Public Works and Government Services Canada | Travaux publics et Services gouvernementaux Canada

RETURN BIDS TO:
RETOURNER LES SOUMISSIONS À:

Drugs, Vaccines and Biologics Division
10 Wellington - 5th floor
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LETTER OF INTEREST
LETTRE D'INTÉRÊT

Title - Sujet RFI Antivirals	
Solicitation No. - N° de l'invitation E60PH-20RFIA/A	**Date** 2020-02-05
Client Reference No. - N° de référence du client E60PH-20RFIA	**GETS Ref. No. - N° de réf. de SEAG** PW-$$PH-884-78446
File No. - N° de dossier ph884.E60PH-20RFIA	**CCC No./N° CCC - FMS No./N° VME**
Solicitation Closes - L'invitation prend fin **at - à 02:00 PM** **on - le 2020-03-05**	**Time Zone** **Fuseau horaire** Eastern Standard Time EST
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 (613) 327-0456 ( )	**FAX No. - N° de FAX** ( ) -
Destination - of Goods, Services, and Construction: **Destination - des biens, services et construction:**	

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
Terrasses de la Chaudière 5th Floo
10 Wellington Street
Gatineau
Quebec
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Canada

REQUEST FOR INFORMATION (RFI)

CANADA'S PANDEMIC INFLUENZA ANTIVIRAL STOCKPILE STRATEGY

Section I:

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

Antiviral drugs are a key component of pandemic influenza preparedness because, until a vaccine becomes available, they are the only pharmaceutical intervention available during an initial pandemic response.

Since 2004, Canadian federal, provincial and territorial (F/P/T) governments have been stockpiling antivirals to help ensure pan-Canadian equitable access to a secure, government-controlled supply of antivirals for use in a pandemic. The goal of antiviral stockpiling is to support the broader Canadian pandemic goals of minimizing serious illness and overall deaths, and minimizing societal disruption.

In Canada, antivirals are held in two government stockpiles: the National Antiviral Stockpile (NAS) and the National Emergency Strategic Stockpile (NESS). The NAS is the collective name for the antiviral stockpiles held and managed by each of the thirteen provinces and territories (P/Ts). The NAS is intended to provide antivirals for all eligible persons living in Canada including federal populations within a jurisdiction (such as on reserve First Nations and correctional facility inmates). In July 2017, F/P/T governments, via the Pan-Canadian Public Health Network Council (PHNC), approved updated recommendations for the use, composition and size of the NAS. These recommendations include:

- a NAS size range of from 17.14% to 23.19% population coverage; and
- a stockpile composition consisting of: from 75 – 82% of oseltamivir; and from 18 – 25% of other antivirals with a resistance profile that differs from oseltamivir.

The NESS antiviral stockpile is held and managed by the Public Health Agency of Canada (PHAC) and is intended to provide surge capacity in support of the P/Ts' response in a pandemic. The recommended target size for antivirals held in the NESS is equivalent to 2.5% of population coverage.

For more information on Canada's overall antiviral strategy, please refer to the Antiviral Annex of the Canadian Pandemic Influenza Preparedness Planning Guidance for the Health Sector.

With efforts underway to replenish and, as needed, to increase the size of antiviral stockpiles, F/P/T governments are working together to develop a long-term strategy for sustainable antiviral stockpile procurement and management with the intention of achieving three main objectives:

1. Reducing the overall costs to F/P/T governments of purchasing, maintaining and managing the stockpiles;
2. Reducing the overall wastage of antivirals held in stockpiles but not used in a pandemic response; and
3. Addressing the logistical challenges of long-term storage; inventory tracking; managing stock rotation; and efficient intra- (and potentially inter-) jurisdictional distribution of antivirals.

To assist in these activities, Public Services and Procurement Canada (PSPC) is seeking industry input on behalf of the Government of Canada (GoC) and the P/T governments on a series of questions / areas of interest as set out in Section II, below.

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. 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) **Time and Place for Submission of Responses**: Suppliers should submit an electronic copy of their response to this RFI by 14:00 EST on March 5, 2020 to the Contracting Authority (refer to item 6).

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

5. Follow-Up Teleconferences/Communications

(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 will be held between end of March 2020 and early April 2020.

(b) Respondents who have provided notice of their interest in participating in a follow-up teleconference may be asked to provide a presentation and/or additional information on key areas of interest. Should a presentation be requested, Respondents should provide an electronic copy to the Contracting Officer at least five (5) business days in advance of the scheduled teleconference.

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

(c) 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 via email to the PSPC Contracting Authority identified below:

Sharon Joy
Supply Specialist
Public Services & Procurement Canada
10 Wellington - TDLC
Gatineau, QC
E-mail Address: sharon.joy@pwgsc-tpsgc.gc.ca
Telephone: (613)327-0456

7. Follow-up with RFI 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 antiviral procurement contracts 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.

Section II:

While industry is requested to respond to the specific questions below, it is also recognized that industry has expertise and experience that could contribute greatly to the development of innovative solutions to meet the objectives set out in Section I. As such, Respondents to this RFI are encouraged to provide additional information or to suggest alternative approaches to those set out herein.

A. Current and Planned Influenza Antiviral Portfolio (Inclusive of Status of Regulatory Authorization in Canada)

1. Please provide up to date information on the antivirals for which you have received authorization from Health Canada (HC) to market in Canada for each of the items listed below. Where there is a difference between treatment and prevention/prophylaxis use (e.g. indications, dosage, etc.), please provide information below for each use:

Finished product:

a. Drug Identification Number (DIN);
b. Brand (Product) Name;
c. Medicinal Ingredient(s);
d. Route(s) of administration;
e. Dosage form(s) (e.g. capsules, tablets, etc.) and strength(s);
f. Packaging format(s) and number of units per format (e.g. bottles, blister packs, inhalers)
g. Packaging presentations (notably, number of primary unit packs per case/carton; number of cases/cartons per pallet; dimensions of: primary unit packs; cases/cartons and pallets; and weight of fully loaded pallet;
h. Shelf-life for the finished product (i.e., indicating (i) the shelf-life authorized by Health Canada, and (ii) the remaining shelf-life that can be assured once delivered to the customer – assuming that orders are filled from new production);
i. Storage requirements for the finished product (e.g., “Store at controlled room temperature (15-30°C)” or as applicable).
j. In use periods (e.g. for concentrated solutions, emergency compounding of oral suspensions (if applicable)); and
k. Indications for use (e.g. effective against which influenza strains, approved age range);
l. Dosage and administration (i.e., per course: number and frequency of doses, duration);

Active Pharmaceutical Ingredient (API):

a. Re-test period for the bulk Active Pharmaceutical Ingredient (API);

b. Storage requirements for the API (e.g., “Store at controlled room temperature (15-30°C)” or as applicable).

2. For those antivirals identified above, are there any changes planned (e.g. package formats, dosage forms, indications, etc.) in the next five (5) years?

a. If yes, please provide details on planned changes.
b. If yes, please provide anticipated timeline for these changes including:

i. Actual or planned date for submission to HC (if HC approval will be necessary);
ii. Anticipated date for regulatory approval by HC (if HC approval will be necessary); and
iii. Anticipated date to introduce the change into the Canadian market.

3. With respect to antiviral shelf life for finished products, or re-test period for bulk API specifically, please provide details on any activities underway or planned for extending the HC approved shelf life, or re-test period of your antiviral(s), including the new shelf life, or new re-test period, that will be sought and the expected timelines for achieving this target. If your plans include a phased approach, please provide details on this approach.

4. Would you (and under what conditions) be prepared to generate accelerated (versus real-time) stability data for the bulk API or for the finished product that could be used to support an extension of the re-test period (for the bulk API) or shelf life (for the finished product) - recognizing that the longer re-test period or shelf life obtained would apply to new production of antivirals only?

5. Do you have plans to seek HC authorization for new antiviral(s) not currently marketed by your company in Canada?

6. If yes to Question 5, please provide details on the new antivirals (as per Question 1 above) and on the anticipated timeline for obtaining regulatory approval in Canada and for marketing these products in Canada.

7. For new antivirals (per Q5 and Q6), please provide information in which countries these antivirals are currently licensed for sale and via what regulatory pathway (e.g. standard, accelerated or an alternate pathway) they were licensed in those countries.

B. Current and Planned Production Capacity / Delivery Time lines

8. For each of the antivirals that you currently market or plan to market in Canada, please provide information on your current production capacity, i.e. the approximate number of capsules / tablets and treatment courses produced per month.

9. Is any of your existing production capacity currently committed through advance purchase agreements that would result in the need to prioritize production and supply to specific customers at the time of an influenza pandemic? What is the duration of this commitment?

10. If yes to Question 9, if Canada were to pursue an advance purchase agreement for access to production capacity, do you have current or future production capacity that could be set aside for Canada and, if so, how much capacity would you be willing to commit (in terms of monthly production of capsules / tablets and treatment courses)? When would this capacity be available to Canada under such an agreement? (see also Section F below)

11. Where are your production and storage facilities located ~~(~~including sites for: production of the API; product formulation (e.g. into capsules, tablets, etc.); packaging and labelling; and finished product storage~~)~~?

12. Do you have plans to increase, decrease or relocate production capacity (for bulk API or product formulation), or introduce significant production process changes?

13. If yes to Question 12:
:

a. By how much will capacity increase or decrease?
b. If moving production, where will the new production facilities be located?
c. If introducing production process changes: will this result in significant downtime in production? If yes, for how long?
d. What is the anticipated timeline for this change?
e. At which production facility(ies) will the change occur?

14. Do you have any current plans for developing API production or product formulation (e.g. encapsulation) capacity in Canada (either directly or via a sub-contractor)?

15. If yes to Question 14, what is the anticipated timeline for these plans?

16. Do you have any current plans for developing final packaging and labelling capacity in Canada (either directly or via a sub-contractor)?

17. If yes to Question 16, what is the anticipated timeline for these plans?

18. What is your current capacity to store antivirals in Canada on behalf of customers (either in-house or via a sub-contractor)?

19. Do you have any current plans to expand storage capacity in Canada (either directly or via a subcontractor)?

20. If yes to Question 19, what is the anticipated timeline for implementing these plans?

21. If you have no current plans, but do have an interest in locating or expanding in Canada either: production of API; product formulation; packaging and labelling; or storage capacity, what factors or conditions do you consider to be critical in making a decision to do so?

22. What is the minimum timeline from receipt of a firm order to final delivery to a customer for:

a. Antivirals that are to be produced inclusive of API production; and
b. Antivirals that are to be formulated from existing API?

23. What factors impact the delivery timeline in each of the above scenarios?

C. Packaging Enhancements for Long-Term Storage / Effective Deployment of Stockpiles

24. What packaging and labelling options do you currently employ, or would you be prepared to introduce, that could enhance long-term storage; efficient deployment; and inventory tracking of antivirals? These could include (but are not limited) to the following:

a. Package durability;
b. Protection against the elements (e.g. plastic sleeves to protect against light; water);
c. Packaging aimed at reducing the overall storage “footprint” of stockpiles;
d. Packaging in bottles vs. blister packs;
e. Clear labelling (e.g. for inventory management);
f. Bar coding for efficient inventory tracking (type and location of bar codes);
g. Other

25. While every effort is made to ensure that antivirals are maintained under recommended storage conditions at all times, the potential exists for excursions or breaches to occur during deployment of product (i.e., during transportation or while in storage in front-line facilities). Such breaches could lead to significant product wastage. Do you have available, or would you be prepared to generate data on the stability of your antiviral product(s) outside of the recommended storage conditions (e.g. duration

of excursion, temperature range of an excursion) that could be used to assess the continued viability of the antiviral following an excursion outside of recommended storage conditions? If yes, please provide details.

D. Contract Terms and Conditions

26. In order to achieve stability and predictability in accessing antivirals over the long-term, the GoC and P/Ts may pursue multi-year contracts through a mix of firm (i.e. mandatory) and optional (i.e. contract term extensions exercisable at the discretion of the GoC) contract years. Do you have a preference for the length of a procurement contract including:

a. Number of firm contract years included; and
b. Number, and length, of options, exercisable at the discretion of Canada to extend the contract?

27. Do you have any limitations on the number of firm years or of option years to which you could commit under Contract, and, if yes, what are these limitations and what is the reason for these limitations?

28. Recognizing that users would have differing needs in each contract year, flexibility in the total quantity of antiviral ordered per year is an important element of a multi-year contract. What requirements or obligations do you foresee as being a necessary component of a contract while still providing such flexibility to contract participants?

29. Two approaches are under consideration for bid evaluation when comparing antivirals with a different HC approved shelf-life (see also Section F). Please provide your comments or suggestions regarding the approaches below, as well as noting any other factors that should be taken into consideration for future procurement activities:

a. Set a mandatory minimum acceptable shelf-life based on **SHORTEST** shelf-life for antivirals authorized in Canada and evaluate bids on a per unit price per year of HC approved shelf-life including estimated costs to contract participants for destroying and replacing expiring stockpiles; or

b. Set a mandatory minimum acceptable shelf-life based on the **LONGEST** shelf-life for antivirals authorized in Canada and require Bidders to offer a strategy for ensuring that contract participants would have uninterrupted access to the antivirals purchased for the duration of the minimum acceptable shelf-life (e.g. vendor managed storage, vendor managed stock rotation of antivirals maintained at participants' storage facilities). Bids would be evaluated based on a per unit price inclusive of all costs associated with the proposed strategy.

E. Contract Pricing

30. Volume based pricing (i.e. prices based on the total quantity of antivirals purchased is an important element of a long-term contract).

a. Would you be prepared to offer volume based pricing based on the quantity purchased over the entire period of a contract?

b. At what purchase volumes would price reductions apply?

c. While it is understood that industry may be reluctant to provide prices outside of a formal Request for Proposals, approximately what percentage discount could apply for each of the volume thresholds provided in response to Question 30b?

d. In order to ensure that all contract users obtain the same price regardless of when they place their order under a contract, would you be prepared to offer a rebate / credit to users for early orders to reflect the new, lower price based on an increase in the total volume purchased? If

yes, please provide details of how your proposed approach to compensate early purchasers could be applied.

31. In addition to price discounts based on purchase volumes, would you be prepared to offer price discounts based on the duration of a contract (i.e. lower prices for a longer firm-year contract)? If yes, approximately what size of discount could be available for what contract period?

32. Are there other, innovative or notable approaches to contract pricing and / or payment that you could suggest that would be interest to the GoC and P/Ts?

F. Management of Stockpiles / Reducing Wastage Due to Expiry

33. The GoC and P/Ts are interested in innovative strategies aimed at enhancing the efficient management of stockpiles and reducing the costs and logistical challenges of stock rotation required due to product expiry. Please indicate your interest in offering the following, and provide details on how they could be implemented:

a. Vendor stored and managed stockpiles of finished product. (e.g. Stored where? Accessed how? Approximate cost? Contingency plans to assure access if held outside of Canada?)

b. Purchaser stored but vendor managed stockpile rotation inclusive of collection and destruction of expired stock, and replacement with new stock. (e.g. Frequency of rotation? Approximate cost?)

c. Vendor stored stockpiles of bulk API for filling / encapsulation when and if requested. (e.g. Stored where? Accessed how? Approximate cost? Contingency plans to assure access if stored outside of Canada? Obligations to take delivery of final product? Timeline for delivery from order?)

d. Reservation of production capacity (with or without the advance purchase of bulk API) to allow for ordering and delivery of a proscribed quantity of antivirals within a specified and contractually mandated period. (e.g. Approximate cost? Timeline for delivery from order? Contingency plans to assure access if produced outside of Canada?).

e. Use of products sourced from outside of Canada with international labeling (with necessary HC regulatory approvals, e.g. via Health Canada's Special Access Programme (SAP), or Access to Drugs in Exceptional Circumstances) to allow options in supplying new antivirals quickly if needed in an emergency.

34. Do you have existing or prior stockpile arrangements / strategies in place with other countries or organizations? If so, what arrangements / strategies are, or have been, employed?

35. Donations of antivirals within a specified period of their existing expiry date may be a means of reducing wastage, if such donations could be coordinated. Does your company have any prior experience with donating antivirals, and would you be prepared to coordinate, and / or contribute to such an activity?

36. P/Ts may elect to hold antivirals beyond their expiry date for possible use as a last resort should there be no antivirals within expiry date immediately available at the time of an influenza pandemic, Please indicate your interest in offering the following with respect to expired antiviral stockpiles:
   a. Storage?
   b. Distribution?
   c. Stability testing and/ or provision of data from stability studies and/or provision of information necessary to support third party stability testing?

G. Other Information of Interest:

37. Respondents to this RFI are encouraged to provide any additional information beyond that requested above, or to suggest alternative approaches to those specifically set out herein that they would like the GoC and P/Ts to take into consideration in future antiviral procurement planning.