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LETTER OF INTEREST
LETTRE D'INTÉRÊT

Title - Sujet Pandemic & Seasonal Influenza RFI	
Solicitation No. - N° de l'invitation E60PH-18RFIP/A	**Date** 2018-06-19
Client Reference No. - N° de référence du client E60PH-18RFIP	**GETS Ref. No. - N° de réf. de SEAG** PW-$$PH-884-74997
File No. - N° de dossier ph884.E60PH-18RFIP	**CCC No./N° CCC - FMS No./N° VME**
Solicitation Closes - L'invitation prend fin **at - à 02:00 PM** **on - le 2018-07-25**	**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: Joy(ph884), Sharon	**Buyer Id - Id de l'acheteur** ph884
Telephone No. - N° de téléphone (819) 420-2964 ( )	**FAX No. - N° de FAX** ( ) -
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Gatineau
Quebec
K1A 0S5

Canada

REQUEST FOR INFORMATION (RFI)

CANADA'S PANDEMIC AND SEASONAL INFLUENZA VACCINE SUPPLY STRATEGY

1. Background and Purpose of the Request for Information (RFI)

Public Services and Procurement Canada (PSPC) is requesting Industry feedback on Pandemic and Season Influenza Vaccine supply on behalf of the Government of Canada and provincial and territorial governments.

In 2011 the Government of Canada entered into a long-term contract to ensure that Canada will have rapid, assured, and priority access to a supply of Pandemic Influenza Vaccine (PIV) manufactured, filled, and finished in Canada, in a quantity sufficient to meet its requirements in the event of an influenza pandemic. This contract, which is in effect until March 31, 2021, constitutes Canada's **Primary PIV Readiness and Supply contract (the "Primary Contract")**.

Also in 2011, the Government of Canada entered into a four (4) year contract to secure access to a second source of supply for up to 10 million (M) doses of PIV, if and when required. That contract expired on March 31, 2015, and Canada is now in the process of replacing it through a competitive tendering process. The new contract, expected to commence in late 2018 with a contract period of at least three (3) years, constitutes Canada's **Back-Up (or Secondary) PIV Readiness and Supply contract (the "Secondary Contract")**.

Canada's current strategy incorporates two main elements:

a) A long-term Primary Contract with a domestic manufacturer of an adjuvanted vaccine capable of supplying 100% of Canada's PIV requirements (i.e. up to 2 doses per person) in priority to all other customers, which includes a guaranteed portion of seasonal influenza vaccine supply; and

b) A short-term Secondary Contract with access to up to 10 M doses of PIV (adjuvanted or unaduvanted), to serve as a back-up to the primary domestic supplier, and which may include a guaranteed portion of seasonal influenza vaccine supply.

The key components (current and proposed) of Canada's PIV strategy are set out in **ANNEX A**.

Input from influenza vaccine manufacturers is being sought in response to a number of questions:

i. On the key components of Canada's PIV strategy **(SEE ANNEX B)**; and

ii. On the current and anticipated influenza vaccine landscape (seasonal and pandemic) including information on actual and anticipated production capacity, production technologies, and vaccine innovations with an emphasis on plans for, or interest in, the Canadian market **(SEE ANNEX C).**

The purpose of this RFI is to obtain industry feedback in order to inform the review and updating, as appropriate, of Canada's Pandemic Influenza Vaccine (PIV) supply strategy in advance of the 2021 expiry of Canada's Primary Contract for PIV.

2. Nature of this Request for Information

This RFI is neither a call for tender nor a Request for Proposal (RFP). No agreement or contract will be entered into based on this RFI. The issuance of this RFI is not to be considered in any way a commitment by the Government of Canada, nor as authority to potential respondents to undertake any work that could be charged to Canada. This RFI is not to be considered as a commitment to issue a

subsequent solicitation or award contract(s) for the work described herein. 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.

Although the information collected may be provided as commercial-in-confidence (and, if identified as such, will be treated accordingly by Canada), Canada may use the information to assist in drafting performance specifications (which are subject to change) and for budgetary purposes.

Respondents are encouraged to identify, in the information they share with Canada, any information that they feel is proprietary, third party or personal information. Please note that Canada may be obligated by law (e.g. in response to a request under the Access of Information and Privacy Act) to disclose proprietary or commercially-sensitive information concerning a respondent (for more information: http://laws-lois.justice.gc.ca/eng/acts/a-1/).

Participation in this RFI is encouraged, but is not mandatory. There will be no short-listing of potential suppliers for the purposes of undertaking any future work as a result of this RFI. Similarly, participation in this RFI is not a condition or prerequisite for the participation in any potential subsequent solicitation.

Respondents will not be reimbursed for any cost incurred by participating in this RFI.

4. Submission of Responses

(a) **Closing date**: Respondents should submit an electronic copy of their response to this RFI by 2:00 pm EST on July 25, 2018 to the Contracting Authority listed below.

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

(c) **Identification of Response**: Each Respondent should ensure that its name and return address, the RFI number, and the closing date appear legibly on the outside of the response if sending via courier.

5. Follow-Up Teleconferences

(a) Canada may hold one-on-one teleconferences with Respondents who provide notice in their written proposal that they wish to participate in a follow-up discussion. Canada currently anticipates holding any such teleconferences late August and early September 2018.

(b) Respondents who have provided notice of their interest in participating in a follow-up teleconference should provide an electronic copy of the presentation for this teleconference to the Contracting Officer at least five (5) business days in advance of the scheduled teleconference.

(c) If scheduled, Respondents will be allotted up to two (2) hours for their teleconference.

(d) Respondents who do not wish to participate in a teleconference, but who would like to provide input can submit only a written proposal for consideration.

6. RFI Authority

Interested Respondents may submit their responses to the PSPC Contracting Authority, identified below, preferably via email:

Sharon Joy
Supply Specialist
Public Services & Procurement Canada
11 Rue Laurier
6B3 Place du Portage Phase III
Gatineau, QC J8X 4A6
E-mail Address: sharon.joy@pwgsc-tpsgc.gc.ca
Telephone: (819)-420-2964

7. Follow-up with Respondents

Canada reserves the right to follow-up with Respondents to this RFI at any time prior to the posting of a formal Request for Proposals (RFP) for new Primary and/or Secondary Contracts in order to request additional information, or to request that Respondents confirm or update the information provided in response to this RFI, without publicly posting a new RFI.

ANNEX A
KEY PANDEMIC INFLUENZA VACCINE STRATEGY COMPONENTS

These key components include the minimum activities, deliverables, and timelines that would be expected of a successful Contractor. This list should not be considered to be all-inclusive and Canada reserves the right to add, remove, or revise this list prior to a formal tendering process for the Primary and or Secondary PIV Readiness and Supply Contracts.

A. Primary PIV Readiness and Supply Contract

1. Contractor must have domestic (i.e. Canadian) capacity to produce, fill, and package an adjuvanted PIV, indicated for use in persons aged six months and above, in sufficient quantity to supply up to 2 doses per person for the entire population of Canada (as per by most recent Statistics Canada survey prior to a PIV order).

2. Contractor's PIV must be produced using a proven technology as demonstrated by the regulatory licensure / authorization (in Canada or globally), prior to contract award, of a seasonal or pandemic vaccine manufactured by the Contractor using the same technology.

3. Contractor must have a previous PIV (i.e. 2009 A(H1N1)) or a pre-pandemic vaccine (e.g. H5N1; H7N9) authorized by Health Canada (HC) at the time of contract award, or must submit such a vaccine to HC for authorization within one (1) year of the contract start date.

4. Contractor must have and maintain a state of pandemic readiness including but not limited to:

(a) Creation and maintenance of inventories of PIV production materials (inclusive of filled adjuvant if not manufactured in Canada), or the assured and rapid access to domestic sources of supply for these materials;

(b) Replenishment of stockpiles of all perishable raw materials; and

(c) Maintenance of unused domestic production capacity such that production can be brought up to full capacity quickly (inclusive of the necessary human resources) so as to meet minimum requirements for quantity and delivery timelines.

5. Canada must have priority access to all filled and finished PIV originating from the Contractor's domestic production facility for the supply of 100% of Canada's PIV order.

6. Delivery by the Contractor of first commercial lots to commence within 19 weeks of receipt of a candidate seed strain, or receipt of any other influenza virus source material applicable to the Contractor's manufacturing technology (e.g. virus genome), from the World Health Organization (WHO).

7. Delivery to Canada by the Contractor must be at a rate of at least 33 M doses per month (7.7 M doses per week).

8. Direct delivery by the Contractor to a minimum of sixty (60) destinations across Canada is required with shipment by air to destinations in the Northwest Territories (NT), Nunavut (NU), the Yukon Territories (YT), and Newfoundland and Labrador (NL).

9. Contractor to supply PIV in multi-dose vials (10 doses per vial). A portion of Canada's order may be supplied in single dose pre-filled syringes or 20 or 50 dose multi-dose vials, if available, and solely at the discretion of Canada.

10. Contractor to have the capacity to stockpile PIV produced for Canada, but not yet delivered.

11. Contractor to have pre-established contingency plans to mitigate the impact to Canada of production or other problems that could limit or delay supply from the domestic production facility.

12. Contract length of ten (10) years commencing April 1, 2021, plus option to extend the contract for a minimum of one (1) additional year.

13. Provisions to incorporate new influenza vaccine production technologies, process enhancements, new packaging formats, etc. if available from the Contractor and acceptable to Canada.

14. Contract to include order "off ramps" and provisions for reducing surplus PIV (e.g. order adjustments and / or delays; provisions for the sale and / or donation of unused vaccine) to increase Canada's flexibility in adapting to changing circumstances during a pandemic.

15. Contractor to be guaranteed a minimum portion of Canada's seasonal public influenza vaccine requirements to be supplied in a formulation and package format acceptable to P/T users.

B. One or More Secondary PIV Readiness and Supply Contract(s)

1. Contractor must have and maintain a state of pandemic readiness with the capacity to produce, fill, and package, either domestically (preferred) or off-shore, a monovalent PIV (inclusive of adjuvant if applicable) acceptable to Canada.

2. Contractor's PIV must be produced using a proven technology as demonstrated by the regulatory licensure / authorization (in Canada or globally), prior to contract award, of a seasonal or pandemic vaccine manufactured by the Contractor using the same technology.

3. Contractor must have a previous PIV (i.e. 2009 A(H1N1)) or a pre-pandemic vaccine (e.g. H5N1; H7N9) authorized by Health Canada (HC) at the time of contract award, or submit such a vaccine to HC for authorization within one (1) year of the contract start date.

4. Contractor must have the capacity to supply to Canada at least 10 M doses if so requested.

5. Delivery by the Contractor of first commercial lots to commence within 22 weeks of receipt of a candidate seed strain, or receipt of any other influenza virus source material applicable to the Contractor's manufacturing technology (e.g. genome), from the WHO.

6. Contractor must deliver to Canada on a weekly basis either a guaranteed minimum number of doses (preferred) or a guaranteed percentage of its production capacity.

7. Direct delivery by the Contractor to a minimum of sixty (60) destinations across Canada is required with shipment by air to destinations in NT, NU, YT, and NL.

8. Contractor to supply PIV in multi-dose vials (10 doses per vial) with a minimum available package size of ten (10) doses. A portion of Canada's order may be supplied in single dose pre-filled syringes or 20 or 50 dose multi-dose vials, if available, and solely at the discretion of Canada.

9. Contractor to have the capacity to stockpile on behalf of Canada PIV produced for Canada, but not yet delivered.

10. Contractor to have pre-established contingency plans to mitigate the impact to Canada of production or other problems that could limit or delay supply from the Contractor's designated production facility.

11. Contract to include order "off ramps" and provisions for reducing surplus PIV (e.g. order adjustments and / or delays; provisions for the sale and / or donation of unused vaccine) to increase Canada's flexibility in adapting to changing circumstances during a pandemic.

12. Contract length of a minimum of three (3) years commencing in late 2021 or early 2022 (start date to be determined) plus options to extend the contract for one (1) or two (2) additional years.

ANNEX B
CANADA'S PANDEMIC AND SEASONAL INFLUENZA VACCINE STRATEGY
QUESTIONS TO INDUSTRY

Respondents are requested to respond to the following questions. Note while most of these questions relate to both the Primary and Secondary Contracts, some may be specific to one or the other of the contracts.

Key PIV Strategy Components

1. Are the key PIV components provided in Annex A complete and clear? Are there concerns with any of these key components? Are there additional components that should be included as part of a pandemic readiness and supply contract?

2. Do you have an interest in bidding on Canada's future requirement for:

(a) A Primary Contract; and / or

(b) A Secondary Contract?

Timeline for Tendering and Contract Award Notification

3. While the timeline for tendering and award of Canada's new Primary and Secondary Contracts will be dependent on the need for consultation and on required award approval processes, it is recognized that Contractors may require advance notice to prepare for the contract start date.

a. For the Primary Contract, how far in advance do you require to be notified of a contract award that would commence on April 1, 2021?

b. For the Secondary Contract, how far in advance do you require to be notified of a contract award that would commence in late 2021 or early 2022?

Contract Length

The proposed period for Canada's next Primary Contract is ten (10) years with an option to extend for at least one (1) additional year. The proposed period for Canada's next Secondary Contract(s) is three (3) years with options to extend for an additional one (1), or two (2) years.

4. What is the preferred minimum length for the Primary Contract? What would an acceptable optional extension period be?

5. What is the preferred minimum length for the Secondary Contract(s)? What would an acceptable optional extension period be?

Pandemic Readiness Fee

6. Current contractual arrangements require that Canada pay a pre-determined annual pandemic readiness (or "reservation") fee in exchange for the Contractor maintaining a state of pandemic preparedness. Are there other approaches that Canada should consider as the basis of payment for the Primary and / or Secondary Contracts?

Linking Pandemic Vaccine Preparedness to Seasonal Influenza Vaccine Supply

Canada's Primary Contractor is allocated a share of the Canadian public market for seasonal influenza vaccine. The previous Secondary Contractor (2011-2015) was also allocated a share of seasonal supply; however, the new Secondary Contract (anticipated to be awarded in late 2018) will not be linked to seasonal supply.

7. What do you consider to be the benefits, or the drawbacks, of linking seasonal supply to the PIV contracts?

8. If future Primary and / or Secondary Contracts are linked to seasonal supply, what is a reasonable share (percentage or minimum number of doses) of Canada's seasonal influenza vaccine supply that should be guaranteed under each of these contracts?

PIV Production and Order Trigger

9. Currently, Canada's PIV contracts link PIV production and order placement to a WHO pandemic declaration or to a recommendation by the WHO that influenza vaccine manufacturers switch from seasonal vaccine production to PIV production. What do you consider to be an appropriate "trigger" for commencing PIV production?

10. How would existing commitments to produce seasonal vaccine impact your switch to PIV production (e.g. would you be required to complete seasonal production first), and what is the time required to make the switch (i.e. time required to stop seasonal vaccine production and begin production of a PIV)?

Priority Access

Priority access to PIV is a mandatory requirement under the Primary Contract, and is preferable, but not mandatory, under the Secondary Contract.

11. How would you ensure that Canada would have priority / early access to PIV if required under a contract?

12. What impact will the WHO's Pandemic Influenza Preparedness Framework (http://www.who.int/influenza/resources/pip_framework/en/) have on priority access, or on your ability to commit to a supply contract with Canada?

Existing Contractual Arrangements

13. 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 vs. firm weekly quantity commitments; purchase order triggers; annual pandemic readiness or reservation fee; allowable "off ramps" to reduce orders; links to seasonal influenza vaccine supply; etc.).

Indemnification

14. Canada has traditionally indemnified the manufacturer of a PIV against 3rd party claims arising from the use of the vaccine if the PIV is authorized by Health Canada via an expedited approval process.

What are your minimum requirements for indemnification by purchasers of PIV under your PIV supply contracts?

Supply Format and Target Populations

15. 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.)?

16. If yes, what specific cohorts do your vaccines target?

Order Placement Timelines, Order "Off Ramps", and Disposal of Surplus PIV:

The 2009 A(H1N1) pandemic highlighted the need to ensure that future contractual arrangements for PIV supply provide Canada with reasonable flexibility to delay or to adjust its order in response to changing circumstances (e.g. a determination that a single dose schedule is sufficient), as well as to dispose of any PIV deemed surplus to Canada's needs in a manner intended to minimize the overall cost to Canada of the PIV purchase and to maximize availability of surplus PIV to other markets.

17. Following the designated trigger event that would require a Contractor to commence pandemic influenza vaccine production, within how many weeks should Canada be required to notify the Contractor of its intent to order PIV and of the quantity of PIV to be ordered?

18. Canada may wish to reserve the right to revise its initial order:

(a) What is a reasonable number of weeks following the designated trigger event within which Canada may adjust (either up or down) its initial order?

(b) What is a reasonable percentage by which Canada should be allowed to adjust (either up or down) its initial order?

(c) Are there specific circumstances only under which Canada should be permitted to adjust its PIV order? If yes, please provide details.

19. Canada may reserve the right to require that some of its final order be held as bulk antigen, or as filled but unlabeled product. If needed, Canada would then require that it be filled and packaged as appropriate, If not needed this vaccine could be directed to other markets. What is you policy on this type of order arrangement? Please provide details.

20. Canada may reserve the right to donate PIV that has been ordered but that is surplus to Canada's needs (whether delivered to Canada or still held by the Contractor). What is your policy on donation of PIV by Canada, or by the Contractor on behalf of Canada (i.e. under what conditions; to whom; in what quantities)?

21. Canada may reserve the right to sell PIV purchased by, but surplus to the needs of Canada and may require the Contractor to assist in this endeavour. What is your policy on the sale by Canada, or by the Contractor on behalf of Canada of PIV (under what conditions; to whom; in what quantities)?

Vaccine Production "Accelerators"

Facilitating the earliest possible access to a vaccine against a pandemic influenza virus strain is critical to minimizing the resultant morbidity and mortality. Recognizing that the timelines associated with traditional production technologies for PIV are lengthy, Canada is interested in exploring strategies that could be included in future contracts to accelerate the availability of PIV. A number of possible "accelerator" Contractor activities are provided below:

i. Production and storage of virus master and working "seed banks" for influenza virus strains of pandemic potential;

ii. Development of an in-house capacity to produce reference reagents for a pandemic vaccine in the event in a delay in accessing these reagents from a WHO Collaboration Centre;

iii. Production of clinical trial lots of vaccines for influenza virus strains of pandemic potential;

iv. Undertaking clinical trials (phase I and phase II) of interest to Canada on vaccines for influenza virus strains of pandemic potential; and

v. Production and storage of stockpiles of vaccines for influenza virus strains of pandemic potential.

For each of these proposed activities, please respond to the following questions:

22. Do you have prior experience with this activity for pandemic preparedness (i.e. under contract with other governments)? If yes, please provide details. If no, is the proposed activity feasible and of interest to you as a manufacturer?

23. What do you consider to be the benefits of this activity to Canada, if any (e.g. time savings; knowledge generation)? Please provide details.

24. What would be the approximate cost associated with this activity?

25. Could this activity be undertaken at the same time as seasonal influenza vaccine production? If no, what would the approximate timeline be for undertaking this activity (i.e. what would the "window of opportunity" for undertaking this activity in a calendar year)?

26. In addition to the accelerator activities proposed, are there other activities that Canada should consider for inclusion in future contracts that could reduce the time line for accessing a pandemic vaccine?

Introduction of New Technology

27. Canada has an interest in ensuring that new technologies beneficial to Canada can be introduced as quickly as possible into the Canadian market. How would you suggest that the introduction of new influenza vaccine technologies be handled during the period of future PIV Preparedness and Supply Contracts?

Objectives of the Secondary Contract

Originally intended solely as a back-up to the Primary Contract to ensure access to vaccine for priority populations in the event of production challenges or delays in supply from the Primary Contractor, Canada's Secondary Contract(s) may also be used to meet the following objectives:

i. Providing Canada with access to additional vaccine in parallel to deliveries from the Primary Contractor to increase early availability of vaccine for Canadians;

ii. Providing Canada with access to alternative influenza vaccine technologies (to that provided by the Primary Contractor), or to vaccines targeted to specific priority populations;

iii. Providing Canada with earlier access (i.e. in advance of vaccine from the Primary Contractor) to a quantity of vaccine for use in vaccinating certain high priority groups; and

iv. Driving innovation by acting as an incentive to develop new vaccine technologies and/or domestic production capacity.

28. What do you see as the primary benefits to Canada of the Secondary Contract(s)? What attributes does your company offer that should be taken into considered by Canada in developing a Statement of Work for future Secondary Contracts?

Number of Secondary Contracts

29. Canada may wish to award more than one Secondary Contract in order to achieve some of the objectives suggested above. If more than one Secondary contract was awarded, what should the minimum purchase commitment be under each contract (i.e. what is the minimum quantity that Canada should be required to order if an option to purchase vaccine under the Secondary Contract(s) was exercised)?

Evaluation of PIV Suppliers

30. A competitive process will be followed for both the Primary and Secondary Contracts, if circumstances permit. In addition to price, how should the following factors be considered in the evaluation of pandemic vaccine suppliers? Which factors does your company consider to be the most important and why?
Note that some of these factors will be deemed to be mandatory for the Primary Contract.

(a) Domestic capacity (production of antigen; filling and packaging of antigen if produced off-shore, production of adjuvant (if applicable), stockpiling of adjuvant (if applicable) if produced off-shore);

(b) PIV manufacturing timeline (time from identification of a pandemic virus strain to commercial availability of first lot for delivery to Canada;

(c) Priority access for Canada;

(d) Security of supply (e.g. protection against embargoes; financial contract security);

(e) Access to technologies different from that offered by the other pandemic supplier(s);

(f) Ability to offer more than one PIV (e.g. a vaccine for the general population and a vaccine targeted to a specific cohort; vaccines produced using different production technologies);

(g) Flexibility in ordering (time to place initial order; ability to adjust (up or down) initial order);

(h) Ability to donate and / or sell unused doses;

(i) Product presentations (e.g. packaged such that re-distribution of vaccine in units of 10 doses can be done without the need for re-packaging); and

(j) Prior supply history for both seasonal and 2009 pandemic H1N1 vaccine (e.g. quantity and types of vaccine supplied, markets supplied, and timing and reliability of availability).

31. Are there other factors that Canada should consider in the evaluation of bids?

In addition to the information provided in response to the above questions, Respondents are welcome to provide any additional information that they wish to be taken into consideration by Canada in the PIV strategy review and update.

ANNEX C
SEASONAL AND PANDEMIC INFLUENZA VACCINE LANDSCAPE
QUESTIONS TO INDUSTRY

Respondents to this RFI are requested to provide input in response to the following questions.

Seasonal Influenza Vaccine Products (Current)

32. What seasonal influenza vaccines do you currently market in Canada or globally? Please describe the marketed products including:

(a) Approved indications for use (e.g. age indication) and any plans (including timelines) to change the approved indications;

(b) Formulation (e.g. trivalent vs. quadravalent; inactivated vs. live attenuated; adjuvanted vs. unadjuvanted; what adjuvant; etc.);

(c) Production technology(ies) used (e.g. egg based; cell based; recombinant; virus like particles expressed in plants; etc.);

(d) Route of administration (e.g. intramuscular, intranasal);

(e) Packaging formats available (e.g. single-dose; multi-dose; syringes or vials) and package sizes (e.g. singles, boxes of 10, etc.);

(f) The countries where the vaccine is licensed/authorized; and

(g) Any other information that you would like to share.

33. If a vaccine specified above is not currently authorized for sale in Canada are there plans to seek regulatory authorization in Canada?

(a) If yes, what is the proposed timeline for this?

(b) If no, why not? What factors would be considered in making the decision to seek authorization in Canada (e.g. likely access to a minimum share of the Canadian market; regulatory submission costs; pandemic preparedness contract in place; etc.)?

34. If you currently market a trivalent influenza vaccine in Canada, do you plan to discontinue this vaccine in the next five (5) years? If so, please provide details.

Seasonal Influenza Vaccine Products (Planned)

35. In the next five (5) years, what new seasonal influenza vaccines (including significant changes to existing vaccines) do you anticipate pursuing regulatory authorization for in Canada or globally? Please describe the anticipated products including:

(a) Proposed initial indications for use (e.g. age indication) and any plans (including timelines) to change the proposed initial indications;

(b) Formulation (e.g. trivalent vs. quadravalent; inactivated vs. live attenuated; adjuvanted vs. unadjuvanted; what adjuvant; etc.);

(c) Production technology(ies) used (e.g. egg based; cell based; recombinant; virus like particles expressed in plants; etc.);

(d) Route of administration (e.g. intramuscular, intranasal);

(e) Packaging formats proposed (e.g. single-dose; multi-dose; syringes or vials) and package sizes (e.g. singles, boxes of 10, etc.);

(f) The countries where licensure / authorization will be sought;

(g) Timeline for introduction; and

(h) Any other information that you would like to share.

36. If regulatory authorization in Canada will not be sought in the next five (5) years for a new vaccine, or for a significant change to an existing vaccine specified above, will authorization be pursued at a later date?

(a) If yes, what is the proposed timeline for this?

(b) If no, why not? What factors would be considered in making the decision to seek authorization in Canada (e.g. likely access to a minimum share of the Canadian market; submission costs; pandemic preparedness contract in place; etc.)?

Pandemic Influenza Vaccine Products

37. If you manufactured and supplied pandemic H1N1 (pH1N1) vaccine in 2009-2010:

(a) What types of pH1N1 vaccines did you manufacture (e.g. adjuvanted vs. unadjuvanted; using what production technology; etc), and in which countries did you manufacture and license / authorize these vaccines?

(b) Approximately how many doses of each type of pH1N1 vaccine manufactured were produced / sold?

(c) What was the approved indication for use of each vaccine?

(d) What were the available packaging formats (e.g. minimum package size) for each vaccine?

38. If you have manufactured pre-pandemic influenza vaccine (i.e. for influenza virus strains of pandemic potential) for stockpiling purposes:

(a) What influenza virus strain was included in the vaccine?

(b) What production platform was used to produce the vaccine (e.g. egg-based, cell-based, recombinant; virus like particles expressed in plants; etc.)?

(c) Was the pre-pandemic vaccine adjuvanted? With what adjuvant?

(d) In what countries are the pre-pandemic vaccines licensed / authorized?

(e) Do you have any plans to seek regulatory authorization of a pre-pandemic vaccine in Canada?

i. If yes, what is the timeline?
ii. If no, why not? What factors would be considered in making the decision to seek authorization in Canada?

Seasonal and Pandemic Influenza Vaccine Production, Filling, and Supply Capabilities (Current and Planned)

39. With respect to your current and planned influenza vaccine antigen production, filling, and supply capabilities:

(a) What is the approximate current total global production capacity for each of your production technologies (please specify the production period - e.g. number of months of production - for which this total refers as well as any other relevant assumptions used) for:

i. seasonal vaccine (specify trivalent or quadrivalent); and
ii. monovalent pandemic vaccine?

(b) In which country(ies) is this antigen production capacity located? Is filling and packaging done at the same location, or in the same country? If not, where is your packaging and filling capacity located?

(c) If an adjuvant is included in your pandemic vaccine, in which country(ies) is the adjuvant manufactured? Filled and packaged (if not pre-mixed with vaccine antigen)?

(d) Do you have existing pandemic vaccine supply arrangements (e.g. an advance purchase agreement) with the country in which your production capacity is located? If yes, does this include a commitment to priority access by the government of this country?

(e) To what extent (e.g. what percentage) is your current production capacity for monovalent pandemic vaccine committed through existing pandemic vaccine advance purchase agreements? How far into the future is this production capacity committed?

(f) What are your plans (if any) for the expansion of your influenza vaccine production capacity (inclusive of filling and packaging) for either existing or new production technologies in the next five (5) years? By how much will capacity be increased and where will the new capacity be located?

(g) Do you have plans to develop new production capacity in Canada, or are you considering the possibility of developing new capacity in Canada?

i. If yes, using what production technology and what is the anticipated timeline for this?

ii. If no, what factors would be considered in making a decision to build or to expand antigen production capacity in Canada?

40. For egg-based production specifically: Are there process improvements / enhancements that are anticipated to be implemented in the next two to five years specifically aimed at:

i. Reducing the overall production timeline; and/or
ii. Improving vaccine effectiveness?

Please provide any information that you are able to share on the proposed process improvements / enhancements.

In addition to the information provided in response to the above questions, respondents are welcome to provide any additional information that they wish to be taken into consideration by Canada in the PIV strategy review and update