

**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 0A1 / Noyau 0A1
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 Meningococcal Quadrivalent Vaccine	
Solicitation No. - N° de l'invitation E60PH-14MENQ/A	Date 2013-12-16
Client Reference No. - N° de référence du client E60PH-14MENQ	
GETS Reference No. - N° de référence de SEAG PW-\$\$PH-884-64180	
File No. - N° de dossier ph884.E60PH-14MENQ	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2014-01-06	
Time Zone Fuseau horaire Eastern Standard Time EST	
F.O.B. - F.A.B. Specified Herein - Précisé dans les présentes Plant-Usine: <input type="checkbox"/> Destination: <input type="checkbox"/> Other-Autre: <input checked="" type="checkbox"/>	
Address Enquiries to: - Adresser toutes questions à: Joy(ph884), Sharon	Buyer Id - Id de l'acheteur ph884
Telephone No. - N° de téléphone (819) 956-6510 ()	FAX No. - N° de FAX () -
Destination - of Goods, Services, and Construction: Destination - des biens, services et construction:	

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
11 Laurier St. / 11, rue Laurier
6B3, Place du Portage III
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

Solicitation No. - N° de l'invitation

E60PH-14MENQ/A

Amd. No. - N° de la modif.

Buyer ID - Id de l'acheteur

ph884

Client Ref. No. - N° de réf. du client

File No. - N° du dossier

CCC No./N° CCC - FMS No/ N° VME

E60PH-14MENQ

ph884E60PH-14MENQ

REQUEST FOR PROPOSAL
FOR
MENINGOCOCCAL QUADRIVALENT VACCINE SUPPLY

**ANY ENQUIRIES REGARDING THE CONTENTS OF THIS DOCUMENT SHOULD BE DIRECTED TO
THE CONTRACTING AUTHORITY:**

**Public Works and Government Services Canada (PWGSC)
Commercial and Consumer Products Directorate
Place du Portage, Phase III, 6B3
11 Laurier Street
Gatineau, QC K1A 0S5**

**Attention: Sharon Joy
Telephone: (819) 956-6510
E-Mail: sharon.joy@tpsgc-pwgsc.gc.ca**

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PART 1 - GENERAL INFORMATION

1. Security Requirement

There is no security requirement associated with this bid solicitation.

2. Requirement

To supply Meningococcal Quadrivalent Vaccine to Identified Users (Canada and Provinces and Territories as listed in Annex C), as described in Annex A.

3. Debriefings

Bidders may request a debriefing on the results of the bid solicitation. Bidders should make the request to the Contracting Authority within 15 working days of receipt of notification that their bid was unsuccessful. The debriefing may be provided in writing, by telephone or in person.

PART 2 - BIDDER INSTRUCTIONS

1. Standard Instructions, Clauses and Conditions

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 issued by Public Works and Government Services Canada.

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.

The 2003 (2013-06-01) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

Subsection 5.4 of 2003, Standard Instructions - Goods or Services - Competitive Requirements, is amended as follows:

Delete: sixty (60) days

Insert: Ninety (90) days

2. 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.

3. Enquiries - Bid Solicitation

All enquiries must be submitted in writing to the Contracting Authority no later than five (5) 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 questions or may request that the Bidder do so, so that the proprietary nature of the question is eliminated, and the enquiry can be answered with copies

to all bidders. Enquiries not submitted in a form that can be distributed to all bidders may not be answered by Canada.

4. **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.

PART 3 - BID PREPARATION INSTRUCTIONS

1. **Bid Preparation Instructions**

Canada requests that bidders provide their bid in separately bound sections as follows:

Section I: Technical Bid (1 hard copy)

Section II: Financial Bid (1 hard copy)

Section III: Certifications (1 hard copy)

Prices must appear in the financial bid only. No prices must be indicated in any other section of the bid.

Canada requests that bidders follow the format instructions described below in the preparation of their bid:

- (a) use 8.5 x 11 inch (216 mm x 279 mm) paper;
- (b) use a numbering system that corresponds to the bid solicitation.

In April 2006, Canada issued a policy directing federal departments and agencies to take the necessary steps to incorporate environmental considerations into the procurement process Policy on Green Procurement

(<http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/politique-policy-eng.html>). To assist Canada in reaching its objectives, bidders should:

- 1) use 8.5 x 11 inch (216 mm x 279 mm) paper containing fibre certified as originating from a sustainably-managed forest and containing minimum 30% recycled content; and
- 2) use an environmentally-preferable format including black and white printing instead of colour printing, printing double sided/duplex, using staples or clips instead of cerlox, duotangs or binders.

