



**RETURN BIDS TO:
RETOURNER LES SOUMISSIONS À:**

**Bid Receiving - PWGSC / Réception des
soumissions - TPSGC**
11 Laurier St. / 11, rue Laurier
Place du Portage , Phase III
Core 0B2 / Noyau 0B2
Gatineau, Québec K1A 0S5
Bid Fax: (819) 997-9776

**REQUEST FOR PROPOSAL
DEMANDE DE PROPOSITION**

**Proposal To: Public Works and Government
Services Canada**

We hereby offer to sell to Her Majesty the Queen in right of Canada, in accordance with the terms and conditions set out herein, referred to herein or attached hereto, the goods, services, and construction listed herein and on any attached sheets at the price(s) set out therefor.

**Proposition aux: Travaux Publics et Services
Gouvernementaux Canada**

Nous offrons par la présente de vendre à Sa Majesté la Reine du chef du Canada, aux conditions énoncées ou incluses par référence dans la présente et aux annexes ci-jointes, les biens, services et construction énumérés ici sur toute feuille ci-annexée, au(x) prix indiqué(s).

Comments - Commentaires

Title - Sujet Annual Influenza Vaccine Vaccins annuelles antigrippal	
Solicitation No. - N° de l'invitation E60PH-22GFLU/A	Date 2021-12-15
Client Reference No. - N° de référence du client E60PH-22GFLU	
GETS Reference No. - N° de référence de SEAG PW-\$\$PH-896-80749	
File No. - N° de dossier ph896.E60PH-22GFLU	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM Eastern Standard Time EST on - le 2022-01-21 Heure Normale du l'Est HNE	
F.O.B. - F.A.B. Plant-Usine: <input type="checkbox"/> Destination: <input checked="" type="checkbox"/> Other-Autre: <input type="checkbox"/>	
Address Enquiries to: - Adresser toutes questions à: Baird, Christa	Buyer Id - Id de l'acheteur ph896
Telephone No. - N° de téléphone (343) 551-3348 ()	FAX No. - N° de FAX () -
Destination - of Goods, Services, and Construction: Destination - des biens, services et construction: SEE HEREIN	

Instructions: See Herein

Instructions: Voir aux présentes

Vendor/Firm Name and Address

**Raison sociale et adresse du
fournisseur/de l'entrepreneur**

Issuing Office - Bureau de distribution

Drugs, Vaccines and Biologics Division/Div.des produits
pharmaceutiques,biologiques et de vaccins
Terrasses de la Chaudière 5th Floo
10 Wellington Street
Gatineau
Quebec
K1A 0S5

Delivery Required - Livraison exigée	Delivery Offered - Livraison proposée
Vendor/Firm Name and Address Raison sociale et adresse du fournisseur/de l'entrepreneur	
Telephone No. - N° de téléphone Facsimile No. - N° de télécopieur	
Name and title of person authorized to sign on behalf of Vendor/Firm (type or print) Nom et titre de la personne autorisée à signer au nom du fournisseur/ de l'entrepreneur (taper ou écrire en caractères d'imprimerie)	
Signature	Date

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PART 1 - INFORMATION AND INSTRUCTIONS

1.1 Summary

This bid solicitation is for an estimated requirement of:

- (a) **7,385,000** doses of Quadrivalent Influenza Vaccine (QIV) with an age indication of 6 months of age and older (PFS Item 1a and MDV Item 1b)
- (b) **1,500,000** doses of Quadrivalent Influenza Vaccine (QIV) with an age indication of 5 years of age and older (PFS Item 2a and MDV Item 2b)

Up to a maximum of two (2) contracts will be awarded for item 1a, 1b and 2b. One contract will be awarded for item 2a. Resulting contracts will be from date of award to March 31, 2023 plus two additional one-year option periods.

The quantities provided below are only an approximation of requirements given in good faith and are subject to change prior to Contract award. Each Identified User reserves the right to alter quantities or to withdraw from participation up until Contract award. A significant change in the Requirement for an item may result in a decision to re-tender that item.

Item	Format	Contract Term (Year 1) 2022-2023	Option Year 1 (Year 2) 2023-2024	Option Year 2 (Year 3) 2024-2025
1a - QIV (6mo+)	PFS	1,835,000	2,000,000	2,000,000
1b - QIV (6mo+)	MDV	5,550,000	6,100,000	6,100,000
2a - QIV (5yr+)	PFS	400,000	400,000	400,000
2b - QIV (5yr+)	MDV	1,100,000	1,100,000	1,100,000

1.2 Security Requirement

There is no security requirement associated with this bid solicitation.

1.3 Requirement

The requirement is detailed under Article 2.2 of the resulting contract clauses.

1.4 Communications Notification

As a courtesy, the Government of Canada requests that successful bidders notify the Contracting Authority in advance of their intention to make public an announcement related to the award of a contract.

1.5 Trade Agreements

This requirement is subject to the Canadian Free Trade Agreement (CFTA), the Canada - European Union Comprehensive Economic and Trade Agreement (CETA), the Revised World Trade Organization Agreement on Government Procurement (WTO-AGP), the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), the Canada - Chile Free Trade Agreement (CCFTA), the Canada - Colombia Free Trade Agreement, the Canada - Honduras Free Trade Agreement, the Canada - Korea Free Trade Agreement, Canada - Panama Free Trade Agreement, the Canada - Peru Free Trade Agreement (CPFTA), the Canada - United Kingdom Trade Continuity Agreement (Canada-UK TCA) and the Canada - Ukraine Free Trade Agreement (CUFTA).

1.6 Standard Instructions, Clauses and Conditions

- (a) All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the Standard Acquisition Clauses and Conditions Manual (<http://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual>) issued by Public Works and Government Services Canada.
- (b) Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the clauses and conditions of the resulting contract.
- (c) The 2003 (2020-05-28) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.
- (d) Subsection 5.4 of 2003, Standard Instructions - Goods or Services - Competitive Requirements, is amended as follows:

Delete: 60 days

Insert: 180 days

1.6.1 SACC Manual Clauses

- (a) C3011T (2013-11-06) - Exchange Rate Fluctuation
- (b) A9033T (2012-07-16) - Financial Capability

1.6.2 Electronic Payment of Invoices

- (a) If you are willing to accept payment of invoices by Electronic Payment Instruments, complete Annex E – Electronic Payment Instruments, to identify which ones are accepted.
- (b) If Annex E – Electronic Payment Instruments is not completed, it will be considered as if Electronic Payment Instruments are not being accepted for payment of invoices.
- (c) Acceptance of Electronic Payment Instruments will not be considered as an evaluation criterion.

1.7 Enquiries - Bid Solicitation

All enquiries must be submitted in writing to the Contracting Authority no later than five calendar days before the bid closing date. Enquiries received after that time may not be answered.

Bidders should reference as accurately as possible the numbered item of the bid solicitation to which the enquiry relates. Care should be taken by Bidders to explain each question in sufficient detail in order to enable Canada to provide an accurate answer. Technical enquiries that are of a proprietary nature must be clearly marked "proprietary" at each relevant item. Items identified as "proprietary" will be treated as such except where Canada determines that the enquiry is not of a proprietary nature. Canada may edit the question(s) or may request that the Bidder do so, so that the proprietary nature of the question(s) is eliminated, and the enquiry can be answered to all Bidders. Enquiries not submitted in a form that can be distributed to all Bidders may not be answered by Canada.

1.8 Submission of Bids

Bids must be submitted only to PWGSC Bid Receiving Unit by the date, time and place indicated on page 1 of the bid solicitation.

Note: For bidders choosing to submit using epost Connect for bids closing at the Bid Receiving Unit in the National Capital Region (NCR) the email address is: tpsgc.dgareceptiondessoumissions-abbidreceiving.pwgsc@tpsgc-pwgsc.gc.ca

Note: Bids will not be accepted if emailed directly to this email address. This email address is to be used to open an epost Connect conversation, as detailed in Standard Instructions [2003](#), or to send bids through an epost Connect message if the bidder is using its own licensing agreement for epost Connect.

1.9 Certifications and Additional Information

Bidders must provide the required certifications and additional information to be awarded a contract.

The certifications provided by Bidders to Canada are subject to verification by Canada at all times. Unless specified otherwise, Canada will declare a bid non-responsive, or will declare a contractor in default if any certification made by the Bidder is found to be untrue, whether made knowingly or unknowingly, during the bid evaluation period or during the contract period.

The Contracting Authority will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply with any request or requirement imposed by the Contracting Authority will render the bid non-responsive or constitute a default under the Contract.

1.9.1 Certifications Required with the Bid

Bidders must submit the following duly completed certifications as part of their bid.

1.9.1.1 Integrity Provisions - Declaration of Convicted Offences

In accordance with the Integrity Provisions of the Standard Instructions, all bidders must provide with their bid, **if applicable**, the declaration form available on the [Forms for the Integrity Regime](http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html) website (<http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html>), to be given further consideration in the procurement process.

