INVITATION TO BID

PRO-1903ITBRF

SEASONAL INFLUENZA NORTHERN HEMISPHERE 2019-2020

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

Section 1: Letter of Invitation

11 February 2019

ITB # PRO-1903ITBRF
SEASONAL INFLUENZA NORTHERN HEMISPHERE 2019-2020

Dear Sir/Madam,

The Pan American Health Organization (PAHO) hereby invites you to submit a bid to this Invitation to Bid **ITB # PRO-1903ITBRF** for SEASONAL INFLUENZA NORTHERN HEMISPHERE 2019-2020 for PAHO Member States. PAHO is the Regional Office of the Americas of the World Health Organization, and the products or services purchased under this ITB will be used for technical cooperation in the health programs of certain countries.

This ITB includes the following sections and annexes.

Sections:

- Section 1 – Letter of Invitation
- Section 2 – Instructions to Bidders (including Data Sheet)
- Section 3 –Technical Offer
- Section 4 – Financial Offer
- Section 5 – PAHO General Terms and Conditions
- Section 6 – Sample Notification Letter

Annexes:

- Annex I – Technical Requirements
- Annex II – Quality Requirements
- Annex III – Information on regulatory status
- Annex IV- Checklist for the Technical documents included in the technical proposal
- Annex V - Yearly review of Products supplied to PAHO Member States and Manufacturing Consistency Report
- Annex VI – Packing & Shipping Instructions
- Annex VII – Sample Shipping Labels
- Annex VIII – In-tend Product Questionnaire
- Annex IX- Bid offer Sheet

Your bid, comprised of a Technical Offer and Financial Offer should be submitted in accordance with Section 2, Instructions to Bidders.

Your bid should be received by PAHO no later than ***5:30 p.m.*** local time through PAHO's electronic tendering system, In-Tend, on ***11 March 2019*** . If your company does not intend to submit a bid, PAHO would appreciate knowing why you would not like to participate.

Should you require any clarification, kindly contact the person identified in the attached Data Sheet as the focal point for queries on this ITB.

PAHO looks forward to receiving your bid and thanks you in advance for your interest in PAHO procurement opportunities.

Yours sincerely,

Daniel Rodriguez,
Director Procurement and Supply Management

Section 2: Instruction to Bidders

A. GENERAL

1. PAHO hereby solicits bids as a response to this Invitation to Bid (ITB). Bidders must strictly adhere to all requirements of this ITB. No changes, substitutions or other alterations to the provisions stipulated in this ITB may be made or assumed unless instructed in writing by PAHO.
2. A Bidder is eligible to bid on this solicitation if the Bidder complies with the conditions detailed in this document and its annexes. Attention should be given to **any eligibility criteria listed at Section 3.**
3. In responding to this ITB, PAHO requires all Bidders to conduct themselves in a professional, objective and impartial manner. Bidders must at all times hold PAHO's interests paramount. Bidders must strictly avoid conflicts with other assignments or their own interests, and act without consideration for future work.

   3.1 All Bidders found to have a conflict of interest will be disqualified. Without limitation on the generality of the above, Bidders, and any of their affiliates, shall be considered to have a conflict of interest with one or more parties in this solicitation process, if they:

   3.1.1 Are, or have been associated in the past, with a firm or any of its affiliates which have been engaged by PAHO to provide services for the preparation of the design, technical requirements, cost analysis/estimation, and other documents used for the procurement of goods or services in this selection process;

   3.1.2 Were involved in the preparation and/or design of the program/project related to the goods or services requested under this ITB; or

   3.1.3 Are found to be in conflict for any other reason, as may be established by, or at the sole discretion of, PAHO.

   3.2 In the event of any uncertainty in the interpretation of what is potentially a conflict of interest, Bidders must disclose the condition to PAHO and seek PAHO's confirmation on whether or not such conflict exists.
4. The following must be disclosed in the Bid, and the failure of such disclosure may result in rejection of the bid:

   4.1 Bidders who are owners, part-owners, officers, directors, controlling shareholders, or key personnel who are family of PAHO staff or the government of the country or implementing partner receiving the goods or services under this ITB;

   4.2 Any matter that could potentially lead to actual or perceived conflicts of interest, collusion, or unfair competition practices.
5. All Bidders must adhere to the UN Supplier Code of Conduct, which may be found at this link: http://www.un.org/depts/ptd/pdf/conduct_english.pdf. Bidders must inform PAHO immediately in writing by an email notice to Shirley Quesada (quesadas@paho.org), if at any time during the bid validity period it is no longer in agreement with the UN Supplier Code of Conduct, debarred by the World Bank, or suspended by any UN organization.
6. This ITB contains confidential and proprietary information from PAHO. It may not be reproduced, in whole or in part, without the express written permission of PAHO, or unless necessary to respond to this solicitation. PAHO makes no promises or guarantees concerning the completeness or accuracy of information contained in this solicitation.

7. The Bidder will acknowledge receipt of this ITB not later than ***22 February 2019*** through PAHO's electronic tendering system, In-Tend, using the "correspondence" tab / in writing via an email.

B. CONTENTS OF BID

8. Bidders are required to complete and submit the following:

   8.1 **Technical Offer**, in which the Bidder will respond to Section 3 and relevant Annexes of this ITB.

   8.1.1 This section should demonstrate the Bidder's response to any technical requirements by identifying how each of PAHO's requirements will be met. Details of technical bid must be laid out and supported by an implementation timetable, including a delivery schedule as detailed in Annex VIII (In-Tend questionnaire).

   8.1.2 **Samples** of the product(s) offered if and as requested at questions 20 and 21 of the **Data Sheet**

   8.2 **Financial Offer**, which will be prepared using the format described in Section 4 and Annex IX of this ITB.

   8.3 **Documents** required in this ITB, including its annexes and/or referenced in the **Data Sheet** at questions 18 and 23.

C. PREPARATION OF BID

9. **Cost**

   9.1 The Bidder will bear any and all costs related to the preparation and/or submission of the bid, regardless of whether its bid was selected or not. PAHO will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the procurement process.

10. **Language**

   10.1 The bid, as well as any and all related correspondence exchanged by the Bidder and PAHO, will be written in the language(s) specified in the **Data Sheet**. Any printed literature furnished by the Bidder written in a language other than the language indicated in the **Data Sheet** must be accompanied by a translation in the preferred language indicated in the **Data Sheet**. For purposes of interpretation of the bid, and in the event of discrepancy or inconsistency in meaning, the version translated into the preferred language will govern.

11. **Currencies**

   11.1 All prices will be quoted in the currency indicated in the **Data Sheet**.

12. **Clarification of ITB and bidders conference**

   12.1 Bidders may request clarification of any of the ITB documents no later than the date indicated in the **Data Sheet**. Any request for clarification must be sent in writing to PAHO via the UNGM correspondence system as indicated in the **Data Sheet**. PAHO will respond in writing, transmitted by electronic means and will transmit copies of the response (including an explanation of the query but without identifying the source of inquiry) to all Bidders who have provided confirmation of their intention to submit a bid.

   12.2 PAHO will endeavor to provide such responses to clarification requests in an expeditious manner, but

any delay in such response will not cause an obligation on the part of PAHO to extend the submission date of the bid, unless PAHO deems at its sole discretion that such an extension is justified and necessary.

12.3 A *one (1) hour* meeting/teleconference will be held for all vendors to clarify technical requirements. The conference will be hosted at PAHO on ***not applicable for this ITB***. Attendance is not mandatory but recommended. You may nominate a lead person from your organization to attend the optional conference. Vendors may attend the meeting in person or by conference call. The meeting information will be provided via UNGM correspondence module.

D. SUBMISSION OF BID

13. By submitting a bid, Bidder expressly accepts all terms and conditions contained in this ITB.

14. In-Tend should be used to submit bids.

14.1 The **Technical Offer** must be submitted as a pdf or a similar format and attached to In-Tend.

14.2 The **Financial Offer** must be made via the Bid Offer Sheet, which is provided at Annex IX. The Bid Offer Sheet must be downloaded, completed, printed, signed, and submitted via In-Tend as a pdf or similarly formatted file.

15. **Deadline for Submission of Bid and Late Bids**

15.1 The Technical Offer and Financial Offer must be received by PAHO not later than 5:30 p.m. Local time via IN TEND on ***11 March 2019*****.**

15.2 Samples must be submitted as detailed in the Data Sheet.

15.3 PAHO will not consider any bid that arrives after the deadline for submission of bid. Any bid received by PAHO after the deadline for submission of bid will be declared late and will be rejected via IN TEND.

16. **Amendment of ITB**

16.1 At any time prior to the deadline for submission of bid, PAHO may for any reason modify the ITB in the form of a Supplemental Information to the ITB. All prospective Bidders will be notified in writing of all changes/amendments and additional instructions through Supplemental Information to the ITB and through the method specified in the **Data Sheet**.

16.2 In order to afford prospective Bidders reasonable time to consider the amendments in preparing their bid, PAHO may, at its discretion, extend the deadline for submission of Bid, if the nature of the amendment to the ITB justifies such an extension.

