RETURN BIDS TO:
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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

SOLICITATION AMENDMENT
MODIFICATION DE L'INVITATION

The referenced document is hereby revised; unless otherwise indicated, all other terms and conditions of the Solicitation remain the same.

Ce document est par la présente révisé; sauf indication contraire, les modalités de l'invitation demeurent les mêmes.

Comments - Commentaires

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

Title - Sujet Influenza Vaccine Strategy	
Solicitation No. - N° de l'invitation E60PH-120001/A	**Amendment No. - N° modif.** 001
Client Reference No. - N° de référence du client E60PH-00012	**Date** 2012-08-14
GETS Reference No. - N° de référence 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	

Instructions: See Herein

Instructions: Voir aux présentes

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**

REASON FOR AMENDMENT:

1. To include Annex “A” - Questionnaire in its entirety

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1. Delete Annex “A” - Questionnaire in its entirety and replace with the following:

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?

3 Seasonal Influenza Vaccine Supply in Canada:

(a) What is the minimum share (as a percentage of the available market, or number of doses) of the Canadian public market that would be of interest to your company for seasonal flu vaccine supply? **Note: Canada's public market demand currently ranges from 9.5 M to 10.5 M doses annually, of which 5 M doses are already committed under an existing long-term contract.**

(b) Do you favour a contract that that guarantees a minimum percentage share of the public market, or one that guarantees a minimum number of doses to be supplied each year?

(c) Is there an upper limit (i.e. a maximum number of doses) on the quantity of seasonal vaccine that you could supply to Canada (e.g. based on availability of uncommitted capacity)? Could this quantity increase over time (i.e., under a long-term contract)? If so, in what time frame?

(d) What is the minimum contract length (i.e., number of years) that would be of interest to your company? What factors should be considered in determining the appropriate length of a new contract?

(e) What impact does the length of a contract have on the price offered to Canada?

(f) What impact does the size of the contract (i.e., volume of doses sold, or share of market) impact the price offered to Canada?

(g) Are there other factors that your company considers important for inclusion in a new seasonal flu vaccine contract?

(h) What does your company consider to be the benefits, or the drawbacks of linking the supply of seasonal vaccine with a requirement to act as a back-up pandemic vaccine supplier to Canada in the evaluation of bids and the award of new supply contracts?

(i) What contingency plans does your company have in place to mitigate potential disruptions in seasonal supply?

(j) How would your company address the need for flexibility in ordering (i.e., a need to increase or decrease demand)? How late into a calendar year could such adjustments be accommodated?

(k) Given the size of Canada's public seasonal vaccine market, how many contracted suppliers do you believe Canada could support?

(l) What mechanisms or processes are in place within your company to ensure that delivery timelines are assured?

(m) Do you currently supply, or plan to supply flu vaccine to the private market in Canada?

(n) What does your company consider to be the benefits, or the drawbacks, of linking different vaccine formulations (i.e. regular TIV and "targeted" vaccines) together in the evaluation of tenders and awarding of contracts? Should a supplier be required to offer multiple vaccines in order to be considered for award of a contract?

(o) What would you recommend as the most expedient and cost effective procurement mechanism for new vaccines (that is, new or innovative technologies that do not yet have an established market and for which initial demand may be unpredictable)?

(p) Are there other innovative solutions and/or options that Canada should consider for inclusion in its seasonal influenza vaccine supply contracts?

4 Back-Up Pandemic Vaccine Supply in Canada:

(a) Is your company interested in being a back-up supplier of pandemic vaccine to Canada?

(b) What does your company consider to be the benefits, or the drawbacks of linking a requirement to act as a back-up pandemic supplier to the supply of seasonal vaccine in the evaluation of bids and the award of new supply contracts?

(c) If a back-up supply contract is linked to seasonal supply, what is a reasonable share of Canada's seasonal supply of flu vaccine that should be linked to Canada's back-up pandemic supply contract?

(d) To what extent (i.e., number of doses) could your company commit to supply to Canada in the event of a pandemic?

(e) Would you require that Canada pay a readiness or "reservation" fee, or are there other incentives that your company would consider in order to commit to acting as a back-up pandemic supplier for Canada?

(f) How would you ensure that Canada would have priority / early access to pandemic vaccine if required?

(g) What types of pH1N1 vaccines did you produce and where did you market these vaccines? Approximately how many doses were produced / sold? What was the approved indication for use? What was the packaging format used (e.g. minimum package size)?

(h) Should all of Canada's pandemic supply capacity (primary and back-up) be domestic? How would you ensure access by Canada to pandemic vaccine that is produced (in whole or in part) outside of Canada?

(i) What kinds of contractual arrangements does your company currently have in place for the supply of pandemic vaccine? (E.g. guarantee of priority access; reserved percentage of capacity; purchase order triggers; annual pandemic readiness fee; allowable "off ramps" to reduce orders; link to seasonal vaccine supply; etc.).

(j) Do you require that a purchaser of pandemic influenza vaccine fully indemnify your company against third party claims that may arise as a result of the use of the vaccine?

(k) Do you have existing pandemic vaccine supply arrangements with the country in which your production capacity is located?

(l) Would you be able to supply a pandemic vaccine in a single dose format (either exclusively, or in combination with a multi-dose presentation)?

(m) Would you be interested in providing pandemic vaccine to Canada to meet the needs of specific target populations (e.g. vaccines for the elderly, children, high-risk groups with weakened immune systems, pregnant women; etc.)?

(n) In addition to price, how should the following factors be considered in the evaluation of back-up pandemic vaccine suppliers? Which factors does your company consider to be the most important and why?

(i) Domestic production;

(ii) Manufacturing timeline (from seed strain to lot availability);

(iii) Priority access for Canada;

(iv) Technologies different from that offered by the primary supplier;

(v) Flexibility in ordering (time to place initial order; ability to adjust (up or down) initial order; ability to donate / sell unused doses);

(vi) Product presentations (e.g. package size);

(vii) Others?

(o) Are there other innovative solutions and/or options that Canada should consider for inclusion in its pandemic (primary and/or back-up) influenza vaccine supply contracts?

5 Influenza Vaccine Product Pipeline:

(a) Please provide an overview of new / enhanced influenza vaccine products / technologies (e.g. quadravalent formulation) that your company expects to introduce over the next 2, 3 and 5 years (i.e., period from 2014 - 2017).

(b) What are the expected benefits of these new products / technologies?

(c) What are your plans for introducing these products in Canada?

(d) What impact do you expect these new technologies to have on product pricing (e.g. what % increase in price would be expected from a trivalent to a quadravalent formulation, if any).

(e) How should technological advancements that arise from time to time being incorporated into a long-term supply contract? How should price differences for new technologies be incorporated into a contract?

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED