

**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 Rotavirus Vaccine	
Solicitation No. - N° de l'invitation E60PH-15ROTA/A	Date 2014-11-14
Client Reference No. - N° de référence du client E60PH-15ROTA	
GETS Reference No. - N° de référence de SEAG PW-\$\$PH-876-66131	
File No. - N° de dossier ph876.E60PH-15ROTA	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2014-12-03	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: Meunier(ph876), Sherry	Buyer Id - Id de l'acheteur ph876
Telephone No. - N° de téléphone (819) 956-3836 ()	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
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

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Solicitation No. - N° de l'invitation

E60PH-15ROTA/A

Amd. No. - N° de la modif.

Buyer ID - Id de l'acheteur

ph876

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

File No. - N° du dossier

CCC No./N° CCC - FMS No/ N° VME

E60PH-15ROTA

ph876E60PH-15ROTA

List of Annexes:

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Forms:

Form 1	Bid Submission
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TITLE: ROTAVIRUS VACCINE**PART 1 - GENERAL INFORMATION****1.1 Security Requirement**

There is no security requirement associated with this bid solicitation.

1.2 Requirement

The requirement is detailed under Article 6.2 of the resulting contract clauses.

1.3 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**2.1 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 (2014-09-25) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

2.2 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.

2.3 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 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.

2.4 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

3.1 Bid Preparation Instructions

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

- (i) Section I: Technical Bid (1 hard copy)
- (ii) Section II: Financial Bid (1 hard copy)
- (ii) 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.

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

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

(c) 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:

- (i) 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
- (ii) 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.

3.2 Section I: Technical Bid

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

(b) For each vaccine proposed, the Bidder must provide:

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- (i) Drug Identification Number (DIN); or
 - (ii) Evidence that the Bidder has submitted a duly completed New Drug Submission to Health Canada, Biologics and Genetic Therapies Directorate (BGTD), no later than the closing date of this RFP and that BGTD has accepted the submission for review. A copy of the application and proof of acceptance of the submission for review by BGTD must be included.
- (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.

3.3 Section II: Financial Bid

- (a) Bidders must submit their financial bid in accordance with the Basis of Payment. The total amount of Applicable Taxes must be shown separately.
- (b) The quantities provided in Basis of Payment and the delivery schedules are only an approximation of requirements given in good faith. The quantities specified 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 up until Contract award. A quantity change, which represents a significant change in the Requirement for an item, may result in a decision to re-tender that item.

3.3.1 SACC Manual Clauses

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

3.4 Section III: Certifications

Bidders must submit the certifications required under Part 5.

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

4.1 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.

4.1.1 Technical Evaluation - Mandatory Technical Criteria

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

4.1.2 Financial Evaluation

Canada will calculate an evaluated price for each item listed in Annex B based on its total price over both the firm and option years. For evaluation purposes only, an administrative cost of \$12.00 per dose will be added to the unit price. The evaluated price for each item will be calculated as follows:

[Year 1 total number of infants x number of doses per infant x (Year 1 unit price + \$12.00)] +
 [Year 2 total number of infants x number of doses per infant x (Year 2 unit price + \$12.00)] +
 [Year 3 total number of infants x number of doses per infant x (Year 3 unit price + \$12.00)]

4.2 Basis of Selection

- (a) A bid must comply with the requirements of the bid solicitation and meet all mandatory evaluation criteria to be declared responsive.
- (b) For each item in Annex B, the responsive bid with the lowest evaluated price will be recommended for award of a contract.
- (c) If there are two or more bids with identical lowest evaluated prices, the names of all Bidders with identical lowest bid prices will be placed in a hat and the winner will be the first name drawn from it. All Bidders with the lowest bid price will be invited to witness the event.

PART 5 - CERTIFICATIONS

Bidders must provide the required certifications and associated information 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 in carrying out any of its obligations under the Contract, 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 certification. Failure to comply and to cooperate with any request or requirement imposed by the Contracting Authority may render the bid non-responsive or constitute a default under the Contract.

5.1 Certifications Precedent to Contract Award

5.1.1 Integrity Provisions - Associated Information

By submitting a bid, the Bidder certifies that the Bidder and its Affiliates are in compliance with the provisions as stated in Section 01 Integrity Provisions - Bid of Standard Instructions 2003. The associated information required within the Integrity Provisions will assist Canada in confirming that the certifications are true.