17. **Withdrawal, Substitution, and Modification of Bid**

17.1 The Bidder has sole responsibility for ensuring the full adherence of its bid to the requirements of this ITB. Failure to provide information requested by PAHO or lack of clarity in the description of goods or services to be provided may result in the rejection of the bid. The Bidder will assume any responsibility regarding erroneous interpretations of or conclusions made by the Bidder about this ITB.

17.2 Prior to the close of bidding, a Bidder may withdraw, substitute, or modify its bid via the In-Tend system.

17.3 A bid requested to be withdrawn cannot be returned via In-Tend.

17.4 No bid may be withdrawn, substituted, or modified in the interval between the deadline for submission of bid and the expiration of the period of bid validity.

18. **Bid Validity Period**

18.1 Bid will remain valid for the period specified in the **Data Sheet** commencing on the submission deadline date also indicated in the **Data Sheet**.

E. OPENING OF BID

19. **Bid Opening**

19.1 Bids will be opened by PAHO at 1889 F Street N.W - 3rd Floor; Washington, D.C. 20006, USA, at 10:00 a.m., local time, on ***13 March 2019.***

19.2 PAHO will open bids in the presence of an ad-hoc committee formed by PAHO of at least three (3) people. Attendance at the bid opening will be as specified in the **Data Sheet**.

19.3 PAHO reserves the right to exercise its sole discretion, for any reason, to reject any and all bids.

F. EVALUATION OF BID

20. **Confidentiality**

20.1 Information relating to the examination, evaluation, and comparison of bid and the recommendation of award will not be disclosed to Bidders or any other persons not officially concerned with such process, even after issuance of Notification Letters.

20.2 Any effort by a Bidder to influence PAHO in the examination, evaluation and comparison of the bid or contract award decisions may, at PAHO's discretion, result in the rejection of its bid.

20.3 In the event that a Bidder is unsuccessful, the Bidder may seek a meeting with PAHO for a debriefing. The purpose of the debriefing is discussing the strengths and weaknesses of the Bidder's submission, in order to assist the Bidder in improving future bids presented to PAHO. The content of other bids and how they compare to the Bidder's submission will not be discussed.

21. **Evaluation of Bid**

21.1 PAHO will examine the bid to confirm that all terms and conditions of the ITB have been accepted by the Bidder without any deviation or reservation. Any additional or varying term and condition proposed by a Bidder shall be void and of no effect.

21.2 The evaluation team will review bids on the basis of their responsiveness to the technical requirements and other requirements contained in this ITB. PAHO will also consider, among other things, value for money, ability to cover country requirements on a quarterly basis, fair and effective competition, past performance, and the Bidder's recent shipping prices.

21.3 PAHO reserves the right to undertake a post-qualification exercise, aimed at determining, to its satisfaction, the validity of the information provided by the Bidder.

22. **Clarification of Bid**

22.1 To assist in the examination, evaluation and comparison of bids, PAHO may, at its discretion, ask any Bidder to clarify its bid.

22.2 PAHO's request for clarification and the Bidder's response will be in writing. Notwithstanding the written communication, no change in the prices or substance of the bid will be sought, offered, or permitted, except to provide clarification or to confirm the correction of any arithmetic errors discovered by PAHO in the evaluation of the bid.

22.3 Any unsolicited clarification submitted by a Bidder, which is not a response to a request by PAHO, will not be considered during the review and evaluation of the bid.

23. **Responsiveness of Bid**

23.1 PAHO's determination of a bid's responsiveness will be based on the contents of the bid itself.

23.2 A substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the ITB without material deviation or omission.

24. **Nonconformities, Reparable Errors and Omissions**

24.1 Provided that a bid is substantially responsive, PAHO may waive any non-conformities or omissions in the bid that, in the opinion of PAHO, do not constitute a material deviation.

24.2 Provided that a bid is substantially responsive, PAHO may request the Bidder to submit the necessary information or documentation, within a reasonable period of time, to correct nonmaterial nonconformities or omissions in the bid related to documentation requirements. Such omission will not be related to any aspect of the price of the bid. Failure of the Bidder to comply with the request may result in the rejection of its bid.

24.3 Provided that the bid is substantially responsive, PAHO will correct arithmetic errors as follows:

24.3.1 if there is a discrepancy between the unit price and the line item total that is obtained by multiplying the unit price by the quantity, the unit price will prevail and the line item total will be corrected, unless in the opinion of PAHO there is an obvious misplacement of the decimal point in the unit price, in which case the line item total as quoted will govern and the unit price will be corrected;

24.3.2 if there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals will prevail and the total will be corrected; and

24.3.3 if there is a discrepancy between words and figures, the amount in words will prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures will prevail subject to the above.

24.4 If the Bidder does not accept the correction of errors made by PAHO, its bid will be rejected.

G. NOTIFICATIONS AND PURCHASES

25. **Right to Accept, Reject, or Render Non-Responsive Any or All Bids**

25.1 PAHO reserves the right to accept or reject any bid, to deem any bid as non-responsive, and to reject all bids at any time prior to issuing any award, without incurring any liability or obligation to inform the affected Bidder(s) of the grounds for PAHO's action.

26. **Award**

26.1 At its sole discretion, PAHO will determine whether to issue an award via Notification letter[1] to any and all Bidders whose bids have been retained (a Bidder who receives a Notification may hereinafter also be referred to as "Supplier"). Notifications will be in substantially the same format as that set forth in Section 6.

26.2 Issuance of a Notification letter does not in any manner whatsoever obligate PAHO to purchase any products from any Supplier. In the event that PAHO purchases any products, it reserves the right to purchase products from one or more Suppliers. Unless otherwise agreed to in writing between PAHO and the Supplier, the Supplier agrees that it will not increase the prices set forth in the Notification, regardless of the amount PAHO purchases.

26.3 If and to the extent that PAHO elects to purchase any products or services from a Supplier, PAHO will issue a Purchase Order for each purchase under substantially the same general terms and conditions as those contained in Section 5 of this ITB. Said Purchase Order, together with this ITB, the Notification and the bid, will constitute the contract for each such purchase. In the event of any inconsistency between these documents, the order of precedence will be: (1) the Purchase Order; (2) this ITB; (3) the Notification, and (4) the bid.

26.4 The Supplier guarantees that, during the validity of the Notification, if it offers or sells at a lower price to anyone, it shall also offer that same price to PAHO. The Supplier shall notify PAHO immediately upon offering or agreeing to sell at a lower price and the price offered to PAHO shall be reduced retroactively, effective as of the date the Supplier offered or agreed to sell at a lower price.

[1] PAHO may also elect to issue a *conditional* Notification letter, in which the final award is contingent on PAHO receiving by the date set forth in the letter certain documents that may not be available at the time of bid opening, e.g., Certificate of Pharmaceutical Product.

H. DATA SHEET

The following data for the supply of goods or services will supplement the provisions above. In case of conflict between the instruction above and the Data Sheet, the provisions in the Data Sheet will prevail.

No.	Data	Specific Instructions / Requirements	
1	Project Title:	ITB – SEASONAL INFLUENZA NORTHERN HEMISPHERE 2019-2020 Ref # PRO-1903ITBRF	
2	Goods/Services/Work Required:	**Vaccines** **PLEASE SEE** ANNEX IX: BID OFFER SHEET	
3	Country:	Countries within the PAHO Region	
4	Language of the Bid:	☒ English	
5	Bids for Parts or Sub-Parts of the Total Requirements	☒ Allowed	
7	Pre-bid Conference will be held on:	☒Not applicable	
8	Period of Bid Validity commencing on the submission date	☒ Through ***31 July 2020***.	
9	Delivery Terms [INCOTERMS 2010]	☒Air ☐Multimodal	☒DAT to the requested place in the purchase order.
10	Consignee	PAHO member states (Specific entity will be defined with the Purchase Order)	
11	Required Delivery Date	Best delivery based on PAHO requirements as per Annex VIII	
12	Delivery Schedule	☒Required (Fill out Annex VIII)	
13	Currency of Bid	☒US Dollar	
14	Clarifications/ Questions Deadline	***22 February 2019*** via the UNGM correspondence system	

15	Bidders Conference	Date/Time: ***not applicable for this ITB***	
16	Contact Details for submitting clarifications/questions[2]	Via In-Tend, using the "correspondence" tab, in writing via an email within the system.	
17	Manner of Disseminating Supplemental Information to the ITB and responses/ clarifications to queries	☒In-Tend	
18	Technical Bid Submission Deadline and Address	☒In-Tend	Date and Time: ***11 March 2019*** not later than 5:30 p.m. local time
19	Required Documents to accompany Technical Bid	☒Refer to Annexes	
20	Financial Bid Deadline and Address	☒In-Tend	Date and Time: ***11 March 2019*** not later than 5:30 p.m. local time
21	Samples Submission Deadline and Address	☒Not applicable	Date and Time:
22	Samples Description	☒Not applicable	
23	Copies of Bid that must be submitted	☒Not applicable	
24	Other Required Documents to accompany Bid	☒Not applicable	
25	Bid Opening	☒ By Invitation	Date, Time, Venue: **Date: *13 March 2019*** Time: 10:00 a.m. local time Venue: PAHO Procurement Department 1889 F Street, NW-3rd Floor Washington DC, USA 20006

[2] *This contact person and address is officially designated by PAHO. If inquiries are sent to other person/s or address/es, even if they are PAHO staff, PAHO will have no obligation to respond nor can PAHO confirm that the query was received.*

26	Type of Procurement Opportunity to be awarded	☒ Notification Letter
27	Duration of Award	☒ Through ***31 July 2020***
28	Payment Terms	☒ 100% within 30 days of whichever is later: receipt of the Supplier's electronic invoice, copy of the shipping documents, and proof of arrival.
29	Performance Security	☒Not Required
30	Penalty Clause	☒ Not applicable

Bottom of Form

Section 3: Technical Offer and Eligibility requirements

The Bidder is required to prepare a Technical Offer via In-Tend. This section should demonstrate the Bidder's response to the technical requirements described in the annexes to this ITB by identifying the following, as applicable:

- specific components proposed;
- how each of the requirements will be met;
- essential performance characteristics;
- how the bid meets or exceeds the requirements.

