National Defence
National Defence Headquarters
Ottawa, Ontario
K1A 0K2

Défense nationale
Quartier général de la Défense nationale
Ottawa (Ontario)
K1A 0K2

REQUEST FOR PROPOSAL / DEMANDE DE PROPOSITION

RETURN BIDS TO / RETOURNER LES SOUMISSIONS À:

Director Services Contracting 3
Attention: Safiya Motala, D Svcs C 3-5-4
By email: safiya.motala@forces.gc.ca

Proposal To: National Defence Canada
We hereby offer to sell to Her Majesty the Queen in right of Canada, in accordance with the terms and conditions set out herein, referred to herein or attached hereto, the goods and services listed herein and on any attached sheets at the price(s) set out therefore.

Proposition à : Défense nationale Canada
Nous offrons par la présente de vendre à Sa Majesté la Reine du chef du Canada, aux conditions énoncées ou incluses par référence dans la présente et aux annexes ci-jointes, les biens et services énumérés ici et sur toute feuille ci-annexée, au(x) prix indique(s).

Title / Titre:
Doxycycline Hyclate for Injection, 100mg

Solicitation No / No de l'invitation:	**Amendment No / No de la modification:**
W6369-22-A043	1

Date of Amendment / Date de la modification:
6 October 2021

Address Enquiries to – Adresser toutes questions à:
Safiya Motala, D Svcs C 3-5-4
safiya.motala@forces.gc.ca

Telephone No. / N° de téléphone:	**FAX No / No de fax:**

Destination:
See herein

Instructions:
Municipal taxes are not applicable. Unless otherwise specified herein all prices quoted must include all applicable Canadian customs duties, GST/HST, excise taxes and are to be delivered Delivery Duty Paid including all delivery charges to destination(s) as indicated. The amount of the Goods and Services Tax/Harmonized Sales Tax is to be shown as a separate item.

Instructions:
Les taxes municipales ne s'appliquent pas. Sauf indication contraire, les prix indiqués doivent comprendre les droits de douane canadiens, la TPS/TVH et la taxe d'accise. Les biens doivent être livrés «rendu droits acquittés», tous frais de livraison compris, à la ou aux destinations indiquées. Le montant de la taxe sur les produits et services/taxe de vente

Solicitation Closes / L'invitation prend fin:

At / à :

02:00 PM Eastern Daylight Time (EDT)

On / le :

9 November 2021

Delivery required / Livraison exigée:	**Delivery offered / Livraison proposée:**
See herein	

Vendor Name and Address / Raison sociale et adresse du fournisseur:

Name and title of person authorized to sign on behalf of vendor (type or print) / Nom et titre de la personne autorisée à signer au nom du fournisseur (caractère d'imprimerie):

Name / Nom: _____ **Title / Titre:** _____

Signature: _____ **Date:** _____

Canada

National Defence

National Defence Headquarters
Ottawa, Ontario
K1A 0K2

Défense nationale

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Ottawa (Ontario)
K1A 0K2

AMENDMENT 1 TO SOLICITATION NUMBER W6369-22-A043 IS RAISED TO:

1. Modify all translated references of “Hyclate de doxycycline injectable, 100 mg” in the French version of Request for Proposal (RFP) #W6369-22-A043 to “Injectable Doxycycline Hyclate, 100mg”;

2. Update the table of contents in the English version of the RFP #W6369-22-A043 to include Annex A – Statement of Requirement and Annex B – Basis of Payment, and to update the page numbers; and

3. Publish a revised English and French version of RFP #W6369-22-A043.

ALL OTHER TERMS AND CONDITIONS REMAIN THE SAME.

National Defence | Défense nationale

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PART 1 - GENERAL INFORMATION

1.1 Security Requirements

A. There are no security requirements for this bid solicitation.

1.2 Requirement

A. The requirement is detailed under Article 6.2– Statement of Requirement of the resulting contract clauses.

1.3 Debriefings

A. Bidders may request a debriefing on the results of the bid solicitation process. Bidders should make the request to the Contracting Authority within 15 working days from receipt of the results of the bid solicitation process. The debriefing may be in writing, by telephone or in person.

1.4 Trade Agreements

A. The requirement is subject to the provisions of the Canadian Free Trade Agreement (CFTA), the Canada-Colombia Free Trade Agreement, the Canada-Honduras Free Trade Agreement, the Canada-Panama Free Trade Agreement, the Canada-Korea Free Trade Agreement (CKFTA), the Canada-Peru Free Trade Agreement, the Canada-European Comprehensive Economic and Trade Agreement (CETA), the World Trade Organization - Agreement on Government Procurement (WTO-AGP), the Canada - Ukraine Free Trade Agreement (CUFTA), the Canada - Chile Free Trade Agreement (CCFTA), and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

PART 2 - BIDDER INSTRUCTIONS

2.1 Standard Instructions, Clauses and Conditions

A. All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the *Standard Acquisition Clauses and Conditions (SACC) Manual* (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

B. Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the clauses and conditions of the resulting contract.

C. The 2003 (2020-05-28), Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation, with the following modification(s):

(i) Section 02, Procurement Business Number, is deleted in its entirety;

(ii) Section 05, Submission of bids, subsection 2, paragraph d., is deleted in its entirety and replaced with the following:

d. send its bid only to the Department of National Defence location specified on page 1 of the bid solicitation or to the address specified in the bid solicitation.

(iii) Section 05, Submission of bids, subsection 2, paragraph e., is deleted in its entirety and replaced with the following:

e. ensure that the Bidder's name, return address, the bid solicitation number, and bid solicitation closing date and time are clearly visible on the bid; and

(iv) Section 05, Submission of bids, subsection 4, is amended as follows:

Delete: 60 days
Insert: 90 days

(v) Section 06, Late bids, is deleted in its entirety;

(vi) Section 07, Delayed bids, is deleted in its entirety and replaced with the following:

07 Delayed bids

1. It is the Bidder’s responsibility to ensure that the Contracting Authority has received the entire submission. Misrouting or other electronic delivery issues resulting in late submission of bids will not be accepted.

(vii) Section 08, Transmission by facsimile, is deleted in its entirety; and

(viii) Section 20, Further information, is deleted in its entirety.

2.2 Submission of Bids

A. Bids must be submitted only to the Department of National Defence (DND) by the date, time, and place indicated on page 1 of the bid solicitation.

B. Due to the nature of the bid solicitation, bids transmitted by facsimile will not be accepted.

2.2.1 Electronic Submissions

A. **Individual e-mails that may include certain scripts, formats, embedded macros and/or links, or those that exceed five (5) megabytes may be rejected by Canada's e-mail system and/or firewall(s) without notice to the Bidder or Contracting Authority.** Larger bids may be submitted through more than one e-mail. Canada will confirm receipt of documents. It is the Bidder's responsibility to ensure that their entire submission has been received. Bidders should not assume that all documents have been received unless Canada confirms receipt of each document. In order to minimize the potential for technical issues, bidders are requested to allow sufficient time before the closing date and time to confirm receipt. Bid documents **submitted** after the closing time and date will not be accepted.

2.3 Enquiries - Bid Solicitation

A. All enquiries must be submitted in writing to the Contracting Authority no later than 10 calendar days before the bid closing date. Enquiries received after that time may not be answered.

B. Bidders should reference as accurately as possible the numbered item of the bid solicitation to which the enquiry relates. Care should be taken by Bidders to explain each question in sufficient detail in order to enable Canada to provide an accurate answer. Technical enquiries that are of a proprietary nature must be clearly marked "proprietary" at each relevant item. Items identified as "proprietary" will be treated as such except where Canada determines that the enquiry is not of a proprietary nature. Canada may edit the question(s) or may request that the Bidder do so, so that the proprietary nature of the question(s) is eliminated and the enquiry can be answered to all Bidders. Enquiries not submitted in a form that can be distributed to all Bidders may not be answered by Canada.

2.4 Applicable Laws

A. Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario OR [insert the name of the province or territory].

B. Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

2.5 Bid Challenge and Recourse Mechanisms

A. Several mechanisms are available to potential suppliers to challenge aspects of the procurement process up to and including contract award.

B. Canada encourages suppliers to first bring their concerns to the attention of the Contracting Authority. Canada's BuyandSell website, under the heading "Bid Challenge and Recourse Mechanisms" contains information on potential complaint bodies such as:

- Office of the Procurement Ombudsman (OPO)
- Canadian International Trade Tribunal (CITT)

C Suppliers should note that there are **strict deadlines** for filing complaints, and the time periods vary depending on the complaint body in question. Suppliers should therefore act quickly when they want to challenge any aspect of the procurement process.

