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

LETTER OF INTEREST
LETTRE D'INTÉRÊT

Title - Sujet Influenza Vaccine Strategy	
Solicitation No. - N° de l'invitation E60PH-120001/A	**Date** 2012-08-13
Client Reference No. - N° de référence du client E60PH-00012	**GETS Ref. No. - N° de réf. de SEAG** PW-$$PH-896-61009
File No. - N° de dossier ph896.E60PH-120001	**CCC No./N° CCC - FMS No./N° VME**
Solicitation Closes - L'invitation prend fin **at - à 02:00 PM** **on - le 2012-08-27**	**Time Zone** **Fuseau horaire** Eastern Daylight Saving Time EDT
F.O.B. - F.A.B. **Plant-Usine:** ☐ **Destination:** ☐ **Other-Autre:** ☐	
Address Enquiries to: - Adresser toutes questions à: Baird, Christa	**Buyer Id - Id de l'acheteur** ph896
Telephone No. - N° de téléphone (250) 363-8471 ( )	**FAX No. - N° de FAX** ( ) -
Destination - of Goods, Services, and Construction: **Destination - des biens, services et construction:** SEE HEREIN	

Comments - Commentaires

Instructions: See Herein

Instructions: Voir aux présentes

Vendor/Firm Name and Address
Raison sociale et adresse du fournisseur/de l'entrepreneur

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**

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

Canada

Item Article	Description	Dest. Code Dest.	Inv. Code Fact.	Qty Qté	U. of I. U. de D.	Unit Price/Prix unitaire FOB/FAM Destination	Plant/Usine	Delivery Req. Livraison Req.	Del. Offered Liv. offerte
1	Canada's Influenza Vaccine Supply Strategy Request for Information	Total		1	Each	$	$		

REQUEST FOR INFORMATION

REGARDING

CANADA'S INFLUENZA VACCINE SUPPLY STRATEGY

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: Christa Baird
Telephone: 250-363-8471
E-Mail: christa.baird@tpsgc-pwgsc.gc.ca

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REQUEST FOR INFORMATION REGARDING

CANADA'S INFLUENZA VACCINE SUPPLY STRATEGY

1 Background and Purpose of this Request for Information (RFI)

Canada's requirements for publicly funded seasonal and pandemic influenza vaccine supply are currently being met through four (4) contracts awarded in 2011 and 2012. Of these, two (2) contracts, collectively covering the supply of 4.8 M doses annually of seasonal trivalent inactivated influenza vaccine (TIV) and including a provision for accessing back-up supply of pandemic vaccine, will expire at the end of March 2014. A third contract, for the supply of a Live Attenuated Influenza Vaccine (LAIV), will expire at the end of March 2013. Contractual options exist to allow the period of each of these contracts to be extended until March 31, 2015, however, no decision has as yet been made on whether these options will be exercised by Canada. The fourth contract, for the supply of 5 M doses annually of TIV and for the primary supply of pandemic influenza vaccine as and when needed, does not expire until March 31, 2021.

To assist in the decision on exercising these contract options, and to ensure an uninterrupted access to a secure supply of influenza vaccines at competitive prices regardless of whether or not these options are exercised, the Government of Canada, working together with provincial and territorial governments, is now seeking to review and revise, as appropriate, its influenza vaccine supply strategy. Canada's current strategy incorporates three main elements:

(a) A long-term pandemic supply contract with a domestic manufacturer capable of supplying 100% of Canada's pandemic vaccine requirements, and including a supply of at least 5 M doses annually of seasonal influenza vaccine;

(b) A second pandemic supply contract with access to up to 10 M doses of pandemic vaccine, to serve as a back-up to the primary domestic supplier, and combined with a portion of seasonal vaccine supply; and

(c) Multiple suppliers of seasonal influenza vaccine which together can offer to Canada access to an array of new and innovative technologies intended to enhance vaccine efficacy, effectiveness and/or improve vaccine uptake in targeted populations.

The development of Canada's current strategy was informed, in part, by a consultation with the vaccine industry undertaken in March 2010. In order to assist in reviewing and updating, as necessary, this strategy, Canada is once again seeking input from the vaccine manufacturing industry.

2 Nature of Request for Information

This is not a bid solicitation. This RFI will not result in the award of any contract. As a result, potential suppliers of any goods or services described in this RFI should not reserve stock or facilities, nor allocate resources, as a result of any information contained in this RFI. Nor will this RFI result in the creation of any source list. Therefore, whether or not any potential supplier responds to this RFI will not preclude that supplier from participating in any future procurement. Also, the procurement of any of the goods and services described in this RFI will not necessarily follow this RFI. This RFI is simply intended to solicit feedback from industry with respect to the matters described in this RFI.

3 Nature and Format of Responses Requested

Respondents are requested to provide their comments, concerns and, where applicable, alternative recommendations regarding how the requirements or objectives described in this RFI could be satisfied. Respondents are also invited to provide comments regarding the content, format and/or organization of any draft documents included in this RFI. Respondents should explain any assumptions they make in their responses.

4 Response Costs

Canada will not reimburse any respondent for expenses incurred in responding to this RFI.

5 Treatment of Responses

(a) **Use of Responses**: Responses will not be formally evaluated. However, the responses received may be used by Canada to develop or modify procurement strategies or any draft documents contained in this RFI. Canada will review all responses received by the RFI closing date. Canada may, in its discretion, review responses received after the RFI closing date.

(b) **Review Team**: A review team composed of representatives of the client (where applicable) and PWGSC will review the responses. Canada reserves the right to hire any independent consultant, or use any Government resources that it considers necessary to review any response. Not all members of the review team will necessarily review all responses.

(c) **Confidentiality**: Respondents should mark any portions of their response that they consider proprietary or confidential. Canada will handle the responses in accordance with the *Access to Information Act*.

6 Industry Consultation:

(a) Canada will meet with respondents who indicate in their responses that they wish to participate in a follow-up meeting. Canada currently anticipates holding any such meetings on September 19 - 20, 2012 in Ottawa, Ontario.

(b) This consultation with industry is designed to allow interested influenza vaccine manufacturers the opportunity to meet one-on-one with members of the Federal / Provincial / Territorial (FPT) Vaccine Supply Working Group (VSWG) - together with other FPT representatives as appropriate and members of the National Advisory Committee on Immunization's (NACI) Influenza Working Group.

(c) In order to allow PWGSC to establish the schedule for such meetings, respondents are requested to contact the Contracting Authority no later than September 5, 2012 (refer to Item 12), together with a list of the individuals from their organization who would be attending the meeting.

(d) Participants will be allotted 1.5 hours for a one-on-one presentation and questions and answers session with the VSWG.

(e) Suppliers are to provide an electronic copy of their response to the Contracting Authority by September 14, 2012.

7 Industry Consultation Topics:

(a) Existing influenza vaccine products and technologies including current and future plans for the Canadian market.

(b) Current and future influenza vaccine production, filling and supply capabilities (seasonal and pandemic).

(c) Seasonal influenza vaccine supply in Canada.

(d) Back-up pandemic influenza vaccine supply in Canada.

(e) Influenza Vaccine Product Pipeline

8 Contents of this RFI

(a) This document remains a work in progress and respondents should not assume that new clauses or requirements will not be added to any bid solicitation that is ultimately published by Canada. Nor should respondents assume that none of the clauses or requirements will be deleted or revised. Comments regarding any aspect of the draft document are welcome.

(b) This RFI contains specific questions addressed to the industry.

9 Questions to Industry

Please refer to Annex A - Questionnaire.

10 Format of Responses

(a) **Cover Page**: If the response includes multiple volumes, respondents are requested to indicate on the front cover page of each volume the title of the response, the solicitation number, the volume number and the full legal name of the respondent.

(b) **Title Page**: The first page of each volume of the response, after the cover page, should be the title page, which should contain:

(i) the title of the respondent’s response and the volume number;

(ii) the name and address of the respondent;

(iii) the name, address and telephone number of the respondent’s contact;

(iv) the date; and

(v) the RFI number.

(c) **Number of Copies**: Canada requests that respondents submit 2 copies of their responses.

11 Enquiries

Because this is not a bid solicitation, Canada will not necessarily respond to enquiries in writing or by circulating answers to all potential suppliers. However, respondents with questions regarding this RFI may direct their enquiries to:

Contracting Authority:	Christa Baird
E-mail Address:	Chirsta.Baird@pwgsc.gc.ca
Telephone:	(250) 363-8471
Address:	Place du Portage III - 6B3, 11 rue Laurier, Gatineau, QC K1A 0S5

12 Submission of Responses

(a) **Industry Consultation:** Suppliers interested in attending the Industry Consultation must provided notice of that interest to the Contracting Authority no later than 16:00 EST on September 5, 2012. An electronic copy of the presentation must be provided to the Contracting Authority no later than September 14, 2012.

(b) **Time and Place for Submission of Responses**: Suppliers who do not wish to attend the Industry Consultation but are interested in providing a written response should deliver it

by 14:00 EST on September 30, 2012 to the Contracting Authority (care of Julia Summers / Julia.Summers@pwgsc.gc.ca /Place du Portage III - 6B3, 11 rue Laurier, Gatineau, QC K1A 0S5).

(c) **Responsibility for Timely Delivery**: Each respondent is solely responsible for ensuring its response is delivered on time to the correct location.

(d) **Identification of Response**: Each respondent should ensure that its name and return address, the solicitation number and the closing date appear legibly on the outside of the response.

ANNEX A - QUESTIONNAIRE

1. Existing influenza vaccine products and technologies including current and future plans for the Canadian market:

(a) What flu vaccine products do you currently market (in Canada and globally)? Please describe the available products including:

(i) approved indications for use;

(ii) formulation (e.g. inactivated vs. live; adjuvanted vs. unadjuvanted; thimerosal-free or thimerosal reduced; etc.);

(iii) production technology used (egg based vs. cell culture; etc.);

(iv) route of administration (IM, nasal, other);

(v) packaging formats available (single dose, multi-dose, vials or pre-filled syringes);

(vi) restrictions on use (e.g. time for use after first dose drawn for multi-dose products);

(vii) shelf-life;

(viii) latex content;

(ix) bar coding used (type, content, on which levels of packaging?);

(x) where marketed; and

(xi) other information as appropriate

(b) If a vaccine is not currently marketed in Canada are there plans to seek authorization here? What are the proposed timelines for this? What factors would drive this decision?

(c) What data can you provide on the stability of your vaccines (seasonal and pandemic) outside of recommended storage conditions (2° - 8° C)?

2. Current and future influenza vaccine production, filling and supply capabilities (seasonal and pandemic):

(a) Approximately what is your current global influenza vaccine manufacturing capacity (number of doses per month) for seasonal vaccine (trivalent or quadravalent); and for monovalent pandemic vaccine?

(b) Where is this capacity located (i.e., what countries)? Are the manufacturing, filling and packaging all done in the same location/country? If not, where is each step of the production process located?

(c) To what extent is your existing capacity committed through existing supply arrangements (for seasonal and/or pandemic influenza vaccine)?

(d) How far into the future is this production capacity committed?

(e) What are your plans for expansion of influenza vaccine production or filling capacity, if any (either for existing, or new production technologies)? By how much will capacity be increased? Where would new capacity be located?

(f) Do you have existing plans to develop, or are you considering the possibility of developing production capacity in Canada? If so, what are the expected timelines for this?

(g) What factors would impact your decision to build/expand production capacity in Canada?