For purposes of this solicitation:

1. For products offered that are WHO prequalified, a Bidder is eligible if it offers a product that has been pre-qualified by WHO at the time the bids for this solicitation are opened.[3,4]

2. For products not prequalified by WHO, a Bidder is eligible if it offers a product that is registered and has been granted a marketing authorization and a lot release (if applicable) by one of the following authorities:

   2.1 Pharmaceuticals:
   - ANMAT (Argentina), ANVISA (Brazil), BGTD (Canada), COFEPRIS (Mexico), CECMED (Cuba), INVIMA (Colombia), ISP (Chile) or FDA (USA), or
   - A stringent regulatory authority (SRA) as defined in WHO's "Guidelines on Submission of Documentation for Prequalification of Finished Pharmaceutical Products Approved by Stringent Regulatory Authorities."[3]

   2.2 Biologicals:
   ANVISA (Brazil), BGTD (Canada), CECMED (Cuba), COFEPRIS (Mexico), ANMAT (Argentina), EMA (Europe), FDA (USA), KFDA (Korea) or TGA (Australia).

[3] Specific to antiretrovirals for treatment of people living with HIV/AIDS, a Bidder is also eligible to bid if it offers a product that has received Approval or Tentative Approval by the United States Food and Drug Administration (i) for sale in the United States or (ii) in association with PEPFAR.

[4] If offers for WHO prequalified products whose supply does not meet the Regional demand, PAHO, at its sole discretion, may consider offers that meet eligibility criteria #2.

[3] WHO Technical Report Series 986, Annex 5, 2014, as updated in WHO Guidance Document "Clarification with Respect to a Stringent Regulatory Organization as Applicable to the Stringent Regulatory Authority (SRA) Guideline" (15 February 2017):
An SRA is "a regulatory authority that is:
a) a member of ICH [formerly the International Conference on Harmonization and currently the International Council for Harmonization] prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labor and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or
b) an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or
c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway."

3. The product offered must meet the specifications of this solicitation.

4. The Bidder agrees to comply with all conditions of this solicitation, as detailed through this document, including the annexes.

Section 4: Financial Offer

1. The Bidder is required to prepare a Financial Offer using the Bid Offer Sheet below. Financial bids will adhere to the following guidelines:

   - Quantities requested in this ITB are provided as good faith estimates of potential requirements. Estimates are based on countries quarterly and annual demand plans for use through ***31 July 2020***. Quantities set forth in this solicitation or any Notification letter shall not constitute any commitment on the part of PAHO to purchase any products. During the course of the year, PAHO will provide the Bidders who receive a Notification letter with updates of rolling forecasts to help manage changes. Similarly, the Bidder will provide PAHO with updates on availability of stocks.
   - Prices, including for freight, will be quoted in US dollars.
   - Prices will be reported only to the ten-thousandth place (no more than four numbers after the decimal point).
   - Only one price per presentation will be accepted. If the bid includes more than one price per presentation, PAHO will consider only the lowest one, regardless of the quantity offered.
   - Bidder should indicate the delivery lead-time for each product on the In-Tend questionnaires. Delivery lead-time, that is, delivery days after receipt of the purchase order, includes time to complete administrative arrangements, packing, marking, issuing shipping documents, and transporting goods to the airport or port for export.
   - Bidders shall quote prices FCA to the international airport nearest to their facilities (INCOTERMS 2010), and provide packing, labeling, and shipping information using the Questionnaires at Annex VIII and provided electronically on In-Tend.
   - For selection purposes, Bids will be compared without freight costs for European and North American companies. Bidders located in other areas of the world shall provide the estimated percentage by which freight costs from their area exceed those from Europe to the Americas, or shall provide a written guarantee to PAHO that freight costs shall not exceed reasonable freight costs from Europe to North America.
   - Any fees related to special handling may be itemized in the commercial invoice. Such fees must be indicated at the time the quote is provided

2. **Bid offer sheet (Annex IX).** This Bid Offer Sheet should be downloaded, completed, signed, and submitted as a pdf or similar file through In-Tend. In compliance with the above referenced Invitation to Bid (ITB), the bids set forth herein shall remain valid through ***31 July 2020***. Bidder understands that pursuant to the terms and conditions set forth in this ITB, PAHO shall issue a Notification to all bidders whose bids have been retained.
3. A Questionnaire (Annex VIII, which is included electronically on In-Tend), should be completed for each vaccine offered. If there is any inconsistency between the signed Bid Offer Sheet and Questionnaires, the information contained in the signed Bid Offer Sheet shall prevail.

Section 5: PAHO General Terms and Conditions

1. LEGAL STATUS OF THE PARTIES/RESPONSIBILITY FOR EMPLOYEES: The Contractor shall be considered as having the legal status of an independent contractor to PAHO. The Contractor's personnel and sub-contractors shall not be considered in any respect to be the employees or agents of PAHO and shall have no right or authority, express or implied, to commit or otherwise obligate PAHO to a third party in any way. The Contractor shall be responsible for the professional and technical competence of the personnel it assigns to perform services under the Contract and will select reliable and competent individuals who will be able to effectively perform the obligations under the Contract and who, while doing so, will respect the local laws and customs and conform to a high standard of moral and ethical conduct.

2. STANDARD OF PERFORMANCE: The Contractor agrees that the goods and/or services provided under this Contract shall conform to the highest professional standards. The Contractor shall conform to all applicable laws, regulations and ordinances promulgated by the government of the country in which the goods or services are provided. Further, the Contractor agrees to utilize any information and/or documents obtained from or provided by PAHO for the purpose of the Contract exclusively for the activities agreed upon between PAHO and the Contractor.

3. ASSIGNMENT: The Contractor shall not assign, transfer, pledge or make other disposition of this Contract, or any part thereof, or of any of the Contractor's rights or obligations hereunder, without the prior written authorization of PAHO. In addition, the assignee or transferee must agree in writing to be bound by all terms and conditions of this Contract.

4. SUBCONTRACTING: The Contractor shall first obtain the written approval of PAHO before subcontracting to a third party any of the Contractor's responsibilities under this Contract. PAHO's approval shall not relieve the Contractor of any of its obligations under this Contract. The terms of any sub-contract shall be subject to and conform to the provisions of this Contract.

5. PURCHASE OF GOODS: If the Contract involves, in whole or in part, the purchase of goods, the following conditions shall apply unless specifically stated otherwise in the Contract:

5.1. PACKAGING OF THE GOODS: The Contractor shall package the goods for delivery in accordance with the highest standards of packaging for the type and quantities and modes of transport of the goods. The goods shall be packed and marked in a proper manner in accordance with the shipping instructions attached to the Contract or, otherwise, as customarily done in the trade, and in accordance with any requirements imposed by applicable law, including regulations for the transportation of hazardous materials, or by the transporters and manufacturers of the goods as per International Standards

5.2. EXPORT LICENSING: The Contractor shall be responsible for obtaining any export licenses required with respect to the goods, products, or technologies, including software that is sold, delivered, licensed or otherwise provided to PAHO or its designee under the Contract. The Contractor shall procure any such license in an expeditious manner.

5.3. TRANSPORTATION AND FREIGHT: Unless otherwise specified in the Contract, the Contractor shall be solely liable for making all transport arrangements and for payment of freight and insurance costs for the shipment and delivery of the goods in accordance with the requirements of the Contract. The Contractor shall ensure that PAHO

or its designee receives all necessary transport documents in a timely manner so as to enable PAHO or its designee to take delivery of the goods in accordance with the requirements of the Contract.

5.4. DELIVERY OF GOODS: The Contractor shall hand over or make available the goods, and PAHO or its designee shall receive the goods, at the place and time designated under the Contract for their delivery. The Contractor shall provide to PAHO or its designee such shipment documentation (including, without limitation, bills of lading, airway bills, and commercial invoices) as are specified in the Contract or, otherwise, as are customarily utilized in the trade. All manuals, instructions, displays and any other information relevant to the goods shall be in the English language unless otherwise specified herein. The entire risk of loss, damage to, or destruction of the goods shall be borne exclusively by the Contractor until physical delivery of the goods to PAHO or its designee in accordance with the terms of the Contract. Delivery of the goods shall not be deemed in itself as constituting acceptance of the goods by PAHO.

5.5. INSPECTION OF GOODS: If the Contract provides that the goods may be inspected prior to delivery, the Contractor shall notify PAHO or its designee when the goods are ready for pre-delivery inspection. Notwithstanding any pre-delivery inspection, PAHO or its designated inspection agents may also inspect the goods upon delivery in order to confirm that the goods conform to applicable specifications or other requirements of the Contract.

5.6. ACCEPTANCE OF GOODS: Under no circumstances shall PAHO or its designee be required to accept any goods that do not conform to the specifications or requirements of the Contract. PAHO or its designee may condition its acceptance of the goods upon the successful completion of acceptance tests as may be specified in the Contract or otherwise agreed in writing by the Parties. In no case shall PAHO or its designee be obligated to accept any goods unless and until PAHO or its designee has had a reasonable opportunity to inspect the goods following delivery. If the Contract specifies that PAHO or its designee shall provide a written acceptance of the goods, the goods shall not be deemed accepted unless and until PAHO or its designee in fact provides such written acceptance. In no case shall payment by PAHO, in and of itself, constitute acceptance of the goods.

5.7. REJECTION OF GOODS: Notwithstanding any other rights or remedies available to PAHO under the Contract, if any of the goods are defective or otherwise do not conform to the specifications or other requirements of the Contract, PAHO or its designee, at their sole option, may reject or refuse to accept the goods. Within thirty (30) days following receipt of notice from PAHO of such rejection or refusal to accept the goods, the Contractor shall, at PAHO's sole discretion and at no additional expense to PAHO, either:

5.7.1. provide a full refund upon return of the goods, or a partial refund upon a return of a portion of the goods, by PAHO or its designee;

5.7.2. repair the goods in a manner that would enable the goods to conform to the specifications or other requirements of the Contract; or

5.7.3. replace the goods with goods that meet the specifications of the Contract.

5.8. In the event that PAHO or its designee elects to return any of the goods for the reasons specified in this Article, PAHO may procure the goods from another source. In addition to any other rights or remedies available to PAHO under the Contract, including, but not limited to, the right to terminate the Contract, the Contractor shall be liable for any additional cost beyond the balance of the Contract price resulting from any such procurement, including, inter alia, the costs of engaging in such procurement. Likewise, the Contractor shall pay all costs relating

to the repair or return of the defective goods as well as the costs relating to the storage of any such defective goods and for the delivery of any replacement goods to PAHO or its designee.

6. WARRANTIES: In addition to and without limiting any other warranties, remedies or rights of PAHO stated in or arising under the Contract, the Contractor warrants and represents that:

6.1. The goods, including all packaging and packing thereof, and/or Services to be provided under the Contract conform to the specifications of the Contract, are fit for the purposes for which they are ordinarily used and for any purposes expressly made known in writing in the Contract, and shall be of even quality, free from faults and defects in design, material, manufacturer and workmanship;

6.2. If the Contractor is not the original manufacturer of the goods to be provided under the Contract, the Contractor shall provide PAHO or its designee with the benefit of all manufacturers' warranties in addition to any other warranties required to be provided under the Contract;

6.3. The goods and/or services are of the quality, quantity and description required by the Contract, including when subjected to conditions prevailing in the place of final destination;

6.4. The goods and/or services are free from any right of claim by any third-party, including claims of infringement of any intellectual property rights, including, but not limited to, patents, copyright and trade secrets;

6.5. All goods are new and unused;

6.6. All warranties will remain fully valid following any delivery of goods and/or services for a period of not less than one (1) year following acceptance of the goods and/or services by PAHO or its designee in accordance with the Contract;

6.7. During any period in which the Contractor's warranties are effective, upon notice by PAHO or its designee that the goods and/or services do not conform to the requirements of the Contract, the Contractor shall promptly and at its own expense:
6.7.1. correct the non-conformities,
6.7.2. replace defective goods with goods of the same or better quality, or
6.7.3. fully reimburse PAHO for the purchase price paid for the defective goods or services, and remove defective goods if applicable.
6.7.4. The Contractor shall remain responsive to the needs of PAHO or its designee for any services that may be required in connection with any of the Contractor's warranties under the Contract.

7. TITLE: The Contractor warrants and represents that the goods delivered under the Contract are unencumbered by any third party's title or other property rights, including, but not limited to, any liens or security interests. Unless otherwise expressly provided in the Contract, title in and to the goods shall pass from the Contractor to PAHO or its designee upon delivery of the goods and their acceptance by PAHO or its designee in accordance with the requirements of the Contract.

8. INTELLECTUAL PROPERTY: All rights, including title, copyright and patent rights in any material produced under the terms of this Contract shall be vested in PAHO or its designee, which shall be entitled to modify or change the materials as it deems fit. The Contractor acknowledges and agrees that such materials constitute works made for

hire for PAHO and that the use or supply to PAHO of the goods or services rendered under this Contract does not infringe any patent, copyright, design, trade name or trademark.

9. INDEMNIFICATION: The Contractor shall indemnify, defend and hold PAHO harmless from any actions or claims brought against PAHO pertaining to the alleged infringement of a patent, copyright, design, trade name, or trademark arising in connection with the goods or services provided hereunder. The Contractor shall also indemnify, hold and save harmless and defend at its own expense PAHO, its officers, agents, servants and employees from and against all suits, claims, demands and liability of any nature or kind, including costs and expenses arising out of acts or omissions of the Contractor or the Contractor's employees, servants or agents in the performance of this Contract.

10. FAILURE TO PERFORM: If the Contractor fails to deliver the goods or perform any of the services for any reason, including failure to obtain the necessary export licenses by the delivery date(s) specified in the Contract, PAHO may, after giving the Contractor reasonable notice to perform and without prejudice to any other rights or remedies under this Contract, exercise one or more of the following rights:

10.1. Procure all or part of the goods and/or services from other sources and hold the Contractor responsible for any excess cost occasioned thereby;

10.2. refuse to accept delivery of all or parts of the goods and/or services;

10.3. terminate the Contract.

11. PAYMENT TIMING: PAHO shall normally, unless otherwise specified in this Contract and subject to certification by the PAHO/WHO Project Officer of satisfactory completion of said services, make payment within thirty (30) days of receipt of (a) the Vendor's invoice and (b) copies of the customary shipping documents and other documents specified in the Contract, whichever (a) or (b) is later.

12. LIQUIDATED DAMAGES: Tick if NOT applicable
PAHO can claim liquidated damages from the Contractor and deduct 0.5% of the value of the Contract for each day of delay, up to a maximum of 10% of the value of the Contract, for late delivery of goods and/or services or for goods and/or services which do not meet the agreed specifications and are therefore rejected by PAHO or its designee. The payment or deduction of such liquidated damages shall not relieve the Contractor from any of its other obligations or liabilities under the Contract.

13. INSURANCE: Tick if NOT applicable

The Contractor shall provide and thereafter maintain insurance against all risks with respect to its property and any equipment used for the execution of this Contract. The Contractor shall provide and thereafter maintain all appropriate workmen's compensation insurance with respect to its employees to cover claims for personal injury or death in connection with this Contract. The Contractor shall also provide and thereafter maintain liability insurance in an adequate amount to cover third-party claims for death or bodily injury arising from or in connection with the provisions of service under this Contract and to cover the loss of or damage to property arising from or in connection with the provision of services under this Contract (including due to the operation of any vehicles, boats, airplanes or other equipment owned or leased by the Contractor or its agents, servants, employees or sub-contractors). Such insurance policy(ies) shall be made out in the joint names of PAHO and the

Contractor, and shall include rights of subrogation. The Contractor shall provide PAHO with a copy of all policy(ies) upon request.

14. CONFIDENTIALITY: "Confidential Information" is any information concerning or relating to the property, business or affairs of PAHO that is furnished to the Contractor or available to the Contractor because of this Contract. The Contractor shall treat all documents, correspondence, decisions and orders concerning the Contract as confidential and restricted in nature and shall not divulge or allow access to them by any unauthorized person. The Contractor may not communicate at any time to any other person, Government or authority external to PAHO any information known to it by reason of its association with PAHO which has not been made public, without PAHO"s written authorization. In addition, the Contractor shall not at any time use such information to private advantage. These obligations do not lapse upon termination of this Contract.

15. PUBLICITY, ADVERTISING, AND USE OF THE PAHO NAME, EMBLEM, OR SEAL: The Contractor shall not use the name, emblem or official seal of PAHO for any purpose other than as expressly authorized in writing by PAHO. The Contractor shall not advertise or otherwise make public that it is furnishing goods or services to PAHO without specific written permission from PAHO in each instance. The provisions of this paragraph shall survive completion of the Contract.

16. MODIFICATION: Neither party may change, modify or revise any aspect of this Contract unless the amendment is made in writing and signed by an authorized PAHO contracting officer and the Contractor.

17. FORCE MAJEURE: Notwithstanding Article 10, neither party shall be held responsible for delay, impossibility, or impracticability in fulfilling the terms of the Contract due to force majeure, which includes but is not limited to: war, riot, civil disorder, earthquake, fire, explosion, flood or other adverse weather conditions, strikes, confiscation or any other factors beyond its control, including but not limited to extraordinary measures taken by a government that adversely affect routine commercial
transactions. The failure of the Contractor or PAHO to fulfill any of their obligations hereunder shall not be considered a breach of, or default under this Contract, insofar as such liability arises from an event of force majeure, provided that the affected party notifies the other and takes all reasonable precautions, due care and reasonable alternative measures, all with the objective of carrying out the terms and conditions of this Contract.