1.9.2 Certifications Precedent to Contract Award

The certifications and additional information listed below should be submitted with the bid but may be submitted afterwards. If any of these required certifications or additional information is not completed and submitted as requested, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Failure to provide the certifications or the additional information listed below within the time frame specified will render the bid non-responsive.

1.9.2.1 Integrity Provisions – Required Documentation

In accordance with the section titled Information to be provided when bidding, contracting or entering into a real procurement agreement of the [Ineligibility and Suspension Policy](http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html) (<http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html>), the Bidder must provide the required documentation, as applicable, to be given further consideration in the procurement process.

1.9.2.2 Federal Contractors Program for Employment Equity - Bid Certification

- (a) By submitting a bid, the Bidder certifies that the Bidder, and any of the Bidder's members if the Bidder is a Joint Venture, is not named on the Federal Contractors Program (FCP) for employment equity "[FCP Limited Eligibility to Bid](#)" list available at the bottom of the page of the [Employment and Social Development Canada \(ESDC\) - Labour's website](#)

<https://www.canada.ca/en/employment-social-development/programs/employment-equity/federal-contractor-program.html#s4>).

- (b) Canada will have the right to declare a bid non-responsive if the Bidder, or any member of the Bidder if the Bidder is a Joint Venture, appears on the "[FCP Limited Eligibility to Bid](#)" list at the time of contract award.
- (c) Canada will also have the right to terminate the Contract for default if a Contractor, or any member of the Contractor if the Contractor is a Joint Venture, appears on the "[FCP Limited Eligibility to Bid](#)" (<https://www.canada.ca/en/employment-social-development/programs/employment-equity/federal-contractor-program.html#s4>) list during the period of the Contract.
- (d) The Bidder must provide the Contracting Authority with a completed Annex D titled Federal Contractors Program for Employment Equity - Certification, before contract award. If the Bidder is a Joint Venture, the Bidder must provide the Contracting Authority with a completed annex Federal Contractors Program for Employment Equity - Certification, for each member of the Joint Venture.

1.10 Evaluation Procedures

- (a) Bids received will be assessed in accordance with the entire requirement of the bid solicitation.
- (b) An evaluation team composed of representatives of Canada and Provincial and Territorial jurisdictions will evaluate the bids.

1.10.1 Technical Bid

- (a) In their technical bid, Bidders should demonstrate their understanding of the requirements contained in the bid solicitation and explain how they will meet these requirements. Bidders should demonstrate their capability and describe their approach in a thorough, concise and clear manner for carrying out the work.
- (b) The technical bid should address clearly and in sufficient depth the points that are subject to the evaluation criteria against which the bid will be evaluated. Simply repeating the statement contained in the bid solicitation is not sufficient. In order to facilitate the evaluation of the bid, Canada requests that Bidders address and present topics in the order of the evaluation criteria under the same headings. To avoid duplication, Bidders may refer to different sections of their bids by identifying the specific paragraph and page number where the subject topic has already been addressed.
- (c) **Bid Submission Form:** Bidders are requested to include the Bid Submission Form – Form 1 with their bids. It provides a common form in which bidders can provide information required for evaluation and contract award, such as a contact name and the Bidder's Procurement Business Number, etc. Using the form to provide this information is not mandatory, but it is recommended. If Canada determines that the information required by the Bid Submission Form is incomplete or requires correction, Canada will provide the Bidder with an opportunity to do so.

1.10.2 Mandatory Criterion

Mandatory evaluation criteria are included in Attachment 1 to Part 1.

1.10.3 Financial Bid

- (a) Bidders must submit their financial bid in accordance with Attachment 1 to Part 1 and the Basis of Payment in Annex B.

1.10.4 Financial Evaluation

Each item for which the Bidder has submitted a bid will be evaluated separately.

- (a) For Item 1a, Canada will calculate an evaluated price, as follows:

Evaluated Price = Year 1 PFS [Unit Price X Estimated Quantity] + Year 2 PFS [Unit Price X Estimated Quantity] + Year 3 PFS [Unit Price X Estimated Quantity]

- (b) For Item 1b, Canada will calculate an aggregate evaluated price, as follows:

Evaluated Price = Year 1 MDV [Unit Price X Estimated Quantity] + Year 2 MDV [Unit Price X Estimated Quantity] + Year 3 MDV [Unit Price X Estimated Quantity]

- (c) For item 2a, Canada will calculate an aggregate evaluated price, as follows:

Evaluated Price = Year 1 PFS [Unit Price X Estimated Quantity] + Year 2 PFS [Unit Price X Estimated Quantity] + Year 3 PFS [Unit Price X Estimated Quantity]

- (d) For item 2b, Canada will calculate an aggregate evaluated price, as follows:

Evaluated Price = Year 1 MDV [Unit Price X Estimated Quantity] + Year 2 MDV [Unit Price X Estimated Quantity] + Year 3 MDV [Unit Price X Estimated Quantity]

1.11 Basis of Selection

- (a) To be declared responsive, a bid must:

- (i) comply with all the requirements of the bid solicitation; and
- (ii) meet all mandatory technical criteria.

- (b) Bids not meeting (i) or (ii) will be declared non-responsive.

- (c) For item 2a, the responsive bid with the lowest evaluated price will be recommended for award of a contract.

- (d) For item 1a, 1b and 2b, the responsive bids with the two lowest evaluated prices will be recommended for award of a contract as follows:

- (i) If the price difference between the two evaluated prices is 20% or less, the Bidder with the lowest evaluated price will be recommended for an award of 60% of the requirement;
- (ii) If the price difference between the two evaluated prices is more than 20%, but less than or equal to 30%, the Bidder with the lowest evaluated price will be recommended for an award of 65% of the requirement;
- (iii) If the price difference between the two evaluated prices is more than 30%, but less than or equal to 40%, the Bidder with the lowest evaluated price will be recommended for an award of 70% of the requirement;

- (iv) If the price difference between the two evaluated prices is greater than 40%, Canada may, in its sole discretion, award 75% or 100% of the requirement to the Bidder with the lowest evaluated price for that item.
- (v) Unless 100% of the requirement is awarded to the Bidder with the lowest evaluated price, the Bidder with second lowest evaluated price will be recommended for award for the balance of the requirement.
- (e) If there are two or more bids with identical lowest evaluated prices, the names of all Bidders with identical lowest evaluated prices will be placed in a hat and the first name drawn will be recommended for an award of 60% of the requirement. The second name drawn will be recommended for award for the balance of the requirement. All Bidders with the lowest evaluated price will be invited to witness the event.
- (f) If a bidder indicates in their bid that they are only able to supply a portion of the requirement in any or all contract years and the results of the basis of selection are such that the bidder will be unable to supply the quantities they would be recommended for award, Canada, at its sole discretion, reserves the right to declare the bid non-responsive and disqualify it, or to recommend the bidder be awarded the maximum quantities stated in their bid and the second Bidder with one of the two lowest evaluated prices be awarded the balance of the requirement.
- (g) To ensure security of supply, Canada, at its sole discretion, reserves the right to limit a Bidder's aggregate AIV contract quantities, including those awarded under this solicitation to 60% of Canada's estimated public market AIV demand.
- Canada's estimated public market AIV demand is the total of publicly funded provincial, territorial and federal AIV demand (excluding specialized influenza vaccines such as live attenuated, cell derived and those specifically targeted for persons aged 65 years and older), which is estimated at 13.2M doses.
- (h) Should the Basis of Selection result in a recommendation for award such that the limitation in (g) will be exceeded and Canada so chooses, the applicable bidder will be recommended for award for to the difference between 60% of Canada's estimated public market AIV demand and their current AIV contract quantities. The balance of the requirement will be recommended for award to the other responsive bid being recommended for award.

1.12 Debriefings

Bidders may request a debriefing on the results of the bid solicitation process. Bidders should make the request to the Contracting Authority within 15 working days from receipt of the results of the bid solicitation process. The debriefing may be in writing, by telephone or in person.

1.13 Bid Challenge and Recourse Mechanisms

- (a) Several mechanisms are available to potential suppliers to challenge aspects of the procurement process up to and including contract award.
- (b) Canada encourages suppliers to first bring their concerns to the attention of the Contracting Authority. Canada's [Buy and Sell](#) website, under the heading "[Bid Challenge and Recourse Mechanisms](#)" contains information on potential complaint bodies such as:
- Office of the Procurement Ombudsman (OPO)
 - Canadian International Trade Tribunal (CITT)

- (c) Suppliers should note that there are **strict deadlines** for filing complaints, and the time periods vary depending on the complaint body in question. Suppliers should therefore act quickly when they want to challenge any aspect of the procurement process.

1.14 Applicable Laws

Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in the province of Ontario.

Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

ATTACHMENT 1 TO PART 1 - TECHNICAL EVALUATION

All mandatory technical criteria and mandatory financial criteria apply to Items 1 and 2.

1.1.1 Mandatory Technical Criteria

- (a) The bid must meet the mandatory technical criteria specified below. The Bidder must provide the necessary documentation to support compliance with this requirement.
- (b) Bids which fail to meet the mandatory technical criteria will be declared non-responsive. All remaining bids will then be evaluated against the mandatory financial criteria.

MANDATORY TECHNICAL CRITERIA		
NUMBER	DESCRIPTION	BID REFERENCE (page, section, etc.)
M1	<p>PRODUCT SELECTION The Bidder must offer at least one of the following Items:</p> <p><u>Item 1a (QIV – PFS 6mo+):</u> Quadrivalent Influenza Vaccine (QIV) with an approved age indication of six (6) months and above, as described in Annex A, Requirement, in Pre-filled syringe (PFS).</p> <p><u>Item 1b (QIV – MDV 6mo+):</u> Quadrivalent Influenza Vaccine (QIV) with an approved age indication of six (6) months and above, as described in Annex A, Requirement, in Multi-dose Vial (MDV).</p> <p><u>Item 2a: (QIV – PFS 5yr+):</u> Quadrivalent Influenza Vaccine (QIV) with an approved age indication of five (5) years of age and above, as described in Annex A, Requirement, in Pre-filled syringe.</p> <p><u>Item 2b: (QIV – MDV 5yr+)</u> Quadrivalent Influenza Vaccine (QIV) with an approved age indication of five (5) years of age and above, as described in Annex A, Requirement, in Multi-dose vial.</p> <p>For each Item proposed, the Bidder must provide: <input type="checkbox"/> Drug Identification Number (DIN)</p>	
M2	<p>ANNUAL INFLUENZA VACCINE CAPACITY <u>Item 1a and 1b – Quadrivalent Influenza Vaccine (QIV) for age indication of 6 months and above – Pre-filled Syringe (PFS) and Multi-dose Vial (MDV):</u></p> <p>The Bidder must demonstrate that it will have the capacity to produce and deliver up to 1.83M doses of QIV in PFS and/or 5.55M doses of QIV in MDV for age indication 6 months and above, as described in Annex A - Requirement, for the contract term and each of the options years.</p>	

	<p><u>Item 2a and 2b – Quadrivalent Influenza Vaccine (QIV) for age indication of 5 years of age and above – Pre-filled Syringe (PFS) and Multi-dose Vial (MDV):</u></p> <p>The Bidder must demonstrate that it will have the capacity to produce and deliver up 400K doses of QIV PFS and/or 1.1M doses of QIV in MDV for age indication 5 years of age and above, as described in Annex A - Requirement, for the contract term and each of the options years.</p>	
<p>M3</p>	<p>ANNUAL SCHEDULE</p> <p>The Bidder must demonstrate how it will meet the Product Availability Schedule, including the overage reserve, as described in clause 2.6.1(e) and 2.6.4 of Part 2, Resulting Contract by providing a plan which includes the key milestones that must be met; including the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) submission requirements described in 2.6.2 of Part 2, Resulting Contract to successfully meet the Product Availability Schedule.</p> <p>If a Bidder is bidding on multiple Items, the Bidder must be able to meet the Product Availability Schedule at 2.6.4 of Part 2, for each Item and must demonstrate how this will be accomplished.</p>	
<p>M4</p>	<p>CONTINGENCY PLANS TO SUPPLY VACCINES IN THE EVENT OF DISRUPTIONS</p> <p>Bidders must describe the mechanism that it uses for developing and updating contingency plans and to describe its contingency plans that are currently in place, including risk mitigation strategies and back-up plans, with respect to dealing with disruptions in the following areas:</p> <ul style="list-style-type: none"> (a) vaccine shortage; (b) shipment delays; (c) vaccine recall; (d) lots that do not meet the Bidder's requirements or Health Canada's requirements and must be replaced in order to meet Canada's order; (e) testing results that may cause shipping delays; and (f) the bidder's: resources, materials, including components, egg supply, antigen production, redundant capacity, partnerships. 	

1.1.2 Mandatory Financial Criteria

MANDATORY FINANCIAL CRITERIA		
NUMBER	DESCRIPTION	BID REFERENCE (page, section, etc.)
<p>MF1</p>	<p>Bidders offering the same product from Items 1a and 2a or 1b and 2b must submit the same price in response to both Items.</p>	

PART 2 - RESULTING CONTRACT CLAUSES

2.1 Security Requirement

There is no security requirement applicable to this Contract.

2.2 Requirement

The Contractor must provide the items detailed under the Requirement at Annex A.

2.3 Standard Clauses and Conditions

All clauses and conditions identified in the Contract by number, date and title are set out in Standard Acquisition Clauses and Conditions Manual (<http://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual>) issued by Public Works and Government Services Canada.

2.3.1 General Conditions

2010A (2021-12-02) General Conditions - Goods - Medium Complexity, apply to and form part of the Contract.

2.3.2 Warranty - Amendment to General Conditions 2010A

Section 09, paragraph 1, of General Conditions 2010A, which forms part of the Contract will not apply to Work with a specified expiry date. The following paragraph replaces section 9, paragraph 1, General Conditions 2010A for Work with a specified expiry date:

- (a) Despite inspection and acceptance of the Work by or on behalf of Canada and without restricting any other provision of the Contract or any condition, warranty or provision implied or imposed by law, the Contractor warrants that the Work conforms to the specifications until the expiration date required by the Requirement. The Contractor must, upon the request of Canada, replace at its own expense (including costs of returns and delivery of replacement Work) as soon as possible any supplies that fail to conform or that deteriorates prior to the expiration date required by the Requirement.
- (b) If full replacement is not available in a timeframe acceptable to Canada, then Canada may, in addition to and without prejudice to any other remedy available, choose from one of the following options for the quantity and Contract value of the Work affected:
 - (i) Full and immediate reimbursement;
 - (ii) Equivalent full credit against future purchases under the Contract; or
 - (ii) Partial replacement and partial reimbursement or partial credit.

2.3.3 Payment Period – Amendment to General Conditions 2010A

Section 15 of General Conditions 2010A is deleted and replaced as follows:

- (a) Canada's payment period is 60 days. The payment period is measured from the date an invoice in acceptable form and content is received in accordance with the Contract or the date the Work is delivered in acceptable condition as required in the Contract, whichever is later. A payment is considered overdue on the 61st day following that date and interest will be paid automatically in accordance with the section 16.

- (b) If the content of the invoice and its substantiating documentation are not in accordance with the Contract or the Work is not in acceptable condition, Canada will notify the Contractor within 15 days of receipt. The 60-day payment period begins upon receipt of the revised invoice or the replacement or corrected Work. Failure by Canada to notify the Contractor within 15 days will only result in the date specified in subsection 1 to apply for the sole purpose of calculating interest on overdue accounts

2.3.4 Anti-forced labour requirements - Amendment to General Conditions 2010A

Section 32 of General Conditions 2010A, which forms part of the Contract is inserted as follows:

1. The Contractor represents and warrants that the Work is not mined, manufactured or produced wholly or in part by forced labour. Regardless of who acts as an importer, the Contractor must not during the performance of the Contract, directly or indirectly, deliver Work to Canada or import Work into Canada the importation of which is prohibited pursuant to ss. 136(1) of the *Customs Tariff Act* and tariff item No. 9897.00.00 of the [Customs Tariff – Schedule](#) (as amended from time to time), because it is mined, manufactured or produced wholly or in part by forced labour.
2. If a tariff classification determination is made under the *Customs Act* that the importation of the Work, or any part of the Work, is prohibited, the Contractor must immediately inform the Contracting Authority in writing. Canada may terminate the Contract for default in accordance with section 2010A 23 - Default by the Contractor if the Work or any part of the Work is classified under tariff item no. 9897.00.00 of the [Customs Tariff – Schedule](#) as mined, manufactured or produced wholly or in part by forced labour. If the Contractor is aware that the Work, or any part of the Work, is being or has been investigated regarding whether it is prohibited from entry pursuant to tariff item No. 9897.00.00, the Contractor must immediately inform the Contracting Authority in writing of that investigation.
3. Canada may terminate the Contract for default in accordance with section 2010A 23 - Default by the Contractor if it has reasonable grounds to believe the Work was mined, manufactured or produced in whole or in part by forced labour or linked to human trafficking. Reasonable grounds for making such a determination may include:
 - a. Findings or Withhold Release Orders issued by the United States Customs and Border Protection, under the US [Trade Facilitation and Trade Enforcement Act](#) (TFTEA) of 2015; or
 - b. Credible evidence from a reliable source, including but not limited to non-governmental organizations.
4. Canada may terminate the Contract for default in accordance with section 2010A 23 - Default by the Contractor if the Contractor has, in the past three years, been convicted of any of the following offences under the [Criminal Code](#) or the [Immigration and Refugee Protection Act](#):

Criminal Code

 - i. section 279.01 (Trafficking in persons);
 - ii. section 279.011 (Trafficking of a person under the age of eighteen years);
 - iii. subsection 279.02(1) (Material benefit - trafficking);
 - iv. subsection 279.02(2) (Material benefit - trafficking of person under 18 years);
 - v. subsection 279.03(1) (Withholding or destroying documents - trafficking);
 - vi. subsection 279.03(2) (Withholding or destroying documents - trafficking of person under 18 years); or *Immigration and Refugee Protection Act*
 - vii. section 118 (Trafficking in persons).

-
5. Canada may terminate the Contract for default in accordance with section 2010A 23 - Default by the Contractor if the Contractor has, in the past three years, been convicted of an offence in a jurisdiction other than Canada that, in Canada's opinion, is similar to any of the offences identified in paragraphs 4(i) to (vii).
 6. For purposes of determining whether a foreign offence is similar to a listed offence, PWGSC will take into account the following factors:
 - i. in the case of a conviction, whether the court acted within its jurisdiction;
 - ii. whether the supplier was afforded the right to appear during the court's proceedings or to submit to the court's jurisdiction;
 - iii. whether the court's decision was obtained by fraud; or
 - iv. whether the supplier was entitled to present to the court every defence that the supplier would have been entitled to present had the proceeding been tried in Canada.
 7. Where Canada intends to terminate the Contract under this section, Canada will inform the Contractor and provide the Contractor an opportunity to make written representations before making a final decision. Written representations must be submitted within 30 days from receiving a notice of concern unless Canada establishes a different deadline.

2.4 Term of Contract

2.4.1 Period of Contract

The period of the Contract is from date of award to March 31 2023, inclusive.

2.4.2 Option to Extend the Contract

- (a) The Contractor grants to Canada the irrevocable option to extend the term of the Contract by up to two (2) additional one year periods under the same conditions. The Contractor agrees that, during the extended period of the Contract, it will be paid in accordance with the applicable provisions as set out in the Basis of Payment.
- (b) The Contracting Authority may exercise the option by sending a written notice to the Contractor at least 60 calendar days before the expiry date of the Contract. The option may only be exercised by the Contracting Authority, and will be evidenced for administrative purposes only, through a contract amendment.

2.4.3 Option Quantity - Additional Doses

- (a) The Contractor grants to Canada the irrevocable option to purchase additional Work in excess of 105% of the Awarded Doses set out at section 2 – Quantity of Annex A - Requirement, to a maximum of 1.5 times the Awarded Doses in any year of the Contract.
- (b) In any year of the Contract, the Option Quantity – Additional Doses may be exercised by Canada at any time, if exercised:
 - (i) After May 31st but before the Contractor has ceased production of the Work for that year, a mutually acceptable delivery schedule for the Additional Option Quantity will be negotiated and evidenced through a contract amendment.

- (ii) After production has ceased for any year, nothing in the Contract will obligate the Contractor to resume production. A mutually acceptable price, quantity and delivery schedule will be negotiated and evidenced through a contract amendment. The price negotiated will be based on the Contract prices.
- (c) Canada reserves the right to purchase additional doses from any supplier capable of delivering influenza vaccine in order to meet seasonal influenza requirements.

2.4.4 Option to Reduce Quantities

- (a) If Canada exercises the Option to Extend the Contract at section 2.4.2, The Contractor grants to Canada the irrevocable option to reduce the Awarded Doses set out at section 2 – Quantity of Annex A – Requirement by up to 15%. Subject to the mutual agreement of the Contractor and Canada, The Awarded Doses set out at Section 2 – Quantity of Annex A – Requirement may be reduced by more than 15%.
- (b) Without restricting any other right of Canada under the Contract, should an Identified User not receive program funding approval or if a program change is announced before February 28th, of any Contract year, that Identified User may withdraw from the Contract in whole or in part.
- (c) In the event of such change under the Contract, there will be no other costs that will be paid to the Contractor as a result of the change.

2.4.5 Option to Add Identified User

The Contractor grants to Canada the irrevocable option to add Identified Users and delivery locations within Canada to the Contract at a price not to exceed the Contract price and subject to the same conditions.

2.5 Authorities

2.5.1 Contracting Authority

- (a) The Contracting Authority for this Contract is:

Christa Baird, Supply Team Leader
Public Works and Government Services Canada
Drugs, Vaccines & Biologics Division
Terrasses de la Chaudière
10 Wellington Street, 5th Floor
Gatineau, Quebec K1A 0S5

Telephone: (343) 551-3348
Email address: christa.baird@pwgsc-tpsgc.gc.ca

- (b) The Contracting Authority is responsible for the management of the Contract, and any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor must not perform work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from anybody other than the Contracting Authority.

2.5.2 Technical Authority

The Technical Authority for the Contract is: **(to be completed upon contract award)**
Name: _____

Organization: _____
Address: _____
Telephone: ____ - ____ - ____
E-mail: _____.

The Technical Authority is responsible for all matters concerning the technical content of the Work under the Contract. Technical matters may be discussed with the Technical Authority; however the Technical Authority has no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

2.5.3 Identified Users

- (a) The list of Identified Users is provided in Annex C.
- (b) The Identified Users are the representatives of the department, agency, province or territory for whom the Work is being carried out under the Contract. The Identified Users have no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

2.5.4 Canada and Public Works and Government Services as Agent

- (a) The Contractor acknowledges that Canada is acting as an agent for Identified Users. Canada will only be funding and paying for Orders placed on behalf of a Federal Government Department or Agency.
- (b) Orders placed by or on behalf of a non-Federal Government Department or Agency Identified User under the Contract are the responsibility of the Identified User for whom or by whom the Order is placed. To the extent that the Contract involves orders placed by Canada on behalf of a non-Federal Government Department or Agency Identified User, Canada is acting as an agent for the Identified User only and the Identified User is solely liable and responsible for funding and payment of those orders.
- (c) The Contractor acknowledges and agrees that, unless otherwise specified, Canada is not liable under the Contract to the extent that it involves Orders placed on or on behalf of a non-Federal Government Department or Agency Identified User, and the Contractor agrees that it must not make any claim or take any proceeding against Canada for any loss, damages, or non-payment in any way related to or arising out of such Orders.

2.5.5 Contractor Representative

NOTE TO BIDDER: Please include the requested information on "FORM 1 - BID SUBMISSION".

- (a) General enquiries:

Name:
Telephone No.:
E-mail address:
- (b) Delivery follow-up:

Name:
Telephone No.:

E-mail address:

2.6 Order and Delivery

2.6.1 Quantities

- (a) **Initial Estimated Quantities:** No later than February 28th of each year of the Contract, Canada will notify the Contractor of the Initial Estimated Quantities to be supplied for the upcoming influenza season. The Initial Estimated Quantities will be at least equal to the Awarded Doses set out at section 2 – Quantity in Annex A - Requirement.
- (b) **Final Estimated Quantities:** No later than May 31st of each year of the Contract, Canada will notify the Contractor of the Final Estimated Quantities to be supplied for the upcoming influenza season. The Final Estimated Quantities will be at least equal to the Initial Estimated Quantities provided in 2.6.1(a).
- (c) **Minimum/Maximum Quantities:** Canada reserves the right to purchase a minimum of 95% to a maximum of 105% of the Final Estimated Quantities.
- (d) **Additional Identified Users:** If Identified Users are added to the Contract, their quantities will be in addition to the maximum quantity in 2.6.1(c).
- (e) **Overage Reserve:** The Overage Reserve is a quantity in excess of the Final Estimated Quantities. The Contractor must produce an Overage Reserve of 5% of the Final Estimated Quantities to ensure Canada is able to purchase the minimum/maximum quantities in accordance with 2.6.1(c). The Contractor may reallocate outside the Contract or destroy the Overage Reserve the earlier of:
 - (i) A date to be agreed to between Canada and the Contractor; and
 - (ii) The expiry date of the Overage Reserve

2.6.2 Biologic and Radiopharmaceutical Drugs Directorate Submission Requirements

It is the Contractor's responsibility to submit to the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) of Health Canada, or its successor, strain update submissions, all vaccine lot samples and batch release protocols, and any other documentation necessary to permit market authorization and release for sale in Canada of influenza vaccine lots in a timely manner and in accordance with BRDD's guidance document on the *Annual update of seasonal influenza vaccines* (<https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/annual-update-seasonal-influenza-vaccines.html>). As a minimum, to ensure that the market authorization and the release of lots by the BRDD will occur early enough to allow the Contractor to meet the requirements of the Contract, the Contractor must submit the required documentation no later than July 31st in each year of the Contract:

- (a) To BRDD: a strain update submission completed as per the BRDD guidance document for influenza strain update requirements.
- (b) To BRDD, with a copy to the Contracting Authority and Technical Authority: a lot release schedule that must include, as a minimum:
 - (i) the final product lot numbers;
 - (ii) the final container lot numbers;
 - (iii) the anticipated number of doses per lot;
 - (iv) the date of sample submission to BRDD for each lot;

- (v) the date of batch release protocol submission to BRDD for each lot; and
 - (vi) the anticipated date of internal lot release by the Contractor.
- (c) For each lot, batch release protocols must be submitted to BRDD a minimum of fourteen (14) calendar days prior to the date the Contractor requires BRDD's regulatory lot release Letter.
- (d) Upon completion of (a) and (b) above, the Contractor must notify the Contracting Authority, in writing, that the requirements have been met, by providing the applicable submission dates.