Section I: Technical Bid

In their technical bid, bidders should explain and demonstrate how they propose to meet the requirements and how they will carry out the Work.

The Bidder is requested to provide full details on its policy for exchanges / credits for returned merchandise, including the return of expired or damaged products, and the return of pharmaceuticals for destruction.

Section II: Financial Bid

Bidders must submit their financial bid in accordance with Annex B: "Basis of Payment.

The quantities provided in Annex "B" and the Delivery Schedule are only an approximation of requirements given in good faith. The quantities specified herein are subject to change prior to Contract award. Each Identified Users reserves the right to alter quantities or to withdraw from participation for any given item. The final total contracted quantity for each item will be confirmed with the proposed Contractor(s) prior to award. A quantity change, which represents a significant change in the Statement of Requirement for an item, may result in a decision to re-tender that item.

1.1 Exchange Rate Fluctuation

C3011T (2010-01-11) - Exchange Rate Fluctuation

Section III: Certifications

Bidders must submit the certifications required under Part 5.

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

1. Evaluation Procedures

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

2. Basis of Selection

A bid must comply with the requirements of the bid solicitation and meet all mandatory technical evaluation criteria to be declared responsive.

Ranking will be established using the firm quantities for all items, **plus 100% of the option quantities.**

- 1. If only one responsive bid is received and the price is fair and reasonable then that Bidder will be recommended for award of a contract for 100% of the final total estimated quantity.
- 2. If more then one responsive bid is received and for the purposes of strengthening the security of supply of these vaccines in Canada:

The Bidder submitting the lowest priced responsive proposal for the contract period (including option years) will be recommended for award of a contract as follows:

- 60% if the price difference is 10% or less ;
- 65% if the price difference is more than 10% and less than 15%;
- 70% if the price difference is 15% or more;

And the second lowest Bidder will be recommended for award for the balance of the quantities according to the price difference proposed on the Bid if the price is considered fair and reasonable.

At the sole discretion of Canada, acting as agent on behalf of the provinces and territories, consideration will be given to award 75% or 100% of the final total estimated quantity to the low bid in the event that the price difference exceeds 25%.

2.1 Split Award - Allocation of Identified Users Between Contracts

For the purpose of this RFP a "Split Award" is defined as the issuance of two (2) contracts dividing the final total estimated quantity (per annum) between two responsive Bidders, in a manner and a proportion as described herein.

Should this RFP result in a Split Award the intention is to allocate participating Identified Users between contracts in accordance with the following:

1. In any given year each individual Identified User will receive Vaccine from only one supplier unless that supplier is unable to fill an order. In such an event the Identified User will be consulted with regard to the acceptability of receiving Vaccine from the alternate supplier.
2. Unless absolutely necessary to do otherwise, each Identified User will be allocated to the same supplier for the full year period of the Contracts.
3. The Low Bidder will receive as close to the appropriate percentage of the final total estimated quantity as allocated to the Low Bidder in accordance with the basis of selection clause, as is possible. The second successful Bidder will receive the remaining quantity.
4. The allocation of the requirement is based on the final estimated quantity. As Identified Users are only obligated to purchase 90% of their estimate, and as an Option exists to increase quantities by up to 20%, there is no guarantee that the final allocation of actual purchases will conform to the desired split.
5. Should new Identified Users be added to the Contracts following the date of award they will be allocated in a manner so as to maintain, as much as is possible, the desired split between the two suppliers.
6. Should it prove to not be possible to act in a manner such as to maintain the desired split (approximately) the allocation of the new Identified Users, or the reallocation of existing Identified Users will be done so as to favor the Low Bidder.

PART 5 - CERTIFICATIONS

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

The certifications provided by bidders to Canada are subject to verification by Canada at all times. 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 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 certification. Failure to comply with this request certifications will also render the bid non-responsive or will constitute a default under the Contract.

1. Mandatory Certifications Required Precedent to Contract Award

1.1 Code of Conduct and Certifications - Related documentation

By submitting a bid, the Bidder certifies that the Bidder and its affiliates are in compliance with the provisions as stated in Section 01 Code of Conduct and Certifications - Bid of Standard Instructions 2003. The related documentation therein required will assist Canada in confirming that the certifications are true.