18. TERMINATION: This Contract may be terminated by PAHO upon written notice delivered to the Contractor at least fifteen (15) days prior to the effective date of termination. In the case of goods being manufactured or packaged to PAHO specifications, the contract may be terminated with at least 45 days written notice from the effective date of termination. In the event of termination, PAHO will compensate the Contractor for goods accepted by PAHO or services provided to PAHO and deemed by PAHO to be satisfactory.

19. SETTLEMENT OF DISPUTES: PAHO and the Contractor shall use their best efforts to settle amicably any dispute, controversy or claim arising out of, or relating to this Contract. Unless any such dispute, controversy or claim between the parties arising out of or relating to this Contract or the breach, termination or invalidity thereof is settled amicably within sixty (60) days after receipt by one Party of the other party's request for such amicable settlement, such dispute, controversy or claim shall be referred by either Party to arbitration in accordance with the UNCITRAL Arbitration Rules then in effect. The arbitral tribunal shall have no authority to award punitive damages. Any arbitration award rendered as a result of such arbitration shall be considered to be the final adjudication of any such controversy, claim or dispute and shall bind the parties.

20. PRIVILEGES AND IMMUNITIES: Nothing contained in this Contract shall be deemed a waiver, express or implied, of any immunity from suit, judicial process, confiscation, taxation, or any other immunity or privilege

which PAHO may enjoy, whether pursuant to treaty, convention, law, order or decree of an international or national character or otherwise, or in accordance with international customary law.

21. TAX EXEMPTION: PAHO is exempt from payments of sales, use and excise taxes, and is exempt from customs duties and charges of a similar nature in respect of articles imported or exported for official use. PAHO may deduct from an invoice any such tax, duties or charges to which it may be entitled by reason of its privileges and immunities.

22. ANTI-TERRORISM: The Contractor certifies that it is not an individual or entity appearing on the New Consolidated List established and maintained by the United Nations Security Council's 1267 Committee. Contractor shall use best efforts to ensure that no funds provided under this Contract will be used to benefit, directly or indirectly, individuals or entities associated with terrorism.

23. PAHO OFFICIAL NOT TO BENEFIT: The Contractor warrants that no PAHO staff shall be permitted to any share or part of the Contract or any benefit that may otherwise arise therefrom. PAHO officials may not accept any type of gift or any offer of hospitality beyond that of nominal value. PAHO expects its Contractors not to offer any benefit such as free goods or services or a work position or sales opportunity to any current or former PAHO staff member in order to facilitate the supplier's business relationship with PAHO.

24. SELF-DEALING: The Contractor may not bid to supply goods or services to PAHO that may be directly or indirectly related to the goods or services provided under this Contract.

25. SEVERABILITY: Any provision of this Contract prohibited by the laws of any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition, without invalidating the remaining provisions of this Contract.

Section 6: Sample Notification

DATE

[Name of Bidder]
[Address]

Solicitation Reference: **PRO-1903ITBRF**
SEASONAL INFLUENZA NORTHERN HEMISPHERE 2019-2020

Dear
Your bid (including all required attachments) dated _____ in response to the Pan American Health Organization, Regional Office of World Health Organization (PAHO) ITB PRO-1903ITBRF, has been retained by PAHO. Pursuant to Section 2, Paragraph 26.1 of the bid solicitation, this Notification is issued to inform you of the products and prices retained by PAHO for purchase from [SUPPLIER NAME] in the event PAHO should have any requirements therefore through ***31 July 2020*** . As stated in Section 2, Paragraph 26.2 of the bid solicitation, issuance of this Notification does not in any manner whatsoever constitute a commitment or guarantee by PAHO for the purchase of any product.

To the extent that PAHO elects to purchase products from [SUPPLIER NAME], PAHO shall issue a Purchase Order pursuant to Section 2, Paragraph 26.3. [SUPPLIER NAME] guarantees the prices set forth in this Notification through ***31 July 2020***.

[Details of each award by vaccine will be attached to this notification.]

Sincerely,

Daniel Rodriguez,
Director, Procurement and Supply Management (PRO)

Annex I: Technical Requirements

All documents submitted by the Bidder as part of the technical proposal must be available in English. If original documents are available in other language(s), the Bidder is required to provide a certified translation in English.

- **Proof of compliance with eligibility criteria**

Technical proposals that do not include proof of compliance with eligibility criteria may be rejected and the technical and financial offer will not be considered.

1. WHO Prequalification letter (if applicable) including the following: date of prequalification, product name (INN and brand name), manufacturer and country of manufacture, product characteristics, shelf-life and packaging information.
2. Certificate of Pharmaceutical Product (CPP) according to the WHO certification scheme on the quality of pharmaceutical products moving in international commerce, issued by the relevant National Regulatory Authority (NRA) listed in eligibility criteria. The CPP needs to include all relevant annexes related to the approval conditions (i.e., product's formulation, composition, inserts and corresponding labeling, including the shelf-life and storage conditions).
3. For biological products only (if applicable), a formal declaration by the Bidder indicating the NRA responsible for lot release of the finished product. In addition, when the offered product is a human derived blood product the formal declaration must also include the NRA responsible for plasma pool release.
4. For pharmaceuticals only (if applicable), proof of therapeutic equivalence reviewed by the NRA of the country of manufacture is required (i.e. Bioequivalence / Bioavailability studies, when applicable, or comparative in vitro dissolution tests, when applicable, according to conditions described in the latest edition of the WHO Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability).

- **Proof of compliance with technical requirements**

5. Manufacturing sites requirements:
   a. List of all sites involved in the manufacturing process, including name, address and responsibilities of each site.
   b. For site(s) involved in the production of the finished product, Good Manufacturing Practices (GMP) certificate(s) issued by the NRA of the country of manufacture must be submitted. If a diluent is required, and its manufacturing site is different from the finished product, the corresponding GMP certificate must be submitted.
6. The Bidder must clarify the availability of the offered product insert (pamphlet) and the primary, secondary and tertiary packaging, including diluent (if applicable) in all four of the requested languages (English, Spanish, Portuguese, and French). A PDF of the insert (pamphlet) and packaging (primary, secondary and tertiary) for the product presentation offered in all available languages must be submitted.

7. The current finished product specifications, including diluent (if applicable), approved by the corresponding NRA. A certificate of analysis or a summary of manufacturing and control (as applicable) may also be submitted.
8. Stability study requirements:
   a. A summary of the stability studies for natural and accelerated storage conditions performed according to international recommended standards for the offered product category (i.e., pharmaceutical, biological). The summary should include result tables and conclusions for three different lots of the presentation offered.
   b. For attenuated liquid vaccines it is mandatory that the submitted data include 0°C and for all products requiring cold chain storage the studies must include 15°C, 25°C and 37°C, at intervals of 24, 48, 72 hours and/or 7, 14 and 28 days.

      Note: To allow resolution of potential cold chain deviations occurring during shipment or storage, bidders must submit all stability studies available for all products requiring cold chain storage, including studies at temperatures below the recommended storage conditions (i.e. freezing point estimations and demonstration of quality attributes not affected above the freezing point) and studies at temperatures above recommended storage conditions. These studies will be utilized for making recommendations on the potential use of products affected by cold chain excursions occurring outside of recommended storage conditions.
9. Most recent Periodic Safety Update Report (PSUR).
10. List of countries where the product is registered and has been granted a marketing authorization. At a minimum the list must include: Country and Number and Date of the Latest Registration/Marketing Authorization (for reference a template is provided; **Annex III – Information on Regulatory Status**).
11. The checklist of the technical documents included in the technical proposal, completed and signed by the corresponding quality assurance representative (**Annex IV - Checklist for the technical documents included in the technical proposal**).

IMPORTANT NOTES:

PAHO understands difficulties encountered by bidders to provide a complete technical proposal at the time of the bid closing. Thus, below information is to clarify that PAHO will receive additional technical documentation from bidders according to the following schedule and scenarios:

A. If WHO announces that there are no changes in influenza vaccine composition from one hemisphere to another hemisphere and year to year: bidders will be expected to provide a complete technical proposal pursuant to the requirements set out in ITB - SEASONAL INFLUENZA NORTHERN HEMISPHERE 2019-2020 Ref. PRO-1903ITBRF by ITB deadline ***11 March 2019*** .[5]

[5] Specific artworks packaging for seasonal influenza vaccine Northern Hemisphere 2019-2020 are expected to be verified prior to shipment to Member States if product offered is awarded.