2.6.3 Estimated Delivery Schedule

No later than July 31st of each year of the Contract, Canada will supply to the Contractor a schedule indicating each Identified User's quantity and mix of Annual Influenza Vaccines (if applicable), that the Contractor must supply that year. This schedule is provided as an estimate only and is subject to change. Identified Users' Orders will be placed as-and-when requested.

2.6.4 Product Availability Schedule

- (a) The Work must be available to be delivered and received by each Identified User indicated on the Estimated Delivery Schedule in accordance with the following schedule:

% of Final Estimated Quantity:	Date:
50%	September 15
25%	October 1
15%	October 15
10% + 5%	October 30, includes 5% overage reserve

- (b) The Contractor agrees that Identified Users' requirements will be given priority over distribution to the private market in Canada. Canada's final estimated quantity must be available and set aside in accordance with the availability dates indicated in 2.6.4(a) above for Identified Users' deliveries before the Contractor provides vaccine to private sector customers.

2.6.5 Order against Contract

- (a) The Work to be performed under the Contract will be on an "as and when requested basis" using an Order against Contract ("Order").
- (b) **Process for Issuing an Order:** If a requirement is identified, an Order will be prepared by the Identified User / Contracting Authority and sent to the Contractor by letter, by e-mail, or by telephone, or any other means agreed to by the parties and evidenced in writing.
- (c) **Contents of an Order:** The Order must contain the following information, if applicable:
- (i) An order number;
 - (ii) quantity and description of goods being ordered;
 - (iii) delivery location;
 - (iv) invoicing address;
 - (v) reference to this contract number and
 - (vi) any other constraints that might affect the work.

No pricing information is to be included in the Order.

- (d) **Delivery:** Unless otherwise indicated in the Order, delivery must be made within seven (7) calendar days from receipt of an Order.

2.6.6 Point of Manufacturing and Shipping

NOTE TO BIDDER: Please include the requested information on "FORM 1 - BID SUBMISSION".

Contractor's Point of Manufacturing is located at: _____

Contractor's Shipping Facilities are located at: _____

2.6.7 Shipping Instructions

- (a) Goods must be consigned to the destinations specified in the Order and delivered DDP Delivered Duty Paid (Identified User), Incoterms 2000 for shipments from a commercial contractor.
- (b) All Orders by following Identified Users must be delivered by air transport, unless the Contracting Authority or the following Identified Users has specifically requested, and has agreed in writing, to have a delivery made by ground transport:
- (i) Newfoundland and Labrador
 - (ii) Nunavut;
 - (iii) Yukon Territories; and
 - (iv) Northwest Territories.

2.7 Liquidated Damages

- (a) **BRDD Submission Requirements:** If the Contractor fails to meet the BRDD Submission Requirements at 2.6.2(c) and Canada does not terminate for default, in whole or in part, for each lot where the Contractor has requested BRDD approve a batch release protocol in less than 14 calendar days, contrary to the BRDD guidance document on the annual update of seasonal influenza vaccines, the Contractor agrees to credit Canada:
- (i) \$2000 per day for the total number of days it failed to provide a 14 calendar day review period; or
 - (ii) 1% of the value of the lot with respect to which it failed to provide a 14 calendar day review period,
- whichever is less.
- (b) **Availability:** If the Contractor fails to meet the Product Availability Schedule at 2.6.4, and Canada does not terminate for default, in whole or in part, and instead provides the Contractor with additional time to meet the requirement, the Contractor agrees to credit Canada:
- (i) 2% of the value of the late Work for late delivery within 2 weeks of the applicable date in the Product Availability Schedule; or
 - (ii) 5% of the value of the late Work for late delivery more than 2 weeks after the applicable date in the Product Availability Schedule.

- (iii) This provision is not applicable with respect to the first 50% of deliveries required for September 15th, providing they are delivered by September 22nd. If those deliveries are made after September 22nd, the first day for liquidated damages to apply will be September 15th.

Additional doses purchased after May 31st as set out in section 2.4.3 Option Quantity – Additional Doses in each year of the contract are excluded from liquidated damages.

- (c) **Overage Reserve:** The Contractor must provide a credit to Canada in accordance with the applicable price per dose in Annex B, Basis of Payment for 50% of the Overage Reserve doses the Contractor is unable to supply.
- (d) The discounts and credits set out in (a), (b) and (c) above constitute liquidated damages. The Parties agree that these amounts are their best pre-estimate of the loss to Canada in the event of the defaults described, and that they are not intended to be, nor are they to be construed as, a penalty.
- (e) If liquidated damages are applicable to a lot under both (a) and (b) above, liquidated damages will only be applied against (a) or (b), whichever is the greater amount.
- (f) To collect the liquidated damages, Canada has the right to hold back, drawback, deduct or set off from and against any money Canada owes to the Contractor from time to time.
- (g) Nothing in this article limits the rights and remedies to which Canada is otherwise entitled under this Contract (including the right to terminate the Contract for default), or the law generally.

2.8 Payment

2.8.1 Basis of Payment

In consideration of the Contractor satisfactorily completing all of the obligations under the Order, the Contractor will be paid the firm unit price in accordance with the basis of payment in Annex B.

Canada will not pay the Contractor for any design changes, modifications or interpretations of the Work, unless they have been authorized, in writing, by the Contracting Authority before their incorporation into the Work.

2.8.2 Minimum Work Guarantee

In this clause,

- (a) "Maximum Contract Value" means the amount specified on page 1 of the Contract, "Total Estimated Cost"; and
- "Minimum Contract Value" means 90% of the Maximum Contract Value.
- (b) Canada's obligation under the Contract is to request Work in the amount of the Minimum Contract Value or, at Canada's option, to pay the Contractor at the end of the Contract in accordance with paragraph (c). In consideration of such obligation, the Contractor agrees to stand in readiness throughout the Contract period to perform the Work described in the Contract. Canada's maximum liability for work performed under the Contract must not exceed the Maximum Contract Value, unless an increase is authorized in writing by the Contracting Authority.

-
- (c) In the event that Canada does not request work in the amount of the Minimum Contract Value during the period of the Contract, Canada must pay the Contractor the difference between the Minimum Contract Value and the total cost of the Work requested.
 - (d) Canada will have no obligation to the Contractor under this clause if Canada terminates the Contract in whole or in part for default.

2.8.3 Limitation of Expenditure

- (a) Canada's total liability to the Contractor under the Contract for all Orders, inclusive of any revisions, must not exceed the "Total Estimated Cost" as defined on page 1 of the Contract.
- (b) No increase in the total liability of Canada will be authorized or paid to the Contractor unless an increase has been approved, in writing, by the Contracting Authority.

2.8.4 SACC Manual Clauses

- (a) H1001C (2008-05-12), Multiple Payments
- (b) G1005C (2016-01-28), Insurance – No Specific Requirement

2.8.5 Electronic Payment of Invoices

The Contractor accepts to be paid using any of the following Electronic Payment Instrument(s):

- (a) Visa Acquisition Card;
- (b) MasterCard Acquisition Card;
- (c) Direct Deposit (Domestic and International);
- (d) Electronic Data Interchange (EDI);
- (e) Wire Transfer (International Only);
- (f) Large Value Transfer System (LVTS) (Over \$25M).

2.9 Invoicing Instructions

- (a) The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.
- (b) Invoices must be submitted to vaccin.vaccine@tpsgc-pwgsc.gc.ca for certification and payment.

2.10 Product Recall or Withdrawal

- (a) In the event of a recall or a withdrawal of Work, the Contractor must notify the Contracting Authority and all Identified Users who have been delivered the recalled or withdrawn Work and must collect and destroy the delivered, recalled, or withdrawn Work at their own cost.
- (b) The Contractor must, upon the request of Canada or an Identified User, replace as soon as possible any recalled or withdrawn Work at their own cost.
- (c) If full replacement is not available in a timeframe acceptable to Canada or an Identified User, then Canada or the Identified User may, in addition to and without prejudice to any other remedy available, choose from one of the following options for the quantity and Contract value of the Work affected:

-
- (i) Full and immediate reimbursement;
 - (ii) Equivalent full credit against future purchases under the Contract; or
 - (iii) Partial replacement and partial immediate reimbursement or partial credit under the Contract.