1.2 Federal Contractors Program for Employment Equity - Bid Certification

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 from Human Resources and Skills Development Canada (HRSDC) - Labour's website.

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.

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](#)" list during the period of the Contract.

The Bidder must provide the Contracting Authority with a completed annex 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.

PART 6 - RESULTING CONTRACT CLAUSES

1. Security Requirement

There is no security requirement applicable to this Contract.

2. Requirement

To supply Meningococcal Quadrivalent Vaccine to Identified Users (Canada and Provinces and Territories) as listed in Annex C, as described in Annex A.

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](#) issued by Public Works and Government Services Canada.

3.1 General Conditions

2010A (2013-04-25) General Conditions - Goods - Medium Complexity, apply to and form part of the Contract.

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:

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 supplies conform to their specifications until the expiration date required by the Requirement. The Contractor must, upon the request of Canada, replace as soon as possible any supplies that fail to so conform or that deteriorate prior to the said expiration date.

However, if full replacement is not available in a timeframe acceptable to Canada, then Canada may choose from one of the following options for the quantity and Contract value of the Work affected:

- Full reimbursement;
- Equivalent full credit against future vaccine purchases; or
- Partial replacement and partial reimbursement or partial credit.

3.3 Canada and Public Works and Government Services as Agent

The Contractor acknowledges that Canada is responsible for providing funding for this Contract only to the extent that the Contract involves any vaccine orders placed on behalf of a Federal Government Department or Agency;

Except as noted above, funding for an order placed on behalf of a Provincial or Territorial Government under the Contract is the responsibility of the Provincial or Territorial Government. To the extent that the Contract involves orders placed by Canada on behalf of a Provincial or Territorial Government, Canada is acting as a purchasing agent for that Government. The Contractor acknowledges and agrees that, unless otherwise specified, Canada is not liable under the Contract to the extent that it involves such orders, 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.

4. Term of Contract

4.1 Period of Contract

The period of the Contract is from April 1st 2014 to March 31, 2015, inclusive.

4.2 Option to Extend the Contract

The Contractor grants to Canada the irrevocable option to extend the term of the Contract by up to two (2) additional one (1) 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.

Canada may exercise this option at any time by sending a written notice to the Contractor at least 90 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.

4.3 Option to Add Identified User

Subject to the mutual agreement of the Contractor and Canada, users may be added to the list of Identified Users and will be entitled to the level of service and quality of the work at a price not to exceed the Contract price and subject to the same conditions of the Contract.

4.4 Options -- Right to Exercise

The options outlined above will remain valid and open for exercise by Canada, in whole or in part, at the discretion of Canada, during the period of the Contract. Exercise of these options will be by written notice, or written notices, from Canada prior to the expiry date of the Contract.

Nothing in the Contract obligates Canada to exercise these options, in whole or in part, and the exercise of these options will be at the sole discretion of Canada.

5. Order and Delivery

5.1 Minimum/ Maximum Quantities

Canada reserves the right to purchase a minimum of 90% to a maximum of 120% of the final total estimated quantity of each item at the Contract prices and subject to the Contract conditions. If additional Identified Users are added to the Contract, their quantities will be in addition to the 20% granted above.

5.2 Authorization for Delivery – Orders

The Contracting Authority may request delivery of the work by electronic correspondence or by any order form approved by the parties. Alternatively, delivery may be requested by telephone, if confirmed in writing, or by any other method if deemed acceptable by Canada and the Contractor.

5.3 Orders / Delivery

Orders against the Contract will be made as-and-when requested by the Contracting Authority during the period of the Contract. Unless otherwise indicated, delivery must be made within seven (7) calendar days from receipt of an order from the Contracting Authority.

5.4 Air Transport-

The Contractor must make all deliveries to the following Identified Users by air transport, unless the Contracting Authority has specifically requested, or has agreed in writing to a Contractor's request, to have a delivery made by ground transport:

- Newfoundland and Labrador;
- Nunavut;
- Yukon Territories; and
- Northwest Territories.

6. Timely Lot Release, Contractor's Responsibility

It is the Contractor's responsibility to submit all vaccine lots to the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada so as to ensure that the release of lots by the BGTD will occur early enough to allow the Contractor to meet the delivery requirements of the Contract.

