b>			
1. <b>Shelf life:</b> 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. <b>Packaging instructions:</b> Standard packaging of the manufacturer as approved by PFDA.			
3. <b>Labeling instructions:</b>			
a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.			
b) <b>In addition to the labelling requirements of FDA:</b>			
i. Each <b>box</b> should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed: <div style="text-align: center;">Philippine Government Property – Department of Health <b>NOT FOR SALE</b></div>			
ii. Each <b>bigger box/corrugated carton</b> should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed: <div style="text-align: center;">Philippine Government Property – Department of Health <b>NOT FOR SALE</b></div>			
Date of Manufacture: _____			
Date of Expiry: _____			
Batch/Lot No.: _____			
<b>E. Product Recall &amp; Disposal:</b>			
1. The Supplier must ensure the quality of products and if there will be problems in the quality,			



Republic of the Philippines Department of Health <b>TECHNICAL SPECIFICATIONS</b>			
Item No. 1	<b>Trastuzumab 150 mg</b>	Quantity / Unit	<b>25,000 vials</b>
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No. 1: <b>PhP112,220,000.00</b>			
<b>PURCHASER'S SPECIFICATION</b>		<b>STATEMENT OF COMPLIANCE</b>	
<p>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;</p> <p>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).</p>			

\_\_\_\_\_  
 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]*

Republic of the Philippines  
Department of Health  
TECHNICAL SPECIFICATIONS

Item No. 2	<b>Trastuzumab 5 mL</b>	Quantity / Unit	<b>8,700 vials</b>
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No. 2: <b>PhP201,964,323.00</b>			
<b>PURCHASER'S SPECIFICATION</b>		<b>STATEMENT OF COMPLIANCE</b>	
<b>A. Detailed Technical Specifications:</b> <ol style="list-style-type: none"> <li>1. <b>Route of Administration:</b> Injection (SC)</li> <li>2. <b>Form and Strength:</b> <ol style="list-style-type: none"> <li>a) 600 mg/5 mL (120 mg/mL)</li> <li>b) Solution for injection, 5 mL vial</li> </ol> </li> </ol>			
<b>B. Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</b> <ol style="list-style-type: none"> <li>1. Valid and current Certificate Product Registration (CPR) or Valid Extension issued by Philippine Food and Drug Administration (PFDA); <p>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 (<b>a copy of the expiring CPR which is stamped with an “Extension of Validity” shall be submitted as proof</b>); [AO 2019-0041]</p> </li> <li>2. Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA). <i>Provided, that the application for renewal was made timely as per DOH AO No. 2016-003:</i> <p><b>In case of expired LTO, the following copies may be submitted:</b></p> <ol style="list-style-type: none"> <li>(i) expired LTO;</li> <li>(ii) application for renewal with FDA document tracking number; and,</li> <li>(iii) Official Receipt as proof of payment of renewal of LTO</li> </ol> </li> <li>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;</li> <li>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;</li> <li>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;</li> </ol> <p><b><i>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</i></b></p>			

Republic of the Philippines  
Department of Health  
TECHNICAL SPECIFICATIONS

Item No. 2	<b>Trastuzumab 5 mL</b>	Quantity / Unit	<b>8,700 vials</b>
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No. 2: <b>PhP201,964,323.00</b>			
<b>PURCHASER'S SPECIFICATION</b>		<b>STATEMENT OF COMPLIANCE</b>	
<i>Price Monitoring System for Government Procurement Activities for Drugs and Medicines.”</i>			
<p>6. Declaration or equivalent document from prospective bidders affirming the existence of a comprehensive pharmacovigilance system within their organizations;</p> <p>7. Sworn Statement <i>using the prescribed form</i>;</p> <p>8. Guarantee letter from Supplier to replace medicines with approved shorter shelf-life six (6) months before expiry date.</p>			
<b>C. <u>Replacement Instructions</u></b>			
Medicines with approved shorter shelf-life, replacement for fresh stocks shall be issued six (6) months before expiry date.			
<b>D. <u>Upon delivery the following shall be complied with:</u></b>			
<p>1. <b>Shelf life:</b> 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.</p> <p>2. <b>Packaging instructions:</b> Standard packaging of the manufacturer as approved by PFDA.</p> <p>3. <b>Labeling instructions:</b></p> <p>a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.</p> <p>b) <b>In addition to the labelling requirements of FDA:</b></p> <p style="margin-left: 40px;">i. Each <b>box</b> should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed:  <div style="text-align: center; margin-left: 80px;">Philippine Government Property – Department of Health <b>NOT FOR SALE</b></div> </p> <p style="margin-left: 40px;">ii. Each <b>bigger box/corrugated carton</b> should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed:  <div style="text-align: center; margin-left: 80px;">Philippine Government Property – Department of Health <b>NOT FOR SALE</b></div> </p> <p style="margin-left: 120px;">Date of Manufacture: _____</p> <p style="margin-left: 120px;">Date of Expiry: _____</p> <p style="margin-left: 120px;">Batch/Lot No.: _____</p>			
<b>E. <u>Product Recall &amp; Disposal:</u></b>			
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;			

Republic of the Philippines  
Department of Health  
TECHNICAL SPECIFICATIONS

Item No. 2	<b>Trastuzumab 5 mL</b>	Quantity / Unit	<b>8,700 vials</b>
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC for Item No. 2: <b>PhP201,964,323.00</b>			
<b>PURCHASER'S SPECIFICATION</b>		<b>STATEMENT OF COMPLIANCE</b>	
<p>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).</p>			

\_\_\_\_\_  
Signature over Printed Name  
*[date of signing]*

In the capacity of:  
Duly authorized to sign bid for and on behalf of:

*[title or other appropriate designation]*  
*[Name of Company]*  
*[Complete office address]*  
*[Contact No.]*  
*[Fax No.]*  
*[Email Address]*

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

# 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) in accordance with Section 8.5.2 of the IRR;

#### Technical Documents

- (b) 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**
- (c) Statement of the bidder's **Single Largest Completed Contract (SLCC)** similar to the contract to be bid, the amount of which should be equivalent to at least *twenty-five percent (25%)* of the ABC for this Project, 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**
- (d) 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**
- (e) 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**
- (f) 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

- (g) 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***

- (h) If applicable, a duly signed joint venture agreement (JVA) in case the joint venture is already inexistence;  
**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)***

- (i) *[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.
- (j) 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).  
***Note: Trastuzumab is included in the list of Vat Exempt Products. Please refer to Bureau of Internal Revenue (BIR) Revenue Memorandum Circular No. 81-2021 on the “List of VAT-Exempt Products” pursuant to RA No. 11534 otherwise known as the Corporate Recovery and Tax Incentives for Enterprises (CREATE) Act.***

### **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);

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 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

- (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 Technical Specifications;
- (d) 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;
- (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, 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."*

- (f) Declaration or equivalent document from prospective bidders affirming the existence of a comprehensive pharmacovigilance system within their organizations;
- (g) Sworn Statement *using the prescribed form*;
- (h) Guarantee letter from Supplier to replace medicines with approved shorter shelf-life six (6) months before expiry date.

**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