PART 3 - BID PREPARATION INSTRUCTIONS

3.1 Bid Preparation Instructions

A. Canada requests that Bidders provide their bid in separately bound sections as follows:

Section I: Technical Bid: one (1) soft copy in PDF format by e-mail;

Section II: Financial Bid: one (1) soft copy in PDF format by e-mail;

Section III: Certifications: one (1) soft copy in PDF format by e-mail; and

Section IV: Additional Information: one (1) soft copy in PDF format by e-mail.

3.2 Section I: Technical Bid

A. In their technical bid, Bidders should explain and demonstrate how they propose to meet the requirements and how they will carry out the Work.

3.3 Section II: Financial Bid

A. Bidders must submit their financial bid in accordance with the Pricing Schedule detailed in Attachment 1 to Part 3.

3.3.1 Electronic Payment of Invoices - Bid

A. If you are willing to accept payment of invoices by Electronic Payment Instruments, complete Attachment 2 to Part 3, Electronic Payment Instruments, to identify which ones are accepted.

B. If Attachment 2 to Part 3, Electronic Payment Instruments is not completed, it will be considered as if Electronic Payment Instruments are not being accepted for payment of invoices.

C. Acceptance of Electronic Payment Instruments will not be considered as an evaluation criterion.

3.3.2 Exchange Rate Fluctuation

A. The requirement does not offer exchange rate fluctuation risk mitigation. Requests for exchange rate fluctuation risk mitigation will not be considered. All bids including such provision will render the bid non-responsive.

3.4 Section III: Certifications

A. Bidders must submit the certifications and additional information required under Part 5.

3.5 Section IV: Additional Information

A. In Section IV of their bid, bidders should provide:

(i) A completed, signed, and dated Page 1 of this solicitation;

(ii) The name of the contact person (provide also this person's title, mailing address, phone number, and email address) authorized by the Bidder to enter into communications with Canada with regards to their bid, and any contract that may result from their bid;

(iii) For Part 2, article 2.5, Applicable Laws, of the bid solicitation: the province or territory if different than specified;

(iv) Any other information submitted in the bid not already detailed.

ATTACHMENT 1 TO PART 3 - PRICING SCHEDULE

A. The Bidder must complete this pricing schedule and include it in its financial bid.

B. The volumetric data included in this pricing schedule are provided for bid evaluated price determination purposes only. They are not to be considered as a contractual guarantee. Their inclusion in this pricing schedule does not represent a commitment by Canada that Canada's future usage of the services described in the bid solicitation will be consistent with this data.

C. The firm rates specified below includes all expenses that may need to be incurred to satisfy the terms of any contract that may result from its bid, including the total estimated cost of any travel and living expenses that may need to be incurred for the Work described in Annex A, Statement of Work of the bid solicitation.

D. Under any resulting contract, Canada will not accept travel and living expenses that may need to be incurred by the contractor for any relocation of resources required to satisfy its contractual obligations.

E. All prices and costs must be submitted in Canadian Dollars, Applicable Taxes excluded, DDP destination, freight charges included, Canadian customs duties and excise taxes included.

1. Pricing Schedule

Initial Requirement

Initial Requirement (Contract award to 31 March 2022)				
Item	**Item Description**	**Quantity**	**Unit Cost (CAD)**	**Total Cost (CAD)**
1	Doxycycline Hyclate for injection, 100mg	15,120 vials	$	$
			Total Evaluated Cost (Item 1)	$

Optional Requirement

Item	Option Period 1	Item Description	Quantity	Unit Cost (CAD)	Total Cost (CAD)
2	1 April 2022 to 31 March 2023	Doxycycline Hyclate for injection, 100mg	15,120 vials	$	$
				Total Evaluated Cost (Item 2)	$

Item	Option Period 2	Item Description	Quantity	Unit Cost (CAD)	Total Cost (CAD)
3	1 April 2023 to 31 March 2024	Doxycycline Hyclate for injection, 100mg	15,120 vials	$	$
				Total Evaluated Cost (Item 3)	$

Item	Option Period 3	Item Description	Quantity	Unit Cost (CAD)	Total Cost (CAD)
4	01 April 2024 to 31 March 2025	Doxycycline Hyclate for injection, 100mg	15,120 vials	$	$
				Total Evaluated Cost (Item 4)	$

Total Evaluated Cost (for bid evaluation purposes) = _____ **Items 1+2+3+4**

ATTACHMENT 2 TO PART 3 - ELECTRONIC PAYMENT INSTRUMENTS

A. The Bidder accepts to be paid by any of the following Electronic Payment Instrument(s):

( ) VISA Acquisition Card;

( ) MasterCard Acquisition Card;

( ) Direct Deposit (Domestic and International);

( ) Wire Transfer (International Only); and

( ) Large Value Transfer System (LVTS) (Over $25M).