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

The Contractor must maintain the vaccine:

- a. at or between 2 to 8 degrees Celsius, or
- b. as stated on the product label, and/or
- c. 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/carrier logs, as applicable.

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 & freeze) may be used.

In the case of the use of a continuous electronic temperature-monitoring device, the Identified User is responsible for returning all electronic monitoring devices to the Contractor within 24 hours of receiving the vaccine at its facility. The Identified User will accept the delivery on a conditional basis until Satisfactory Documentation is received. Acceptance of the delivery is conditional upon receipt of Satisfactory Documentation. The Contractor must provide Satisfactory Documentation to the Identified User within three (3) business days of the Contractor's receipt at its facility of the required devices and documentation from the Identified User.

"Satisfactory Documentation" means a written Certificate of Conformity which 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 vaccine as indicated on the vaccine packaging has not been impacted by temperature excursions during transport.

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 vaccine, as indicated on the vaccine packaging label or 12 months following the end of the period of the Contract, whichever is the later.

Failure of the Contractor to provide Satisfactory Documentation 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.

Acceptance by a 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.

During the evaluation of the Transport Conditions by the Contractor, the Identified User will ensure that the vaccine is maintained according to the storage recommendations stated in the product monograph.

8. Packaging

All shipments of goods under the Contract must clearly indicate on packing slips and on the outside of outer packages/cartons, the following:

- Contractor's Name;
- Manufacturer's Brand Name;

Additionally, each package, carton, vial, ampoule, bottle, and pre-filled syringe (if applicable) must also clearly indicate the following:

- Drug Identification Number (DIN) and NATO Stock Number (NSN) (if applicable);
- Global Trade Identification Number (GTIN);
- Lot Number; and
- Expiry Date.

The Contractor must 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, should comply with GS1 standards and the Canadian Automated Identification of Vaccine Products process (if applicable);

The Contractor must identify partly packed carton(s)/box(es).

Packaging is to be in accordance with good commercial standards to ensure safe arrival at destination. The Contractor must ensure that all goods are properly labeled and packaged in compliance with the BGTD Regulations.

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

9. **Shipping Instructions - Delivery at Destination**

Goods must be consigned to the destinations specified in the Contract and delivered DDP Delivered Duty Paid (Identified User), Incoterms 2000 for shipments from a commercial contractor.

The Contractor must deliver the Vaccine to, as a minimum, the destinations specified in Annex C, in accordance with the directions of Canada (in consultation with the Identified Users).

10. **Dangerous Goods/Hazardous Products**

- a) The Contractor must ensure proper labeling and packaging in the supply and shipping of dangerous goods/hazardous products to the Identified User.
- b) The Contractor will be held liable for any damages caused by improper packaging, labeling or carriage of dangerous goods/hazardous products.
- c) The Contractor must clearly mark all merchandise labels with the percentage of volume that is a hazardous item. Failure to do so will result in the Contractor being held responsible for damages caused in the movement of goods/products by government vehicles or government personnel.
- d) The Contractor must adhere to all applicable laws regarding dangerous goods/hazardous products.

11. **Authorities**

11.1 **Contracting Authority**

The Contracting Authority for this Contract is:

Sharon Joy
Public Works and Government Services Canada
Drugs, Vaccines & Biologicals
Place du Portage, Phase III, 6B3
11 Laurier Street

Gatineau, QC K1A 0S5

Tel: (819) 956-6510 Email: sharon.joy@pwgsc-tpsgc.gc.ca

The Contracting Authority is responsible for the management of the Contract and the Contracting Authority must authorize any changes to the Contract in writing. 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.

11.2 Contractor Representative

Name and telephone number of the person responsible for:

General enquiries:

Name: _____

Telephone No.: _____

Facsimile No.: _____

E-mail address: _____

Delivery follow-up:

Name: _____

Telephone No.: _____

Facsimile No.: _____

E-mail address: _____

12. Payment

12.1 Basis of Payment - Firm Unit Price(s)

In consideration of the Contractor satisfactorily completing all of the obligations under the Contract, the Contractor will be paid a firm unit price as specified in Annex B.