2.11 Product Dating

The Work produced for a given annual influenza season must be dated with an expiry date which is June 30 (or later) of the year in which that season ends (e.g. Work for the 2022/2023 season must bear an expiry date of June 30, 2023). Exceptions may be made:

- (a) If the expiry date granted by the Regulator is earlier than June 30th and the Contractor implements measures to assure availability of sufficient vaccine for the duration of the Identified Users' influenza immunization programs; or
- (b) For Work produced in the future utilizing new technologies, subject to the prior agreement of Canada.

2.12 Returns

In addition to and without prejudice to any other remedy available, for work:

- (a) Damaged during shipment from Contractor, the Contractor must provide full credit or replacement or refund for all returned Work where Contractor was contacted within 5 days of delivery to and acceptance by the Identified User. Damaged Work will be returned FCA Free Carrier (Identified User) Incoterms 2000 to the address specified below. The Contractor is responsible for shipping costs.
- (b) As a minimum the Contractor will provide credit for up to 5% of the total quantity actually ordered, including any optional doses ordered for expired, unopened Work that is returned with the original packing slip no later than December 31st in which the season ends (i.e. season 2022/2023, returns must be made by December 31, 2023). Returns are to be shipped DDP Delivery Duty Paid (to the address indicated below) Incoterms 2000 by the Identified User. The Identified User is responsible for shipping costs.
- (c) Contractor's Returns Facilities:

NOTE TO BIDDER: Please include the requested information on "FORM 1 - BID SUBMISSION".

Address:
Contact Name:
Telephone:
Facsimile:
Email:

2.13 Inability to Supply

- (a) In the event that the Contractor is unable to supply the Work in accordance with the terms and conditions of the Contract, whether as the result of vaccine discontinuation or for any other reason, the Contractor will provide a substitute product acceptable to the Identified User at a price no greater than firm unit price specified in Annex B.
- (b) Should the Identified User be required to purchase the Work from an alternate source at a higher price, the Contractor must reimburse the Identified User for the difference between the price paid to the alternate source and the firm unit price specified in Annex B.
- (c) Should the Identified User be required to purchase the Work from an alternate source, Canada reserves the right to adjust the Work.

2.14 Notice of Anticipated Shortage

- (a) The Contractor must notify the Contracting Authority when it becomes aware of a potential problem, delay, or event that may lead to a shortage of any of the quantities listed in Annex B. Such notice must include a description of the nature of the problem or delay or event, the anticipated impact on the requirements of the Contract, the steps being taken by the Contractor to rectify the situation or to minimize the impact on this Contract, and the expected date by which the shortage will be fully corrected.
- (b) For the purpose of this clause "shortage" is defined as the inability to meet the Product Delivery Schedule and any delivery requirement in whole or in part.

2.15 Reporting

2.15.1 Lot Release

Updates: Beginning July 31st of each year of the Contract, the Contractor must provide the Contracting Authority with updates every two weeks to the preliminary schedule for lot release on the production status as it relates to the estimated delivery schedule. The updates must continue until it has been demonstrated that enough doses have been approved for release to meet the Final Estimated Quantity and the Overage Reserve.

2.15.2 Delivery

- (a) The Contractor must submit weekly reports, in electronic format, on the progress of the Work delivered to Identified Users, starting from the date of the first delivery up to and including the date of the last delivery (normally between September and January of each influenza season).
- (b) Prior to each delivery, the Contractor must advise the Identified User of the shipping date, delivery date, method of shipment, number of doses per case, number of cases per skid, total number of doses shipped, number of doses on back-order (if applicable), lot number and the lot expiry date.

2.15.3 Adverse Event Following Immunization (AEFI) Reporting Requirement

The Contractor must comply with all Identified Users' AEFI reporting requirements. The requirements are set out at in the user guide *User guide to completion and Submission of the AEFI reports* (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-aefi-reports.html>) issued by the Public Health Agency of Canada.

2.16 Certifications

2.16.1 Compliance

Unless specified otherwise, the continuous compliance with the certifications provided by the Contractor in its bid or precedent to contract award, and the ongoing cooperation in providing additional information are conditions of the Contract and failure to comply will constitute the Contractor in default. Certifications are subject to verification by Canada during the entire period of the Contract.

2.16.2 Federal Contractors Program for Employment Equity - Default by the Contractor

The Contractor understands and agrees that, when an Agreement to Implement Employment Equity (AIEE) exists between the Contractor and Employment and Social Development Canada (ESDC) - Labour, the AIEE must remain valid during the entire period of the Contract. If the AIEE becomes invalid, the name of the Contractor will be added to the "FCP Limited Eligibility to Bid" list. The imposition of such a sanction by ESDC will constitute the Contractor in default as per the terms of the Contract.

2.17 Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in the province of Ontario.

2.18 Dispute Resolution

- (a) The parties agree to maintain open and honest communication about the Work throughout and after the performance of the contract.
- (b) The parties agree to consult and co-operate with each other in the furtherance of the contract and promptly notify the other party or parties and attempt to resolve problems or differences that may arise.
- (c) If the parties cannot resolve a dispute through consultation and cooperation, the parties agree to consult a neutral third party offering alternative dispute resolution services to attempt to address the dispute.
- (d) Options of alternative dispute resolution services can be found on Canada's Buy and Sell website under the heading "[Dispute Resolution](#)".

2.19 Priority of Documents

If there is a discrepancy between the wording of any documents that appear on the list, the wording of the document that first appears on the list has priority over the wording of any document that subsequently appears on the list.

- (a) the Articles of Agreement;
- (b) the general conditions 2010A (2021-12-02) Goods (Medium Complexity);
- (c) Annex A: Requirement;
- (d) Annex B: Basis of Payment;
- (e) Annex C: Identified Users;
- (f) the Orders (including all of its annexes, if any)
- (g) the Estimated Delivery Schedule, as revised from time to time, and
- (h) the Contractor's bid dated _____, as clarified on _____, as amended on _____.

ANNEX A – REQUIREMENT

1. Scope

The Contractor must supply the following Annual Influenza Vaccines (AIV) which must be considered safe for use in persons with latex allergies:

- (a) **Item 1a: Quadrivalent Influenza Vaccine (QIV) – Pre-filled Syringe (PFS) with an approved age indication of six (6) months of age and above** *(to be included at contract award if awarded this item)*

A Quadrivalent Influenza Vaccine (QIV) in pre-filled syringe (PFS) authorized for sale in Canada by Health Canada with an approved age indication of six (6) months of age and above.

The vaccine supplied must be an inactivated, quadrivalent, split virion or subunit vaccine containing two strains of influenza virus Type A and two strain of influenza virus Type B. The strain composition must conform to the requirements of the World Health Organization (WHO) and the National Advisory Committee on Immunization (NACI) for the year in which the vaccine is to be supplied under the Contract.

- (b) **Item 1b: Quadrivalent Influenza Vaccine (QIV) – Multi-Dose Vial (MDV) with an approved age indication of six (6) months of age and above** *(to be included at contract award if awarded this item)*

A Quadrivalent Influenza Vaccine (QIV) in multi-dose vial (MDV) authorized for sale in Canada by Health Canada with an approved age indication of six (6) months of age and above.

The vaccine supplied must be an inactivated, quadrivalent, split virion or subunit vaccine containing two strains of influenza virus Type A and two strain of influenza virus Type B. The strain composition must conform to the requirements of the World Health Organization (WHO) and the National Advisory Committee on Immunization (NACI) for the year in which the vaccine is to be supplied under the Contract.

- (c) **Item 2a: Quadrivalent Influenza Vaccine (QIV) – Pre-filled Syringe (PFS) with an approved age indication of five (5) years of age and above** *(to be included at contract award if awarded this item)*

A Quadrivalent Influenza Vaccine (QIV) in pre-filled syringe (PFS) authorized for sale in Canada by Health Canada with an approved age indication of five (5) years of age and above.

The vaccine supplied must be an inactivated, quadrivalent, split virion or subunit vaccine containing two strains of influenza virus Type A and two strain of influenza virus Type B. The strain composition must conform to the requirements of the World Health Organization (WHO) and the National Advisory Committee on Immunization (NACI) for the year in which the vaccine is to be supplied under the Contract.

- (d) **Item 2b: Quadrivalent Influenza Vaccine (QIV) – Multi-Dose Vial (MDV) with an approved age indication of five (5) years of age and above** *(to be included at contract award if awarded this item)*

A Quadrivalent Influenza Vaccine (QIV) in multi-dose vial (MDV) authorized for sale in Canada by Health Canada with an approved age indication of five (5) years of age and above.

The vaccine supplied must be an inactivated, quadrivalent, split virion or subunit vaccine containing two strains of influenza virus Type A and two strain of influenza virus Type B. The strain composition must conform to the requirements of the World Health Organization (WHO) and the National Advisory Committee on Immunization (NACI) for the year in which the vaccine is to be supplied under the Contract.

1.1 Product Monograph

The Contractor must provide the Contracting Authority with an updated Product Monograph in each year of the contract when it becomes available.

2. Quantity

The total number of AIV doses awarded to the Contractor is (*quantity to be inserted at contract award*) (the "Awarded Doses").