B. If WHO announces that the influenza vaccine will have changes in the composition from one hemisphere to another: bidders will be expected to provide those formula independent technical requirements from ITB Ref. PRO-1903ITBRF listed in (a) below not later than the deadline set in the ITB, and the remaining set of formula dependent technical requirements that are listed in (b) below when they become available, but no later than ***13 September 2019*** .

a) Formula independent documents from ITB PRO-1903ITBRF (p. 23):

1. WHO Prequalification letter (if applicable) including the following: date of prequalification, product name (INN and brand name), manufacturer and country of manufacture, product characteristics, shelf-life and packaging information.
2. Certificate of Pharmaceutical Product (CPP) according to the WHO certification scheme on the quality of pharmaceutical products moving in international commerce, issued by the relevant National Regulatory Authority (NRA) listed in eligibility criteria. The CPP needs to include all relevant annexes related to the approval conditions (i.e., product's formulation, composition, inserts and corresponding labelling, including the shelf-life and storage conditions). **Bidders should provide the CPP from a previous composition strain of influenza virus vaccine Northern Hemisphere for the purpose of the technical evaluation as a proof of compliance with the eligibility criteria.**
3. For biological products only (if applicable), a formal declaration by the Bidder indicating the NRA responsible for lot release of the finished product. In addition, when the offered product is a human derived blood product the formal declaration must also include the NRA responsible for plasma pool release.
5. Manufacturing sites requirements:
    a. List of all sites involved in the manufacturing process, including name, address and responsibilities of each site.
    b. For site(s) involved in the production of the finished product, Good Manufacturing Practices (GMP) certificate(s) issued by the NRA of the country of manufacture must be submitted. If a diluent is required, and its manufacturing site is different from the finished product, the corresponding GMP certificate must be submitted.
9. Most recent Periodic Safety Update Report (PSUR).
10. List of countries where the product is registered and has been granted a marketing authorization. At a minimum the list must include: Country and Number and Date of the Latest Registration/Marketing Authorization (for reference a template is provided; Annex III – Information on Regulatory Status) (template attached hereto for reference).
11. The checklist of the technical documents included in the technical proposal, completed and signed by the corresponding quality assurance representative (Annex IV - Checklist for the technical documents included in the technical proposal) (template attached hereto for reference).

b) Formula dependent documents (i.e. documents that are issued based on the vaccine annual composition), from ITB PRO-1903ITBRF (p. 23-24):

2. Certificate of pharmaceutical product (CPP) according to the WHO certification scheme on the quality of pharmaceutical products moving in international commerce, issued by the relevant National Regulatory Authority (NRA) listed in eligibility criteria. The CPP needs to include all relevant annexes related to the approval conditions (i.e., product's formulation, composition, inserts and corresponding labeling, including the shelf life and storage conditions).
6. The Bidder must clarify the availability of the offered product insert (pamphlet) and the primary, secondary and tertiary packaging, including diluent (if applicable) in all four of the requested languages (English, Spanish, Portuguese, and French). A PDF of the insert (pamphlet) and packaging (primary, secondary and tertiary) for the product presentation offered in all available languages must be submitted.
7. The current finished product specifications, including diluent (if applicable), approved by the corresponding NRA. A certificate of analysis or a summary of manufacturing and control (as applicable) may also be submitted.
8. Stability study requirements:
    a. A summary of the stability studies for natural and accelerated storage conditions performed according to international recommended standards for the offered product category (i.e., pharmaceutical, biological). The summary should include result tables and conclusions for three different lots of the presentation offered.
    b. For attenuated liquid vaccines it is mandatory that the submitted data include 0°C and for all products requiring cold chain storage the studies must include 15°C, 25°C and 37°C, at intervals of 24, 48, 72 hours and/or 7, 14 and 28 days.

    Note: To allow resolution of potential cold chain deviations occurring during shipment or storage, bidders must submit all stability studies available for all products requiring cold chain storage, including studies at temperatures below the recommended storage conditions (i.e. freezing point estimations and demonstration of quality attributes not affected above the freezing point) and studies at temperatures above recommended storage conditions. These studies will be utilized for making recommendations on the potential use of products affected by cold chain excursions occurring outside of recommended storage conditions.

Instructions for submission of technical documents

- The documents set forth in Sub-Sections 1 to 11 above must be submitted as individual files and each file must be sent as a PDF, regardless of whether documents from previous years have been submitted to PAHO.
- All documents submitted must correspond to the documents included in the checklist and must follow the corresponding nomenclature (Technical requirement #11 – Annex IV Checklist for the Technical Documents Included in the Technical Proposal).
- The information for each product (Sub-Sections 1 to 11) must be provided through In-Tend USING THE "ATTACH DOCUMENTS" bottom and using the checklist recommended nomenclature for each document. When uploading the documents please make sure to indicate to what product the document is for using the dropdown.

Annex II: Quality Requirement

IMPORTANT NOTE: As stated in the WHO position paper issued in November 2012, WHO recommends influenza vaccination in pregnant women as a priority, since they represent the group most vulnerable to illness and death from influenza. Similarly, vaccinating pregnant women allows for the protection of children under 6 months old, who have a high burden of disease from Influenza and are not a target population for vaccination. Currently there are 31 countries in the Americas vaccinating against influenza in pregnant women and a significant increase in the number of countries vaccinating this population is expected. Therefore, to attend the requirements of countries for the vaccination of pregnant women, preference will be given to those vaccines that clearly include in the insert the recommendation of use in this target population.

I. Production

Products purchased by PAHO shall conform to the following:

1. General and product specific guidelines related to production, quality, safety, efficacy and potency adopted by WHO Expert Committees.
   i. **Pharmaceuticals**: WHO Expert Committee on Specifications for Pharmaceutical Preparations guidelines available at: http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_992/en/
   ii. **Biologicals**: WHO Expert Committee on Biological Standardization guidelines available at: http://www.who.int/biologicals/en/

2. Electronic devices for temperature measurement

   For all products requiring cold chain storage (biologicals and pharmaceuticals) purchased as a result of this solicitation, suppliers shall ensure storage and distribution of the products comply with WHO Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products: http://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelGuidanceForStorageTransportTRS961Annex9.pdf

   Additionally, Suppliers shall include temperature indicator electronic devices for temperature measurements that have the minimum features established in the Guidelines on the International Packaging and Shipping of Vaccines, WHO/IVB/05.23, (http://whqlibdoc.who.int/hq/2005/WHO_IVB_05.23_eng.pdf).

   The Supplier must include one prequalified electronic shipping indicator (E006 category) with USB interface per insulated vaccine shipping unit and the content of the device shall be readable without the need of special software of any kind. (Please refer to the WHO Guidelines on the International Packaging and Shipping of Vaccines, the chapter related to Temperature Monitoring Devices: (http://whqlibdoc.who.int/hq/2005/WHO_IVB_05.23_eng.pdf).

For shipping units exceeding 800mm in height, it is recommended the use of two shipping indicators positioned according to the cold and hot spots identified in the thermal-mapping. Insulated shipping units should not exceed 1600mm in height.
A list of prequalified electronic shipping indicators, E006 category, with USB interface is available in the WHO website PQS catalogue.
(http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=35). PAHO does not accept devices classified as user programmable temperature data loggers.

WHO no longer recommends the use of the vaccine cold chain monitor card (CCM) and/or freeze indicators in international shipments. However, only when batteries for electronic devices do not perform under freezing temperatures, CCM may be used.

If a claim is received for cold chain excursions the information obtained from electronic monitoring devices will be compared with stability data required in the technical proposal (see Annex I. Proof of compliance with technical requirements, 8. Stability study requirements).

3. Changes in production, formulation, packaging or labeling of products

The Supplier shall inform PAHO of any changes in the production, formulation, packaging or labeling of products supplied to PAHO pursuant to the prior year's bid. Supplier shall provide the authorization by WHO and/or the corresponding NRA of the formulation or other production changes.

II. Licensure and Registration

1. Products produced and delivered under a Purchase Order shall be manufactured under a current license issued by the National Regulatory Authority of the country of manufacture. The Supplier shall submit evidence of licensure to PAHO prior to issuance of Purchase Order. Any suspension or termination of the license, for any reason, shall be reported immediately to PAHO.

2. Some countries require that products to be used in the country be licensed/registered with the appropriate regulatory authority. When licensure/registration is required by NRAs, compliance is the sole responsibility of the Supplier. PAHO recommends that manufacturers have their products licensed accordingly.

III. The Supplier Must Be Willing to Provide the Following Documents if Requested by the Consignee and/or PAHO:
   i. Quality Control Methodology (compendial monograph or validated method)
   ii. Other technical documents and data requested for clarification or to resolve any potential claims (e.g. Sources of the Active Pharmaceutical Ingredient(s) utilized in the finished product and the corresponding quality assurance documents, manufacturing process description, clinical trial data showing the product efficacy, etc.).

IV. Shelf Life

Products shall be supplied with the maximum shelf life attainable with current production technology recommended by WHO. If the product requires a diluent, the diluent shall have at least the same shelf life as the corresponding product. Unless authorized in writing in advance by PAHO, **the remaining shelf life at time of dispatch of the products shall not be less than 75 percent of the total product's shelf life for pharmaceuticals and biologicals, and for vaccines**[6] **no less than 18 months.**

V. Production lots

A single lot shall be assigned to any given country whose vaccine request constitutes a quantity less than the production lot size.

VI. Presentation

Product presentation shall be specified in the Purchase Order.