5.1.2 Federal Contractors Program for Employment Equity - Bid Certification

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- (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" (http://www.labour.gc.ca/eng/standards_equity/eq/emp/fcp/list/inelig.shtml) list available from Employment and Social Development Canada (ESDC) - Labour's (http://www.labour.gc.ca/eng/standards_equity/eq/emp/fcp/index.shtml) website.
- (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" (http://www.labour.gc.ca/eng/standards_equity/eq/emp/fcp/list/inelig.shtml) list during the period of the Contract.
- (d) The Bidder must provide the Contracting Authority with a completed annex Federal Contractors Program for Employment Equity - Certification (Annex D to Part 5), 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.

5.2 Additional Certifications Precedent to Contract Award

The certifications listed below should be completed and submitted with the bid, but may be completed and submitted afterwards. If any of these required certifications 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 comply with the request of the Contracting Authority and to provide the certifications within the time frame will render the bid non-responsive.

PART 6 - RESULTING CONTRACT CLAUSES

6.1 Security Requirement

There is no security requirement applicable to this Contract.

6.2 Requirement

The Contractor must provide the items detailed under the Requirement at Annex A to Identified Users as listed in Annex C.

6.3 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.

6.3.1 General Conditions

2010A (2014-09-25) General Conditions - Goods - Medium Complexity, apply to and form part of the Contract.

6.3.2 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.

6.4 Term of Contract

6.4.1 Period of Contract

The period of the Contract is from April 1, 2015 to March 31, 2016, inclusive.

6.4.2 Option to Extend the Contract

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

6.4.3 Option to Add Identified User

Subject to the mutual agreement of the Contractor and Canada, additional Identified Users may be added to the Contract at a price not to exceed the Contract price and subject to the same conditions.

6.5 Authorities

6.5.1 Contracting Authority

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

Sherry Meunier
Supply Team leader
Public Works and Government Services Canada
Drugs, Vaccines & Biologicals
Place du Portage, Phase III, 6B3
11 Laurier Street
Gatineau, QC K1A 0S5

Telephone: (819) 956-3836
Facsimile: (819) 956-7340
Email address: sherry.meunier@pwgsc-tpsgc.gc.ca

- (b) 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.

6.5.2 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.

6.5.3 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 an 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 an 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 an 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.

6.5.4 Contractor Representative

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

(a) General enquiries:

Name: _____
 Telephone No.: _____
 Facsimile No.: _____
 E-mail address: _____

(b) Delivery follow-up:

Name: _____
 Telephone No.: _____
 Facsimile No.: _____
 E-mail address: _____

6.6 Ordering**6.6.1 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 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) price, quantity and description of goods being ordered;
 - (iii) delivery location;
 - (iv) invoicing address; and
 - (v) any other constraints that might affect the work.
- (d) **Delivery:** Unless otherwise indicated in the Order, delivery must be made within seven (7) calendar days from receipt of an Order.
- (e) **Charges for Work under a Order:** The Contractor must not charge the Identified User anything more than the price set out in the Order unless the Identified User has issued an Order amendment authorizing the increased expenditure. The Identified User will not pay the Contractor for any design changes, modifications or interpretations of the Work unless they have been approved, in writing, by the Contracting Authority before being incorporated into the Work.
- (f) **Consolidation of Orders for Administrative Purposes:** The Contract may be amended from time to time to reflect all Orders issued to date, to document the Work performed under those Orders for administrative purposes.

6.6.2 Minimum Work Guarantee - All the Work

- (a) In this clause,

"Maximum Contract Value" means the amount specified in the "Limitation of Expenditure" clause set out in the Contract; and

"Minimum Contract Value" means \$to be inserted at contract award.

- (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.

6.6.3 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: _____

6.6.4 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 the Biologics and Genetic Therapies Directorate (BGTD) Regulations.
- (f) 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.

6.6.5 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.

6.6.6 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) In the case of the use of a continuous electronic temperature-monitoring device, the Identified User will accept the Work on a conditional basis until a Certificate of Conformity is received. 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.
- (d) A written "Certification of Conformity" confirms that:

- (i) the required Transport Conditions were maintained during transport;
 - (ii) the integrity and quality of the vaccine has not been affected by temperature excursions during transport, and
 - (iii) the expiry date of the Work as indicated on the vaccine packaging has not been impacted by temperature excursions during transport.
- (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) 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.
- (g) 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.
- (h) 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.

6.6.7 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.

6.7 Payment

6.7.1 Basis of Payment - Firm Unit Price(s) or Firm Lot Price

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.

6.7.2 Limitation of Expenditure - Cumulative Total of all Orders

- (a) Canada's total liability to the Contractor under the Contract for all Orders, inclusive of any revisions, must not exceed the sum of \$to be inserted at contract award. Customs duties are included, as applicable and Applicable Taxes are extra.

- (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.

6.7.3 SACC Manual Clauses

- (a) C6000C (2011-05-16), Limitation of Price
- (b) H1001C (2008-05-12), Multiple Payments

6.8 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) The original and one copy of all invoices are to be forwarded to each Identified User for certification and payment at the Invoicing address specified at Annex C.

6.9 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.

6.10 Product Dating

All Work supplied must have a shelf life of no less than 12 months remaining on the date of delivery, unless prior authorization is obtained from the Contracting Authority / Identified User (as Applicable). Failure to obtain authorization may result in the return of the shipment, at the Contractor's cost.

6.11 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) 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 expired, unopened Work returned with the original packing slip within one (1) year after expiry date. Returns are to be shipped FCA Free Carrier (identified User) Incoterms 2000 to the address indicated below. The Contractor is responsible for shipping costs.
- (c) That had a minimum shelf life of 12 months upon delivery to and acceptance by the Identified User, the Contractor must provide full credit in the amount of the invoiced price for expired, unopened Work returned with the original packing slip within one (1) year after expiry date for a minimum of five percent (5%) of quantity purchased under the Contract. 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.
- (d) Contractor's Return Facilities:

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

Address:
Contact Name:
Telephone:
Facsimile:
Email:

6.12 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 an Order in full or the failure to maintain the minimum stockpile

6.13 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 final total estimated quantity in the Contract.

6.14 Stockpile

- (a) At all time during the period of the Contract, the Contractor must maintain a minimum stockpile of 20% 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.
- (b) 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.
- (c) 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.

6.15 Reporting

6.15.1 Periodic Usage Reports:

The Contractor must provide a monthly report for each item. The monthly report must be submitted in an electronic format to the Contracting Authority by the first Monday of the every month. The monthly report must summarize the following:

- (a) Orders by Identified Users on a month by month basis;
- (b) Percentage of commitment fulfilled by each Identified User;
- (c) Status of Working Inventory including number of doses of the Work currently on hand, date of availability of next Health Canada released lot, number of doses (or duration of expected supply) of next Health Canada released lot; and
- (d) Status and maintenance of the Stockpile. At a minimum, the amount of doses contained in the Stockpile and the shelf life of the Stockpile must be provided.

6.15.2 Adverse Event Following Immunization (AEFI) Reporting Requirement

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

6.16 Certifications

6.16.1 Compliance

The continuous compliance with the certifications provided by the Contractor in its bid and the ongoing cooperation in providing associated information are conditions of the Contract. Certificates are subject to verification by Canada during the entire period of the Contract. If the Contractor does not comply with any certification, fails to provide the associated information, 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.

6.16.2 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.

6.17 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.

6.18 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 (2014-09-25) Goods (Medium Complexity);
- (c) Annex A: Requirement;
- (d) Annex B: Basis of Payment;
- (e) Annex C: Identified Users and Delivery Points;
- (f) Annex D, Federal Contractors Program for Employment Equity - Certification (*if applicable*); and
- (g) the Contractor's bid dated _____

6.19 Insurance

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

ANNEX A - REQUIREMENT

1. Scope

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

2. Quantity

See Annex B - Basis of Payment

3. Vaccine Format (s)

Format(s): Single dose

4. Trace back Through Automated Identification of Vaccines

- (a) 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 Work 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 the Biologics and Genetic Therapies Directorate. 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. Timely Lot Release, Contractor's Responsibility

The Contractor must submit all vaccine lots to BGTD 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.

6. Vaccine Identification Database System

- (a) The Contractor must provide the following information within 10 business days of a lot release by Biologics and Genetic Therapies Directorate of the the Public Health Agency of Canada for the purpose of updating the Vaccine Identification Database System:
 - (i) GTIN (if applicable);
 - (ii) DIN;
 - (iii) Product
 - (iv) Lot Number; and
 - (v) Expiry date.

- (b) Data may be sent in either word or excel format to AIVP-IAVP@phac-aspc.gc.ca.

7. Provision of 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) educational materials intended for use by public health practitioners if requested in Order.

7.1 Types and Content of Educational Material

- (a) 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.

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.

- (b) 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.).

7.2 Timing of Availability of Educational Materials

Educational materials should be provided in advance of shipments of the Work 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.

ANNEX B - BASIS OF PAYMENT

1. Pricing Information

All prices are firm unit prices. Each firm unit price is applicable for all destinations in Canada.

Item 001: Rotavirus Vaccine

Trade name: _____ Drug Identification Number (DIN) : _____

Year	Maximum Firm quantity	Maximum Firm quantity as doses	Firm Unit price (DDP Designated User)
April 1, 2015 to March 31, 2016 (Firm)	Require sufficient quantity based on product monograph to immunize cohorts of 393,622 infants	393,622 infants x _____ doses/infant = _____ Total doses	\$ _____ per dose
Year	Maximum Estimated quantity	Maximum Estimated quantity as doses	Firm Unit price (DDP Designated User)
April 1, 2016 to March 31, 2017 (Option)	Require sufficient quantity based on product monograph to immunize cohorts of 393,622 infants	393,622 infants x _____ doses/infant = _____ Total doses	\$ _____ per dose
April 1, 2017 to March 31, 2018 (Option)	Require sufficient quantity based on product monograph to immunize cohorts of 393,622 infants	393,622 infants x _____ doses/infant = _____ Total doses	\$ _____ per dose

2. Delivery Schedule:

- (a) The table below represents Canada's maximum estimated requirement.
- (b) The actual monthly quantities requested on Identified Users' Orders may not conform to the estimated amounts.

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- (c) In each year of the Contract, the Contractor is guaranteed to receive Orders totalling a minimum of 75% of the total annual maximum quantity.
- (d) If additional Identified Users are added to the Contract, their quantities will be in addition to the minimum and maximum quantities described above.

2015-2016 Estimated Quantities

FPT	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Quantity (Infants) Apr - Mar	Overage (Infants)	Min (Infants)
DND	1	1	1	1	1	1	1	1	-	1	1	-	10		8
HC-AB	600	-	-	-	-	-	-	-	-	-	-	-	600		450
AB	-	-	-	-	-	-	-	6,250	6,250	6,250	6,250	17,500	42,500	8,500	38,250
BC	3,400	3,300	3,300	3,400	3,400	3,400	3,300	3,300	3,300	3,300	3,300	3,300	40,000	8,000	36,000
MB	2,400	550	500	1,000	900	1,150	1,200	900	700	1,100	900	950	12,250	2,450	11,025
NT	80	80	80	80	80	80	80	80	80	80	80	80	960	192	864
ON	10,000	10,000	10,000	10,000	10,000	10,000	10,000	12,000	12,000	12,000	14,000	17,500	137,500	27,500	123,750
PEI	110	120	120	120	110	120	110	120	120	120	120	110	1,400	280	1,260
QC	3,000	6,500	7,500	6,500	7,500	6,500	6,500	6,500	6,500	6,500	7,500	6,500	77,500	15,500	69,750
SK	1,250	1,250	1,250	1,250	1,250	1,250	1,250	1,250	1,250	1,250	1,250	1,250	15,000	3,000	13,500
YT	75	25	25	25	25	25	25	50	50	25	25	25	400	80	360
TOTAL	13,500	13,500	13,500	13,500	13,500	13,500	13,500	13,500	13,500	13,500	13,500	13,500	328,120	65,502	295,217

Maximum 2014-15 Estimate	393,622
Minimum Work Guarantee (75%)	295,217
Scopile (20%)	78,724

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ANNEX C – IDENTIFIED USERS AND DELIVERY POINTS

Jurisdiction	Shipping
Department of National Defence	Various authorized users. Refer to orders.
Health Canada Alberta	Edmonton, AB
Alberta	Fort Saskatchewan, Alberta
British Columbia	Vancouver, BC
Quebec	Boucherville, Québec
Manitoba	Winnipeg, MB
Northwest Territories -Stanton Territorial Hospital	Yellowknife, NT
Northwest Territories -Inuvik Regional Hospital	Inuvik, NT
Northwest Territories - Yellowknife Public Health Unit	Yellowknife, NT
Ontario	Concord, Ontario
Prince Edward Island	Charlottetown, PEI
Saskatchewan	Regina, SK
Yukon	Whitehorse, YT

ANNEX D to PART 5 - BID SOLICITATION 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 any 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 (http://www.labour.gc.ca/eng/standards_equity/eq/emp/fcp/index.shtml) 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 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)

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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 #	
	Facsimile #	
	E-mail	
Contractor Representative – Delivery follow-up	Name	
	Title	
	Telephone #	
	Facsimile #	
	E-mail	
Returns	Address to return product	
	Contact Name	
	Telephone #	
	Facsimile #	
	E-mail	
Point of Manufacturing/Shipping	Manufacturing	
	Shipping	
Contractor's Bid Dated		

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FORM 1 - BID SUBMISSION

Bidders who are incorporated, including those bidding as a joint venture, must provide a complete list of names of all individuals who are currently 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:

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; and
4. 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