The Awarded Doses applicable to the option years will be confirmed, if Canada exercises the Option to Extend the Contract at section 2.4.2.

3. Vaccine Format (s)

AIV supplied in a multi-dose format must be delivered in 5 ml vials, containing 10 doses. Each multi-dose vial must be overfilled sufficiently to ensure availability of 10 doses.

AIV supplied in pre-filled syringes must be delivered without attached needles, with removable needles or with fixed needles that fully comply with all applicable provincial/territorial safety needle legislation.

Pre-filled syringes that are supplied with a fixed needle must be safety engineered devices that fully comply with all applicable safety needle legislation in effect in each province.

The minimum package size must be 10 doses, unless otherwise agreed to by Canada.

Over the period of the Contract, the Contractor may offer other packaging options consistent with emerging technology. Canada retains the right to refuse any such offerings.

4. Trace back Through Automated Identification of Vaccines

- (a) The Contractor must be prepared to implement automated identification of vaccines supplied under this Contract in accordance with the recommendations and implementation schedule of the Canadian Automated Identification of Vaccine Product Advisory Committee. This obligation is also subject to any other requirements that may be specified by Health Canada. If the Contractor is currently using automated identification of vaccine products or implements it during the life of the Contract, then the Contractor must provide details to the Identified Users on the contents of this system (e.g., what information is included in the bar code.) prior to delivery or implementation.
- (b) In the event that the Contractor plans to introduce a new Automated Identification of Vaccine Product system, the Contractor must first ensure that the Identified Users are advised and have implemented the appropriate technology to properly use the new Automated Identification of Vaccine Product system.

5. Contingency Plans

- (a) The Contractor must have pre-established and documented contingency plans in the event of production problems and/or unavailability of capacity at the proposed production site and/or any other problems, and must be fully capable of implementing its contingency plans. The contingency plans must include sufficient detail to demonstrate that the Work will be provided in conformity with all Contract requirements.
- (b) The Contractor must submit updated contingency plans to the Contracting Authority by April 1st of each calendar year.
- (c) The Contractor must immediately notify the Contracting Authority of any occurrence requiring the implementation of the contingency plans. Furthermore, the Contractor must immediately notify the Contracting Authority of any requirement that cannot be met as a result from the implementation of the contingency plans.

6. Packaging

Packaging for the Work must clearly indicate on packing slips and on the outside of outer packages and cartons, as applicable, the following:

- (a) On each package and carton:
 - (i) Contractor's Name;
 - (ii) Manufacturer's Brand Name;
- (b) On each package, carton, vial, ampoule, bottle, and pre-filled syringe (if applicable) the following:
 - (i) Drug Identification Number (DIN) and NATO Stock Number (NSN) (if applicable);
 - (ii) Global Trade Identification Number (GTIN) (if applicable);
 - (iii) Lot Number; and
 - (iv) Expiry Date.
- (c) Identify the carton(s) which contain the packing slip. If the Contractor will use the GTIN, then Bar codes on shipping package (i.e., shrink wrapped product), secondary and primary package, including variable data, must comply with GS1 standards and the Canadian Automated Identification of Vaccine Products process (if applicable);
- (d) The Contractor must identify partly packed carton(s) and box(es).
- (e) Packaging is to be in accordance with good commercial standards to ensure safe arrival at destination. In addition to the Contract Requirement, the Contractor must ensure that all goods are properly labeled and packaged in compliance with Health Canada Regulations.

7. Maintenance of the Cold Chain During Transportation and the Use of Cold Chain Monitors

- (a) The Contractor must maintain the vaccine:
 - (i) at or between 2 to 8 degrees Celsius, or
 - (ii) as stated on the product label, or
 - (iii) in accordance with temperature conditions supported by stability data

throughout transport from the Contractor to the Identified User ("Transport Conditions"). The Contractor must provide evidence to that effect from the data analysis of the temperature monitoring device or carrier logs, as applicable.

- (b) The Contractor must use a continuous electronic monitoring device and a receiving notice specifying acceptance criteria must be included in the shipment. At the request of a Identified User, a color cold chain chemical indicator (heat and freeze) may be used.
- (c) Upon request, the Contractor must provide a Certificate of Conformity to the Identified User within three (3) business days of the Contractor's receipt of the monitoring device or the device's data in the case of an electronic information transfer. Unless the monitoring device is disposable, the Identified User will return all electronic monitoring devices to the Contractor within 24 hours of receiving the Work.
 - (i) A "Certificate of Conformity" confirms that:
 - (A) the required Transport Conditions were maintained during transport;
 - (B) the integrity and quality of the vaccine has not been affected by temperature excursions during transport, and
 - (C) the expiry date of the Work as indicated on the vaccine packaging has not been impacted by temperature excursions during transport.
 - (ii) Failure of the Contractor to provide a Certificate of Conformity within this timeframe will entitle the Identified User to return the product to the Contractor for full replacement at no additional cost to the Identified User.
- (d) During the evaluation of the Transport Conditions by the Contractor, the Identified User will ensure that the Work is maintained according to the storage recommendations stated in the product monograph.
- (e) The Contractor must maintain a record of the shipment and transport data when using an electronic monitoring device for the purpose of addressing any future enquiries from the Identified User. The Contractor must keep these records, as a minimum, until 12 months after the expiry date of the Work, as indicated on the vaccine packaging label or 12 months following the end of the period of the Contract, whichever is the later.
- (f) Acceptance by an Identified User of a shipment not meeting the Transport Conditions is not a waiver of Transport Conditions for future shipments experiencing similar Transport Conditions either by the Identified User in question or by other Identified Users.

8. Market Prioritization

Unless otherwise authorized in writing by the Contracting Authority, the Contractor agrees that Identified Users' requirements will be given priority over distribution to the private market in Canada.

9. Timely Lot Release, Contractor's Responsibility

The Contractor must submit all vaccine lots to Health Canada so as to ensure that the release of lots by the Health Canada will occur early enough to allow the Contractor to meet the delivery requirements of the Contract.

10. Customer Service

10.1 Customer Support / Call Centre Enquiries:

The Contractor must maintain a bilingual (English and French) Customer Support Desk (reached via a toll free telephone number and e-mail account) throughout the term of the contract to provide immediate customer support to Identified Users and to Public Health Providers. As a minimum, the support desk must be reachable during business hours (that is, from 8:00 a.m. Newfoundland Standard Time to 5:00 p.m. Pacific Standard Time, with adjustments as necessary for daylight savings time) five days per week (Monday - Friday) for as long as Identified Users are immunizing, typically from September 1st to April 30th of each Contract year.

The Customer Support Desk must be able to, as a minimum:

- (a) Respond to general enquiries on product information concerning the use of the AIV supplied, their indications, contra-indications, dosage and administration, drug interactions, storage and handling requirements, etc.;
- (b) Provide medical and technical advice and guidance in response to detailed technical and scientific questions;
- (c) Provide up-to-date information on product holds or suspensions and on product recalls and withdrawals;
- (d) Provide technical advice concerning the continued ability to use vaccine which has experienced a cold chain excursion;
- (e) Provide order status for Identified Users including real-time tracking of shipments; and
- (f) Log reports received on adverse events following immunization.

Dependent upon the type of enquiry received, a response should be communicated to the Requestor on the same, or the next business day. Some enquiries requiring more detailed review and investigation by the Contractor may take longer, however the Contractor must inform the Requestor of the steps being taken to respond in full to an enquiry and of the expected time line for a complete response. When requested, responses should be received in writing.

10.2 Logistics/Communication Support

The Contractor must, as a minimum

- (a) Provide advance notice to the Contracting Authority of production and delivery schedules (i.e. expected availability; timely updates on status of announced schedules; immediate notification of interruptions or delays in production and delivery schedules; etc.);
- (b) Provide advance notice to Identified Users of expected delivery dates following an order, and of any issues which may negatively impact or delay a delivery as soon as the Contractor becomes aware of such an issue.
- (c) Initiate and coordinate product holds, recalls or withdrawals, if necessary; provide clear and concise instructions to the Identified Users on the activities necessary to implement the hold, recall or withdrawal; and provide regular updates on the status of same; and
- (d) Coordinate Trace Back requirements.

11. Provision of Unbranded Educational Materials - Upon request

In support of all Work supplied under the contract, and in accordance with industry practice, the Contractor must provide bilingual (English and French) unbranded educational materials intended for use by public health practitioners if requested in the Order.