12.2 Payment Period – Amendment to General Conditions 2010-A

The general conditions 2010A (2013-04-25) Goods (Medium Complexity), are incorporated by reference into and form part of the contract. At 2010A 15 Payment Period

Delete: thirty (30) days

Insert: sixty (60) days

12.3 SACC Manual Clauses

SACC Manual Clause G1005C (2008-05-12), Insurance

12.4 Multiple Payment (if awarded)

Canada will pay the Contractor upon completion and delivery of units in accordance with the payment provisions of the Contract if:

- (a) an accurate and complete invoice and any other documents required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;
- (b) all such documents have been verified by Canada;
- (c) the Work delivered has been accepted by Canada.

13. Invoicing Instructions

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.

Invoices must be distributed as follows:

The original and one copy of all invoices are to be forwarded to PWGSC to the following address:

Public Works and Government Services Canada

Manager, Drugs, Vaccines & Biologics
Place du Portage, Phase III, 6B3
11 Laurier Street
Gatineau, QC K1A 0S5

14. Certifications

14.1 Compliance

Compliance with the certifications and related documentation provided by the Contractor in its bid is a condition of the Contract and subject to verification by Canada during the term of the Contract. If the Contractor does not comply with any certification, provide the related documentation or if it is determined that any certification made by the Contractor in its bid is untrue, whether made knowingly or unknowingly, Canada has the right, pursuant to the default provision of the Contract, to terminate the Contract for default.

14.2 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 HRSDC-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 HRSDC will constitute the Contractor in default as per the terms of the Contract.

15. Applicable Laws

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

16. 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 (2013-04-25) Goods (Medium Complexity);
- (c) Annex A: "Requirement";

- (d) Annex B: "Basis of Payment";
 (e) Annex C: "Identified Users and Delivery Points";
 (f) Annex D: "Return Policy";
 (g) Annex E, Federal Contractors Program for Employment Equity - Certification; and
 (h) the Contractor's bid dated _____ .

17. Product Specific Clauses

17.1 Point of Manufacturing/Shipping

State point of manufacture/shipping of goods or where service is to be performed:

Manufacturing: _____

Shipping: _____

17.2 Adverse Event Following Immunization (AEFI) Reporting Requirement

The Contractor must comply with all Identified Users' AEFI reporting requirements.

17.3 Product Recall and/or Withdrawal

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 for collecting and destroying the recalled or withdrawn Work.

The Contractor must, upon the request of Canada, replace as soon as possible any recalled and/or withdrawn Work.

However, if full replacement is not available in a timeframe acceptable to Canada, then Canada may choose from one of the following options for the quantity and Contract value of the Work affected:

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

17.4 Returns Policy on Vaccines Supplied

17.4.1 Returns - Less than 12 month Shelf Life Upon Delivery

For Work that has expired which had a shelf life of less than 12 months upon delivery to and acceptance by the Identified User, the Contractor must provide full credit or replacement or refund for all returned, unopened Work to the Identified User.

17.4.2 Minimum 12 month Shelf Life Upon Delivery

For Work that had a minimum shelf life of 12 months upon delivery, the Contractor must provide full credit in the amount of the invoiced price for expired, unopened Work returned to the Contractor by the Identified Users within one (1) year after its expiry date, for five percent (5%) of quantity purchased under the Contract.

17.5 Inability to Supply

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.

In the event of the unavailability of a required format, the Contractor will supply another format acceptable to the Identified User at the equivalent firm unit price, or less.

Should the Identified User be required to purchase the unavailable Work or format 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.

17.6 Stockpile

At all time during the period of the Contract, the Contractor must maintain a minimum stockpile of three (3) months finished stock (stored in Canada and released by BGTD) for each item included in the Work. It is the Contractor's sole responsibility to rotate the stockpile as necessary to ensure that a minimum of twelve (12) month shelf-life is maintained. The stockpile is subject to inspection by Canada at anytime during the period of the Contract.

Ninety (90) days prior to the end of the contract period, if an option to extend the period of the contract has not been exercised, the Contractor will be permitted to draw down against the full amount of the stockpile.

Throughout the period of the Contract, the Contractor must provide a monthly report summarizing the status and maintenance of the stockpile. As a minimum, the report will include: the amount of doses contained in stockpile and the shelf life of the stockpile. The monthly report must be submitted in an electronic format to the Contract Authority by the first Monday of every month.