VII. Labeling

i. Product labels shall conform to WHO guidance documents (as Specified in Annex II, I. Production) and any additional requirements indicated in Annex VI, Section I (Packaging and Labeling).
ii. Labels shall be in the language of the country of destination, which will be specified in the Purchase Order. Multilingual labels are acceptable.
iii. Product labels must be consistent with the label evaluated by the WHO Prequalification Programme and/or the responsible NRA granting market authorization.
iv. Under no circumstances shall labels include any of the following: "donation" or "free medicine."
v. Re-labeling or over-labeling is not acceptable, unless agreed to in writing by PAHO.
vi. Vaccines with risk of damage under freezing conditions should include a warning label of "Do not freeze".

VIII. Testing

Unless otherwise indicated by PAHO in the Purchase Order, all goods supplied under this solicitation shall be subject to random quality control tests by the National Regulatory Authority and/or an independent third party reference laboratory selected by PAHO to ensure conformity with the Purchase Order specifications. The decision not to test shall not constitute a waiver of any of its rights, or release Supplier of any of its obligations set forth in herein or the Purchase Order. Non-conforming goods may be rejected at PAHO's discretion in accordance with the terms of the Purchase Order. PAHO may, at its discretion, submit goods to a third party reference laboratory selected by PAHO for additional testing. PAHO may request the Supplier to furnish additional samples and/or Reference Standards to the reference laboratory for testing. The decision of the reference laboratory shall be considered final.

IX. Yearly review of products supplied to PAHO

[6] Exceptions may be granted for vaccines with a total product's shelf life of 24 months or less.

PAHO requires the awarded bidder provide a yearly review of products supplied to PAHO Member States and a manufacturing consistency report. This information should be submitted as specified in **Annex** V and should be provided on a yearly basis.

X. Right to share information with PAHO Member States

PAHO at its sole discretion may share with the corresponding National Regulatory Authorities from the recipient country, documents from the technical proposal or other documents and data requested for clarification or to resolve any potential claims or inquiries.

Annex III: Information on Regulatory Status

The Bidder shall indicate all countries (globally) where the product offered is registered and has been granted a marketing authorization in the following table.

NOTES:

1. Please indicate if there is a special designation for the medicine (e.g.: orphan drug status)
2. If the medicine is not registered, please indicate "Not Registered" in the column "Registration number

BIDDER NAME AND ADDRESS:		
ITB # PRO-1903ITBRF		
PRODUCT (Submit one checklist per offered product):		
COUNTRY	**REGISTRATION NUMBER**	**DATE OF THE LATEST REGISTRATION (MM/YY)**

Annex IV:
Checklist for the Technical Documents Included in the Technical Proposal

BIDDER NAME AND ADDRESS:
ITB # PRO-1903ITBRF
PRODUCT (Submit one checklist per offered product):

Nomenclature assigned for technical requirements must follow the indications in the table below. Bidder can only modify Manufacturer name and Product name. The table below indicates the text that can be modified, which is marked by the text in parenthesis [ ]. No other special characters than underscores can be used.
For the Product name, please do not use brand names and include the corresponding INN according to the Bid Offer Sheet. The number of characters used for naming PDF files must not exceed 60 characters. Abbreviations can be used (i.e. DTaP-Hib instead of Diphtheria, Tetanus adsorbed, acellular pertussis and Haemophilus influenza type b conjugated vaccine).

Technical Requirement	File Name (PDF required)	Submitted
Number	***Technical requirement X_[Insert Manufacturer name_ Insert Product name]***	☑ or N/A
1	1. WHO PQ_Manufacturer name_Product name	
2	2. CPP_Manufacturer name_Product name	
3	3. Supplier declaration_Manufacturer name_Product name	
4	4. TE_Manufacturer name_Product name	
5a	5a. Sites_Manufacturer name_Product name	
5b	5b. GMP_Manufacturer name_Product name	
6a	6a. Insert_Manufacturer name_Product name	
6b	6b._Packaging_Manufacturer name_Product name	
7	7. FPS_Manufacturer name_Product name	
8a	8a.Stability summary_Manufacturer name_Product name	
8b	8b. Stability CCP_Manufacturer name_Product name	
9	9. PSUR_Manufacturer name_Product name	
10	10. Annex I - Reg_Manufacturer name_Product name	
11	11. Annex II - Checklist_Manufacturer name_Product name	

*Legend: Document has been submitted: **☑;** Document does not apply to this product: **N/A**
*If more than one PDF document is submitted under a technical requirement, the supplier needs to specify the additional documents following the same nomenclature, adding a specific mention to the document provided (i.e.: Supplier declaration **3b**_Manufacturer name_Product name_**Diluent**)

We hereby certify all technical proposal requirements included in this list were reviewed, approved and authorized for submission by our quality assurance representative.

Signature of Quality Assurance representative: _____
DATE: (*INSERT DAY/MONTH/YEAR*)

Annex V : Yearly Review of Products Supplied to PAHO Member States and Manufacturing Consistency Report

MANUFACTURER NAME AND ADDRESS:
ITB # PRO-1903ITBRF
PRODUCT (Submit one Annex per product):

The Supplier at the end of the calendar year must provide, in electronic format, an overview to PAHO WDC office a list of products supplied to PAHO Member States (Section A) and a manufacturing consistency report (Section B).

A. List of products supplied to PAHO Member States categorized by product, corresponding lots, Member States supplied and number of doses supplied (template provided below);

The products included in the list below were supplied as a result of ITB # (*INSERT CORRESPONDING ITB #*) between (*insert day/month/year*) and (*insert day/month/year*) to PAHO Member States.

Product (INN/Dose/Presentation)	Lot(s) Number(s)	PAHO Member States supplied	Number of doses supplied

B. Analysis of manufacturing consistency in comparison with approved quality specifications for all lots manufactured in the latest calendar year. The format used to submit this report remains at the discretion of the Supplier.

Annex VI: Packaging, Labeling, and Shipping

I. Packaging and Labeling

A. Vaccines must be packed in accordance with the Guidelines on the International Packaging and Shipping of Vaccines, published by WHO under reference WHO/IVB/05.23,2005,found at: http://whqlibdoc.who.int/hq/2005/WHO_IVB_05.23_eng.pdf or any updated version of the document.

B. All vaccines shall be shipped according to the classifications set forth in Table I of the WHO Guidelines on the International Packaging and Shipping of Vaccines (http://whqlibdoc.who.int/hq/2005/WHO_IVB_05.23_eng.pdf).

C. Supplier should provide a Technical description of the shipping container, approved by WHO prequalification team, including weight, cubic measurement, insulation and type of refrigerant to be used for each biological product (if applicable).

D. Vaccines, diluents and droppers with risk of damage under freezing conditions should include a warning water resistance label of "Do not freeze" on each face of the outer package, which should be visible for personnel handling the goods during transit or at destination.

E. The IATA Time and Temperature Sensitive label with the manufacturer's recommended temperature range must be affixed to all insulated shipping units.

F. A label or marking should be affixed on the outer shipping unit indicating the maximum stacking capacity or "DO NOT STACK".

G. Manufacturer's wishing to use insulated pallet shippers, shall provide copy of the packaging validation report. The following should be taken into consideration for pallet shippers:
   a. The insulated pallet shipper's platform shall enable handling by equipment, such as forklift.
   b. The shippers should not exceed the standard ISO (No. 6780) pallet sizes (US pallet 1200mm x 1000mm or Euro pallet 1200mm x 800mm).
   c. Wooden pallets shall be heat treated as per International Standards for Phytosanitary Measures (ISPM) No.15 and a certificate should be provided with the shipping documents.
   d. Supplier should include two shipping indicators per pallet shipper as defined in the Annex II Quality requirements.

II. Quantity Guarantee

The Supplier must be willing to accept orders of any quantity, particularly orders of small quantities**.**

III. Delivery of Goods

Orders via air freight require handing-over the goods to the freight forwarder within ten (10) working days from the date of delivery stated in the Purchase Order. As part of Bid, suppliers must indicate if they will be able to comply**.**

IV. Consignee Information

Complete consignee's name, address and fax/phone numbers will be specified in the Purchase Orders issued by PAHO. In special situations, the Purchase Order may specify shipment to a different country address. In these cases, the address provided in the PAHO Purchase Order shall govern.

V. Shipping Instructions

A. All shipments of biological products shall be booked as temperature-controlled cargo. Unless stated otherwise in the Purchase Order, these products shall be shipped via prepaid and insured air freight. Insurance coverage shall include the cost of the product, the freight and the insurance. Shipments shall be insured for 110% of their DAT, CIP, or DDP value. If a direct flight is not available, the number of transfer points shall be held to the minimum and only those equipped with cold storage facilities shall be utilized.

B. Shipments are to be booked well in advance and flight details shall be furnished to PAHO by e-mail only, no less than five business days prior to the date of arrival of the product. Unless otherwise specified by PAHO, the notification of flight details shall include:

1. Purchase Order number.
2. Type of product, batch number, type of WHO prequalified shipping indicator(s) and number of doses.
3. Number of cartons, gross and net weights in kilos.
4. Date and time of departure and arrival, airline flight number(s), all transit routes and dates and port of entry
5. Complete airway bill number.
6. The notation in the AWB: "Consignee shall arrange for immediate collection" and "Freight agent/Carrier shall inform consignee and PAHO Washington D.C. immediately by phone and/or email if the shipment does not arrive."
7. Manufacturer full name and address.

C. All clauses included in the Purchase Order shall be carefully followed.

D. Suppliers shall comply with all shipping instructions provided in the Purchase Order.

E. Air freight consignments shall be shipped to arrive from Monday through Thursday or as otherwise specified in the Purchase Order. Biological Product(s) shall not be shipped to arrive on Fridays, weekends or national holidays without prior approval of PAHO.

F. House airway bills or back-to-back consignments are not permitted for the final flight segment unless approved in writing in advance by PAHO.

G. The following information shall be included in the airway bill:

1 Under the caption, “Consignee’s name and address”:
Complete consignee’s information as stated in the Purchase Order
Consignee’s information should be the same as stated on commercial invoice.

2 Under the caption, “Nature and Quantity of Goods”:
Product description (not brand name) and number of vials and doses. Type of pre-qualified shipping indicator(s) used in the shipment.

3 Under the captions, “Rate/Change” and “Total”, include the appropriate figures in local currency or in United States Dollars. The total amount of airway bill must be equivalent to the freight amount mentioned in the invoice. Airway bills containing the phrase “AS AGREED” are not acceptable.

4 Under the caption, “Handling Information”, the notation:
“BIOLOGICAL PRODUCT FOR HUMAN USE, HIGHLY PERISHABLE, DO NOT DELAY. Notify consignee by telephone immediately upon arrival.”
This field must also indicate the manufacturer’s recommended temperature range (temperature must be informed in Celsius).

H. Unless otherwise indicated by PAHO in the Purchase Order, one original set of the following documents shall be sent to the consignee as far in advance of shipment as possible to facilitate initiation of the customs clearance process prior to the arrival of the product. The courier tracking information that original documents were sent to consignee shall be provided to the PAHO procurement office. Another original set shall accompany the shipment. Finally, prior to the departure of the shipment, a full set of such documents shall be emailed to PAHO in Washington D.C., USA. Any costs related to this service shall be itemized and invoiced together with the freight and insurance charge.

Shipping Documents and required distribution:

Type of Document	Consignment	Consignee	PAHO Washington D.C., Procurement Area
Airway bill (when applicable)	Original	Copy	Electronic copy
Bill of Landing (when applicable)	N/A	2 Originals	Original
Commercial invoice	Original	Original + 2 copies	Electronic copy
Packing List	Original	Copy	Electronic copy
Packing slip identifying the temperature shipping indicator number with the box number.	N/A	Copy	Electronic copy
Insurance Certificate	Original	Original	Electronic copy
Certificate of Origin (License)	Original	Copy	Electronic copy
Certificate of good manufacturing practices (GMP)	Copy	Copy	Electronic copy
Certificate of Pharmaceutical Product (CPP) issued for the recipient country or for multi-recipient countries document. *Free Sale Certificate (FSC) may be required by some Member States	Copy	Copy	Electronic copy
Certificate of Analysis for finished product (and diluent when applicable)	Copy	Copy	Electronic copy
Lot Release Certificate from the National Regulatory Authority (NRA) for finished product and plasma pool (when applicable, for human plasma derivatives)	Copy	Copy	Electronic copy
Summary Protocol of manufacturing and quality control	Copy	Copy	Electronic copy
TSE (Transmitting Animal Spongiform Encephalopathy) statement letter indicating if the manufacturing process include any raw material of bovine origin (may be required by some member states.)	Original	Copy	Electronic copy
	The 1st set of original documents, shall accompany consignment and be placed with the pouch of the AWB to ensure it is handed to the consignee upon arrival of shipment. ①	The original set of documents shall be sent via courier service, at least five (5) business days prior to arrival of shipment.	**Electronic copies** of documents shall be emailed at least five (5) business days prior to arrival of shipment to the PAHO Washington, D.C. Procurement Area.

① Original documents must not be placed inside the carton as these documents are required for customs clearance procedures, which occur prior to having access to the cartons (being kept at customs). This set of documents should be attached to the airway bill.

PAHO reserves the right to review any of the technical documents required for shipping the product to the consignee and take appropriate remedial actions if necessary. In addition to the technical documents specified in the table above, the Supplier shall indicate for each lot, the number of doses or quantity being shipped, its destination, the date of shipment and the corresponding PAHO Purchase Order number.

Additional documents may be required depending on the destination. In such cases, detailed instructions will be provided in the Purchase Order.

I. The commercial invoice shall and/or packing list shall indicate the lot number(s) and the date(s) of expiration of the finished product(s), including diluent (if applicable) being supplied.

J. For Spanish speaking countries the description of the goods in the invoice shall be in Spanish.

K. Goods, Freight and insurance charges must be itemized separately in the invoice. Packing list must include: gross, net and volume weight. Freight vouchers (if any) must be attached to the goods.

L. For biological products, the supplier shall also provide a packing slip or equivalent document showing the electronic shipping indicator number and the corresponding shipping unit number.

M. Transshipment involving several carriers shall be avoided whenever possible. The maximum transit time from supplier's facility to the final destination shall not exceed 72 hours, unless previously authorized in writing by PAHO.

N. If the shipment is transferred to a different carrier in the transshipment point, a copy of the airway bill for the last flight segment should be e-mailed to the PAHO Procurement office before the arrival at the destination.

VI. Price

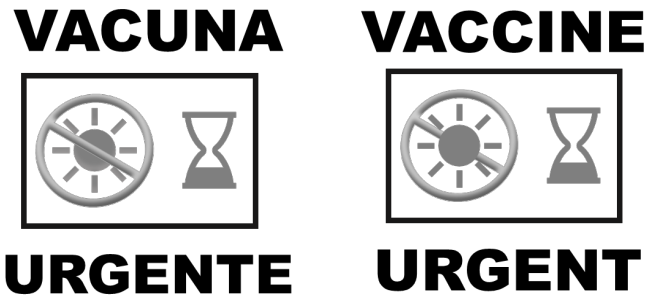
Unless otherwise expressly agreed to in writing between PAHO and the Supplier, the prices for the products shall be those set forth in the Notification.

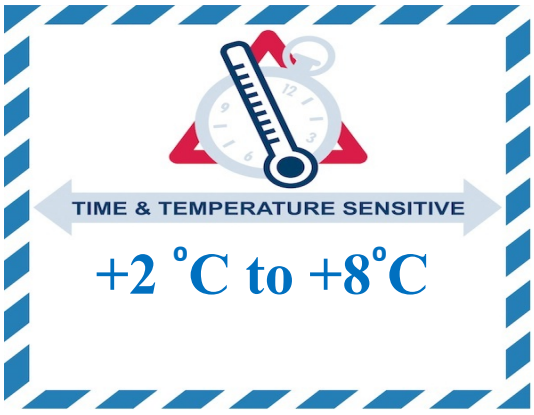
VII. Payment

A. Unless otherwise specified in the Purchase Order, payment shall normally be made within thirty (30) days of receipt of the Supplier's electronic invoice, copy of the shipping documents, and proof of arrival, whichever is later. Payment shall not be considered to be evidence of final acceptance. Each invoice shall, at a minimum, identify the applicable Purchase Order number, product number, type of product, number of doses delivered, batch number, expiration date, unit price, total price and banking information. Freight and insurance charges shall be in accordance with the terms of the Purchase Order.

B. Any fees related to special handling may be itemized in the commercial invoice. Such fees must be indicated at the time the quote is provided.

Annex VII – Sample Shipping Labels





Annex VIII – In-Tend Product Questionnaires

ANNEX IX: BID OFFER SHEET
SEASONAL INFLUENZA NORTHERN HEMISPHERE 2019-2020
PRO-1903ITBRF

This Bid Offer Sheet should be downloaded, completed, signed, and submitted as a pdf or similar file through In-Tend. In compliance with the above referenced Invitation to Bid (ITB), the bids set forth herein shall remain valid through ***31 July 2020***. Bidder understands that pursuant to the terms and conditions set forth in this ITB, PAHO shall issue a Notification to all bidders whose bids have been retained. Actual purchases shall be made through Purchase Orders. Bidder understands that nothing contained herein constitutes a commitment by PAHO to purchase any products whatsoever.

Please provide your best/earliest supply plan.

NORTHERN HEMISPHERE 2019-2020			
TRIVALENT VACCINE	**Quantity Requested (Doses)**	**Quantity Offered (Doses)**	**Unit Price, FCA (US$/dose)**
ADULT 1 DOSE Please specify offered presentation:	**3,310**		
ADULT 10 DOSE VIAL	**4,637,000**		
PEDIATRIC 20 DOSE VIAL	**1,440,000**		
QUADRIVALENT VACCINE	**Quantity Requested (Doses)**	**Quantity Offered (Doses)**	**Unit Price, FCA (US$/dose)**
ADULT 1 DOSE Please specify offered presentation:	**7,900**		
ADULT 10 DOSE VIAL	**6,100**		
PEDIATRIC 20 DOSE VIAL	**1,600**		

(Signature) (Date)

Name and Address:
Telephone:
E-Mail:

Name and Title of Person Authorized to Sign the Bid:
E-Mail:
Offer:
Date:

Name and Title of Person to Contact on Supply and Delivery Matters:
Telephone:
E-Mail: