



RETURN BIDS TO:

RETOURNER LES SOUMISSIONS À:

Bid Receiving - PWGSC / Réception des soumissions -
TPSGC
10 Wellington Street
Gatineau
Québec
K1A 0S5

**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
Terrasses de la Chaudière 5th Floor
10 Wellington Street
Gatineau
Quebec
K1A 0S5

Title - Sujet Cisatracurium	
Solicitation No. - N° de l'invitation E60PH-20CTRA/B	Amendment No. - N° modif. 001
Client Reference No. - N° de référence du client E60PH-20CTRA	Date 2020-05-15
GETS Reference No. - N° de référence de SEAG PW-\$SPH-893-78719	
File No. - N° de dossier ph893.E60PH-20CTRA	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2020-05-27	
Time Zone Fuseau horaire Eastern Daylight Saving Time EDT	
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: Vettoretti(ph893), Eric	Buyer Id - Id de l'acheteur ph893
Telephone No. - N° de téléphone (613) 286-6065 ()	FAX No. - N° de FAX (819) 956-8303
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

This additional document is an amendment to the original Request for Information in order to update the questionnaire with the following revised tables.

Supply Questions <i>ONLY additional supply (Not needed to meet current demand or proposed to mitigate a current shortage)</i>	Solution for Injection	Other Dosage Form (please provide specifications)
1. Specify the <u>unit strength</u> , <u>vial size</u> , and <u>pack size</u> (e.g. 2mg tablets, bottles of 100)		
2. The additional quantity available by June 30, 2020.		
3. The additional monthly quantity available July 1, 2020 and beyond.		
4. Estimated unit price (per XXX) of finished product, including to deliver to final destination.		
5. Are you currently supplying this product to the Canadian market? If yes, answer a-d below. If no, answer 6a-f below.		
a. Confirm that the quantities identified are in excess to supply that has already been earmarked.		
b. Do you have capacity to increase production of the product (Yes/No) If yes, please specify possible quantity/ month and anticipated lead time for availability of product once a contract is finalized. Specify conditions, if any.		
c. Provide details of the market		

authorization (i.e. DIN(s))		
d. Provide the Drug Establishment License number of the Canadian manufacturer or importer, as the case may be.		
6. If product is not authorized for sale in Canada, a. Do you currently have a submission with Health Canada? If Yes, please specify the type of authorization being sought (e.g. NOC, exceptional importation and sale) and include a submission number, if applicable.		
b. Provide a list of countries in which the product is authorized for sale, if applicable As an attachment, provide the product labelling, if available		
c. Is the product fabricated outside of Canada? If yes, has a Canadian importer been identified? Provide the Drug Establishment License number of the importer, if applicable.		
d. Provide information about the product fabrication building(s) (Country name, Company name, Building address, Drug Establishment License number, if applicable)		
e. Provide information about the product Packing/Labelling		

Building(s) (Country name, Company name, Building address)		
f. Provide information about the product Testing Building(s) (Country name, Company name, Building address)		

Vendor Managed Inventory Questions	Solution for Injection	Other Dosage Form (please provide specifications)
1. The total quantity available that could be vendor held and managed (in Canada) on behalf of the Government of Canada for up to 24 months (inventory must be rotated out to ensure a minimum of 14 months of remaining shelf life).		
2. Storage location		
3. Estimated monthly cost for vendor held and managed inventory (flat rate or per (e.g., units, package, pallet, etc. – please specify) of finished product (if applicable).		
4. Expected hours of operation for shipment requests are Monday to Friday during normal business hours.		
5. Expected turnaround time for shipment requests (from time request is received to the shipment leaving the depot) is one business day.		
6. Minimum order size when shipping out of vendor held inventory (if applicable)		

API Questions (If conditional to availability)	Solution for Injection	Other Dosage Form (please provide specifications)
1. The quantity of API available immediately (i.e. within 7 days) both in metric tons and the approximate number of finished units that could be produced.		
2. How many units are produced per		

metric tonne of bulk API?		
3. What is the shelf life of bulk API?		
4. What is the production time required to deliver finished products from the date of request to produce from bulk API?		
5. The additional quantity of API available monthly, July 1, 2020 and beyond		
6. Estimated price of API per metric tonne		
7. Estimated additional cost per unit to manufacture from bulk API to finished product, including delivery to final destination		
8. Estimated monthly cost for vendor held and managed inventory (per metric tonne) of API (if applicable)		
9. API Fabrication Building (Country name, Company name, Building address, DEL Number if available)		
10. API Product Packing/Labelling Building (Country name, Company name, Building address, DEL Number if available)		
11. API Product Testing Building (Country name, Company name, Building address, DEL Number if available)		

Please specify any caveats of conditions that would apply to the questions provided above. Additionally, for the inventories (units and API) described above, identify what quantities are currently held domestically and what is contingent on being imported into Canada.