11.1 Types and Content of Unbranded Educational Material

- (a) Unbranded educational materials to be provided by Contractor may include, but are not limited to:
- (i) provider instruction pamphlets;
 - (ii) brochures;
 - (iii) posters;
 - (iv) product monographs (standard and large print); and
 - (v) dosage cards.
- (b) Unbranded Educational materials must, as a minimum:
- (i) Include information relevant to the efficacy and onset of immunization coverage; the benefits of vaccination versus not being immunized; any potential adverse reactions and how to manage them; any potential interactions with other pharmaceutical products; guidelines for storage and use of the vaccine; the stability of product including continued stability if subject to temperature fluctuations (outside of recommended storage conditions); and the inter-changeability of the product with similar products.
 - (ii) Contain or reference available scientific data related to efficacy, effectiveness, immunogenicity and safety in the anticipated target population including sub-segments (e.g. by age and medical conditions); and
 - (iii) Provide instructions on mixing and re-constitution (if necessary) and on use and administration (including best practices, recommended syringe size and needle gauge / length for different populations, if any, instructions for ensuring all doses can be routinely withdrawn from a multi-dose vial, etc.).

11.2 Timing of Availability of Unbranded Educational Materials

Unbranded educational materials should be provided prior to September 15 in each contract year and in a timely manner so as to allow for advance preparation of recommendations, guidelines and surveillance programs. At the latest, educational materials must be provided with the deliveries and then on an on-going basis thereafter, highlighting any information that has changed.

12. Technical Information and Data

The Contractor is requested to provide to the Technical Authority, where available, Technical Information and Data concerning the vaccines being delivered under the Contract, including such information as: Clinical trial data - Canadian and International; Product safety data - Canadian and International; and Product quality and stability data.

Unless specifically prohibited by the Contractor in writing, the information and data provided will be shared, on a confidential and need to know basis, within the Public Health Agency of Canada and Health Canada as well as with Provincial and Territorial public health officials and with experts in the field who provide public health advice to these officials, to inform recommendations regarding the use of AIV. Any

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information or data shared in this manner will contain the notices provided by the Contractor concerning the confidential or proprietary nature of the material submitted and the restrictions with respect to publication or further dissemination.

If Canada wishes to present some aspect of the information or data in a scientific forum it will obtain the prior permission of the Contractor in writing.

ANNEX B – BASIS OF PAYMENT

1. Pricing Information

All prices are firm unit prices, in Canadian dollars, transportation charges included, custom duties included; and where applicable, zero rated for Goods and Services Tax (GST) or Harmonized Sales Tax (HST). Provincial sales taxes are not applicable. Each firm unit price is applicable for all destinations in Canada.

2. Annual Influenza Vaccines:

Item 1a: Quadrivalent Annual Influenza Vaccine (QIV) – Pre-filled Syringe (PFS) 6mo+ (to be included at contract award if applicable)			
Item 1b: Quadrivalent Annual Influenza Vaccine (QIV) – Multi-dose Vial (MDV) 6mo+ (to be included at contract award if applicable)			
Brand Name: _____			
Volume (doses)	Contract Term (Year 1) 2022-2023	Option Year 1 (Year 2) 2023-2024	Option Year 2 (Year 3) 2024-2025
1a. PFS (DIN_____)	\$_____/dose	\$_____/dose	\$_____/dose
1b. MDV (DIN_____)	\$_____/dose	\$_____/dose	\$_____/dose

Item 2a: Quadrivalent Annual Influenza Vaccine (QIV) – Pre-filled Syringe (PFS) 5yr+ (to be included at contract award if applicable)			
Item 2b: Quadrivalent Annual Influenza Vaccine (QIV) – Multi-dose Vial (MDV) 5yr+ (to be included at contract award if applicable)			
Brand Name: _____			
Volume (doses)	Contract Term (Year 1) 2022-2023	Option Year 1 (Year 2) 2023-2024	Option Year 2 (Year 3) 2024-2025
2a. PFS (DIN_____)	\$_____/dose	\$_____/dose	\$_____/dose
2b. MDV (DIN_____)	\$_____/dose	\$_____/dose	\$_____/dose

ANNEX C – IDENTIFIED USERS

1. Federal Departments and Agencies:

- (a) Correctional Service Canada
- (b) Department of National Defence
- (c) Health Canada
- (d) Public Health Agency of Canada
- (e) Royal Canadian Mounted Police

2. Provinces and Territories:

- (a) Alberta / Alberta Health and Wellness
- (b) British Columbia / British Columbia Centre for Disease Control
- (c) Quebec / Logistics Support Unit Inc. / SigmaSanté
- (d) Manitoba / Manitoba Health
- (e) New Brunswick / New Brunswick Department of Health
- (f) Newfoundland/Labrador / Department of Health & Community Services
- (g) Northwest Territories / Stanton Territorial Hospital / Inuvik Territorial Hospital / Yellowknife Public Health Unit
- (h) Nova Scotia / Nova Scotia Department of Health and Wellness
- (i) Nunavut/ Qikiqtani General Hospital / Kitikmeot Regional Hospital / Kivalliq Regional Health Centre
- (j) Ontario / Ministry of Health and Long-term Care
- (k) Prince Edward Island / Provincial Pharmacy
- (l) Saskatchewan / Saskatchewan Disease Control Laboratory
- (m) Yukon / Whitehorse General Hospital

ANNEX D – FEDERAL CONTRACTORS PROGRAM FOR EMPLOYMENT EQUITY

I, the Bidder, by submitting the present information to the Contracting Authority, certify that the information provided is true as of the date indicated below. The certifications provided to Canada are subject to verification at all times. I understand that Canada will declare a bid non-responsive, or will declare a contractor in default, if a certification is found to be untrue, whether during the bid evaluation period or during the contract period. Canada will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply with any request or requirement imposed by Canada may render the bid non-responsive or constitute a default under the Contract.

For further information on the Federal Contractors Program for Employment Equity visit Employment and Social Development Canada (ESDC) - Labour website.

Date : _____ (YYYY/MM/DD) (If left blank, the date will be deemed to be the bid solicitation closing date.)

Complete both A and B.

A. Check only one of the following:

- A1. The Bidder certifies having no work force in Canada.
- A2. The Bidder certifies being a public sector employer.
- A3. The Bidder certifies being a federally regulated employer being subject to the *Employment Equity Act*.
- A4. The Bidder certifies having a combined work force in Canada of less than 100 permanent full-time and/or permanent part-time employees.

A5. The Bidder has a combined workforce in Canada of 100 or more employees; and

- A5.1. The Bidder certifies already having a valid and current Agreement to Implement Employment Equity (AIEE) in place with ESDC-Labour.

OR

- A5.2. The Bidder certifies having submitted the Agreement to Implement Employment Equity (LAB1168) to ESDC-Labour. As this is a condition to contract award, proceed to completing the form Agreement to Implement Employment Equity (LAB1168), duly signing it, and transmit it to ESDC-Labour.

B. Check only one of the following:

- B1. The Bidder is not a Joint Venture.

OR

- B2. The Bidder is a Joint Venture and each member of the Joint Venture must provide the Contracting Authority with a completed annex Federal Contractors Program for Employment Equity - Certification. (Refer to the Joint Venture section of the Standard Instructions)

ANNEX E – ELECTRONIC PAYMENTS INSTRUMENTS

Canada requests that Bidders complete option 1 or 2 below:

1. Electronic Payment Instruments will be accepted for payment of invoices.

The following Electronic Payment Instrument(s) are accepted:

- VISA Acquisition Card;
- MasterCard Acquisition Card;
- Direct Deposit (Domestic and International);
- Electronic Data Interchange (EDI);
- Wire Transfer (International Only);
- Large Value Transfer System (LVTS) (Over \$25M)

2. Electronic Payment Instruments will not be accepted for payment of invoices.

The Bidder is not obligated to accept payment by Electronic Payment Instruments.

Acceptance of Electronic Payment Instruments will not be considered as an evaluation criterion.

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FORM 1 - BID SUBMISSION		
Bidder's full legal name		
Bidder's Address		
Bidder's Procurement Business Number (PBN)		
Province in Canada the Bidder wishes to be the legal jurisdiction applicable to any resulting Contract (if other than as specified in solicitation)		
Contractor Representative – General enquiries	Name	
	Title	
	Telephone #	
	E-mail	
Contractor Representative – Delivery follow-up	Name	
	Title	
	Telephone #	
	E-mail	
Returns	Address to return product	
	Contact Name	
	Telephone #	
	E-mail	
Point of Manufacturing/Shipping	Manufacturing	
	Shipping	

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FORM 1 - BID SUBMISSION	
Contractor's Bid Dated	
Bidders who are incorporated, including those bidding as a joint venture, must provide a complete list of names of all individuals who are currently Board of Directors of the Bidder. Bidders bidding as sole proprietorship, including those bidding as a joint venture, must provide the name of the owner.	
On behalf of the Bidder, by signing below, I further confirm that I have read the entire bid solicitation including the documents incorporated by reference into the bid solicitation and: <ol style="list-style-type: none">1. The Bidder considers itself and its Products able to meet all the mandatory requirements described in the bid solicitation;2. This Bid is valid for the period requested in the bid solicitation;3. All the information provided in the bid is complete, true and accurate; and4. If the Bidder is issued a Contract, it will accept all the terms and conditions set out in the resulting contract included in the bid solicitation.	
Signature of Authorized Representative of Bidder	