17.7 Notice of Anticipated Shortage

The Contractor must notify the Contracting Authority when it becomes aware of a potential problem, delay, etc. 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, the anticipated impact on the delivery 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.

For the purpose of this clause "shortage" is defined as the inability to meet a scheduled delivery requirement in full or the failure to maintain the minimum stockpile

ANNEX A - REQUIREMENT

1.1 Scope -

The Contractor must supply Meningococcal Quadrivalent vaccine, duly authorized for sale in Canada.

1.2 Quantity - See Basis of Payment Annex B

1.3 Vaccine Format (s)

Format(s): vials and/or prefilled syringes

1.4 Product Dating

All vaccine supplied must have a shelf life of **no less than 12 months** remaining on the date of delivery.

1.5 Trace back Through Automated Identification of Vaccines

The Contractor must meet the current packaging requirements as described in the Contract. In addition, the Contractor must be prepared to implement automated identification of the vaccine products supplied under this Contract in accordance with the recommendations and implementation schedule of the Canadian Automated Identification of Vaccine Product (AIVP) advisory committee. This requirement will also be subject to any other requirements that may be specified by the BGTD. 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 its implementation.

In the event that the Contractor plans to introduce a new automated identification system, the Contractor must first ensure that the Identified Users are advised and have implemented the appropriate technology to properly use the new system.

1.6 Vaccine Identification Database System (VIDS)

The Contractor will provide the following information within 10 business days of a lot release by Biologics and Genetic Therapies Directorate (BGTD) of Health Canada to the Public Health Agency of Canada for the purpose of updating VIDS.

Data to be sent in either word or excel format to AIVP-IAVP@phac-aspc.gc.ca as follows:

- 1) Global Trade Identification Number (GTIN)
- 2) Drug Identification Number (DIN)
- 3) Product
- 4) Lot Number
- 5) Expiry date

1.7 Provision of Educational Materials - Upon request:

In support of all items supplied under the contract, and in accordance with industry practice, the Contractor must provide bilingual (English and French) educational materials intended for use by Public Health Practitioners upon request by the identified users.

Types and Content of Educational Material: Educational materials to be provided may include, but are not limited to: provider instruction pamphlets; brochures; posters; product monographs (standard and large print); and dosage cards. Educational material is of particular importance if a vaccine is new to a Identified User; is targeted for specific populations (as opposed to use in the general population); or otherwise differs in use, administration, or format from the traditional multi-dose vial TIV currently used by the Identified Users.

Information to be made available to practitioners 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.).

Timing of Availability of Material:

Information should be provided in advance of vaccine shipments and in a timely manner so as to allow for advance preparation of recommendations, guidelines and surveillance programs; and then on an on-going basis thereafter, highlighting any information that has changed.

Annex B

BASIS OF PAYMENT

All prices are firm unit prices. Prices are inclusive of all costs, DDP Delivered Duty Paid (Identified User), Incoterms 2000, in Canadian funds, transportation charges included, customs duties included, if applicable, and Applicable Taxes are zero-rated. Each firm unit price is applicable for all destinations in Canada.

Item 001 - Meningococcal Quadrivalent Vaccine - FIRM YEAR April 1, 2014- March 31, 2015

Trade Name: _____

Drug Identification Number (DIN): _____

Format(s): _____

Year (FIRM)	Cohort Age	Estimated Quantity	Estimated Quantity as doses	Firm Unit price per dose	Extended Total Estimated Price
2014-15 Firm Year	Infants 2 mos to 11mos	190	190 infants x _____ doses/infant = _____ total doses	\$ _____/dose	\$ _____
2014-15 Firm Year	infants 12mos to 23 mos	280	280 infants x _____ doses/infant = _____ total doses	\$ _____/dose	\$ _____
2014-15 Firm Year	Children & Adults 2 years to 55 years	184,560	184,560 children/adults x _____ doses/children = _____ total doses	\$ _____/dose	\$ _____

Item 002 - Meningococcal Quadrivalent Vaccine - Option Year 1 April 1, 2015- March 31, 2016

Year (Option)	Cohort Age	Estimated Quantity	Estimated Quantity as doses	Firm Unit price per dose	Extended Total Estimated Price
2015-16 Option Yr 1	Infants 2 mos to 11mos	190	190 infants x _____ doses/infant = _____ total doses	\$ _____/dose	\$ _____

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2015-16 Option Yr 1	infants 12mos to 23 mos	280	280 infants x _____ doses/infant = _____ total doses	\$ _____/dose	\$
2015-16 Option Yr 1	Children & Adults 2 years to 55 years	203,580	203,580 children/adults x _____ doses/children = _____ total doses	\$ _____/dose	\$

Item 003 - Meningococcal Quadrivalent Vaccine - Option Year 2 April 1, 2016- March 31, 2017

Year (Option)	Cohort Age	Estimated Quantity	Estimated Quantity as doses	Firm Unit price per dose	Extended Total Estimated Price
2016-17 Option Yr 2	Infants 2 mos to 11mos	190	190 infants x _____ doses/infant = _____ total doses	\$ _____/dose	\$
2016-17 Option Yr 2	infants 12mos to 23 mos	280	280 infants x _____ doses/infant = _____ total doses	\$ _____/dose	\$
2016-17 Option Yr 2	Children & Adults 2 years to 55 years	208,740	208,740 children/adults x _____ doses/children = _____ total doses	\$ _____/dose	\$

Attach the estimated delivery schedule - (to be provided upon contract award)

Annex C – Identified Users

Jurisdiction	Shipping	Jurisdiction	Shipping
CSC - Quebec Region	Cowansville, QC	New Brunswick	Saint John, NB
CSC - Pacific Region	Abbotsford, BC		
CSC - Prairie Region Saskatoon, SK	Various authorized users Refer to orders		
Department of National Defence	Various authorized users. Refer to orders.	Newfoundland/Labrador	St. John's, NL
Health Canada Alberta	Edmonton, AB	Northwest Territories - Stanton Territorial Hospital Northwest Territories - Inuvik Regional Hospital Northwest Territories - Yellowknife Public Health Unit	Yellowknife, NT Inuvik, NT Yellowknife, NT
Health Canada Manitoba	See addresses listed below at annex C-1	Nova Scotia	Dartmouth NS
Health Canada Winnipeg (First Nations & Inuit Health Branch)	Various authorized users Refer to orders	Nunavut - Baffin Region Nunavut - Kitikmeot Region Nunavut - Kivalliq Region	Iqaluit, NU Cambridge Bay, NU Rankin Inlet, NU
Health Canada Workplace Health & Safety (OHS)	Ottawa, On K1A 0K9	Ontario	Concord, Ontario
Alberta	Fort Saskatchewan, Alberta	Prince Edward Island	Charlottetown, PEI
British Columbia	Vancouver, BC	Saskatchewan	Regina, SK
Quebec	Boucherville, Québec	Yukon	Whitehorse, YT
Manitoba	Winnipeg, MB		

Annex C-1(Health Canada Manitoba)

DELIVERY ADDRESS	DELIVERY ADDRESS	DELIVERY ADDRESS
Berens River, Manitoba	Nelson House, Manitoba	South Indian Lake, Manitoba
Bloodvein, Manitoba	Hodgson, Manitoba	Split Lake, Manitoba
Brochet, Manitoba	Norway House, Manitoba	St. Theresa Point, Manitoba
Cross Lake, Manitoba	Oxford House, Manitoba	Tadoule Lake, Manitoba
Island Lake, Manitoba	Pauingassi, Manitoba	Wasagamack, Manitoba
God' s Lake Narrow s, Manitoba	Negginan, Manitoba	York Landing, Manitoba
God' s River, Manitoba	Pukatawagan, Manitoba	
Lac Brochet, Manitoba	Red Sucker Lake, Manitoba	
Little Grand Rapids, Manitoba	Shamattawa, Manitoba	

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ANNEX D
RETURN POLICY
(to be included at contract award)

ANNEX E
FEDERAL CONTRACTORS PROGRAM FOR EMPLOYMENT EQUITY - CERTIFICATION

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 such request by Canada will also render the bid non-responsive or will constitute a default under the Contract.

For further information on the Federal Contractors Program for Employment Equity visit HRSDC-Labour's 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 employees (combined work force includes: permanent full-time, permanent part-time and temporary employees [temporary employees only includes those who have worked 12 weeks or more during a calendar year and who are not full-time students]).

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 HRSDC-Labour.

OR

- ☐ A5.2. The Bidder certifies having submitted the Agreement to Implement Employment Equity (LAB1168) to HRSDC-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 HRSDC-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)