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

4.1 Evaluation Procedures

A. Bids will be assessed in accordance with the entire requirement of the bid solicitation including the technical evaluation criteria.

B. An evaluation team composed of representatives of Canada will evaluate the bids.

4.1.1 Technical Evaluation

4.1.1.1 Mandatory Technical Criteria

The following mandatory technical criteria must be demonstrated with supporting documentation in the form of certifications which must be provided with the Bidder's response at the time of bid submission. Failure to submit supporting documentation that clearly demonstrates the mandatory technical criteria listed below, may render the bid non-compliant and will not be given further consideration. Any information proposed as options or additions to the work will NOT be evaluated.

<table>
<tr><th>#</th><th>MANDATORY TECHNICAL CRITERIA</th></tr>
<tr><td>M1</td><td>The Bidder must demonstrate that their proposed Doxycycline Hyclate for injection, 100mg has the following Certification and Compliance:

Must be manufactured in accordance with current Good Manufacturing Practices (cGMP) as set out in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7:https://database.ich.org/sites/default/files/Q7%20Guideline.pdf.

The documentation provided as part of the bid package must include the following:

a. A Certificate of Analysis representative of the batch or lot to be delivered. Certificates must be signed by the manufacturer's Quality Assurance department; and

b. Evidence of cGMP compliance. Evidence may include, but is not limited to, a valid Health Canada Establishment License or inspection reports from the regulatory national competent authority from Canada, the United States, the United Kingdom or a member state of the European Union within the last five (5) years.</td></tr>
<tr><td>M2</td><td>The Bidder must demonstrate that their proposed Doxycycline Hyclate for injection, 100mg meets all of the following specifications:

<table>
<tr><th>REQUIREMENT</th><th>SPECIFICATION</th></tr>
<tr><td>Active ingredient</td><td>Alpha-6-deoxy-5-oxytetracycline</td></tr>
<tr><td>Dose/strength (unit)</td><td>100 mg</td></tr>
<tr><td>Volume</td><td>10 – 50 mL</td></tr>
<tr><td>Dosage Form</td><td>Lyophilized powder for reconstitution</td></tr>
<tr><td>Route of Administration</td><td>Intravenous</td></tr>
</table>
</td></tr>
</table>

	Labelling	The contractor must provide a copy of the most up to date product labeling in English or French.
	Primary packaging	The primary packaging must include the product name, strength, lot/batch number, expiry date or date of manufacture.
	Secondary packaging	Any secondary packaging must include the product name, strength, lot/batch number, expiry date or date of manufacture.
	Physicochemical characteristics	Light yellow crystalline powder for reconstitution. Preservative-free.
	Shelf-life	The drug product must have a minimum shelf-life of 24 months from the date of manufacture.
	Sterility	Sterile
	The documentation provide by the Bidder, as part of their bid package, must include the following: • An executed Certificate of Analysis; • A copy of the package insert, product labelling and a picture of the product; and • The drug insert and packaging information must be in English or French.	
M3	The Bidder must provide the following documentation as part of the bid package: • Health Canada issued Notice of Compliance in accordance with Division 8 of the Canadian Food and Drug Regulations; or • A signed written attestation demonstrating their willingness to support an application to the Health Canada Special Access Program (SAP). The SAP application will be filed by the client, the Canadian Forces Health Services Group (CF H Svcs Gp).	

4.1.2 Financial Evaluation

A. The price of the bid will be evaluated as follows:

(i) Canadian-based bidders must submit firm prices, Canadian customs duties and excise taxes included, and Applicable Taxes excluded; and

(ii) Foreign-based bidders must submit firm prices, Canadian customs duties, excise taxes and Applicable Taxes excluded. Canadian customs duties and excise taxes payable by Canada will be added, for evaluation purposes only, to the prices submitted by foreign-based bidders.

B. Unless the bid solicitation specifically requires bids to be submitted in Canadian currency, bids submitted in foreign currency will be converted to Canadian currency for evaluation purposes. The rate given by the Bank of Canada in effect on the bid solicitation closing date, or on another date specified in the bid solicitation, will be applied as a conversion factor to the bids submitted in foreign currency.

C. Although Canada reserves the right to award the Contract either on an FOB plant or FOB destination, Canada requests that bidders provide prices FOB their plant or shipping point and FOB destination. Bids will be assessed on an FOB destination basis.

D. For the purpose of the bid solicitation, bidders with an address in Canada are considered Canadian-based bidders and bidders with an address outside of Canada are considered foreign-based bidders.

4.2 Basis of Selection - Lowest Evaluated Price, Mandatory Technical Criteria

A. A bid must comply with the requirements of the bid solicitation and meet all mandatory technical evaluation criteria to be declared responsive. The responsive bid with the lowest evaluated price will be recommended for award of a contract.

B. Should two (2) or more responsive bids achieve an identical lowest evaluated price, the earliest bid received based on the date and time stamp of the email, will be recommended for award of a contract.

PART 5 - CERTIFICATIONS AND ADDITIONAL INFORMATION

A. Bidders must provide the required certifications and additional information to be awarded a contract.

B. The certifications provided by Bidders to Canada are subject to verification by Canada at all times. Unless specified otherwise, Canada will declare a bid non-responsive, or will declare a contractor in default if any certification made by the Bidder is found to be untrue, whether made knowingly or unknowingly, during the bid evaluation period or during the contract period.

C. The Contracting Authority will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply and to cooperate with any request or requirement imposed by the Contracting Authority will render the bid non-responsive or constitute a default under the Contract.

5.1 Certifications Required with the Bid

A. Bidders must submit the following duly completed certifications as part of their bid.

5.1.1 Integrity Provisions - Declaration of Convicted Offences

A. In accordance with the Integrity Provisions of the Standard Instructions, all bidders must provide with their bid, **if applicable**, the Integrity declaration form available on the Forms for the Integrity Regime website (http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html), to be given further consideration in the procurement process.

5.2 Certifications Precedent to Contract Award and Additional Information

A. The certifications and additional information listed below should be submitted with the bid but may be submitted afterwards. If any of these required certifications or additional information is not completed and submitted as requested, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Failure to provide the certifications or the additional information listed below within the time frame specified will render the bid non-responsive.

5.2.1 Integrity Provisions - Required Documentation

A. In accordance with the section titled "Information to be provided when bidding, contracting, or entering into a real procurement agreement" of the *Ineligibility and Suspension Policy* (http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html), the Bidder must provide the required documentation, as applicable, to be given further consideration in the procurement process.

5.2.2 Federal Contractors Program for Employment Equity - Bid Certification

A. By submitting a bid, the Bidder certifies that the Bidder, and any of the Bidder's members if the Bidder is a Joint Venture, is not named on the Federal Contractors Program (FCP) for employment equity "FCP Limited Eligibility to Bid" list available at the bottom of the page of the Employment and Social Development Canada (ESDC) - Labour's website (https://www.canada.ca/en/employment-social-development/programs/employment-equity/federal-contractor-program.html#).

B. Canada will have the right to declare a bid non-responsive if the Bidder, or any member of the Bidder if the Bidder is a Joint Venture, appears on the “FCP Limited Eligibility to Bid“ list at the time of contract award.

PART 6 - RESULTING CONTRACT CLAUSES

The following clauses and conditions apply to and form part of any contract resulting from the bid solicitation.

ARTICLES OF AGREEMENT

6.1 Security Requirements

A. There is no security requirement applicable to the Contract.

6.2 Requirement

A. Contractor must provide the item(s) detailed under the Requirement at Annex A.

6.2.1 Optional Goods and/or Services

A. The Contractor grants to Canada the irrevocable option to acquire the goods, services, or both described at Annex A, Requirement, of the Contract under the same conditions and at the prices and/or rates stated in the Contract. The option may only be exercised by the Contracting Authority and will be evidenced, for administrative purposes only, through a contract amendment.

B. The Contracting Authority may exercise the option at any time before the expiry of the Contract by sending a written notice to the Contractor.

6.3 Standard Clauses and Conditions

A. All clauses and conditions identified in the Contract by number, date and title are set out in the *Standard Acquisition Clauses and Conditions (SACC) Manual* (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

6.3.1 General Conditions

A. 2010A (2020-05-28), General Conditions - Goods (Medium Complexity), apply to and form part of the Contract, with the following modification:

(i) Article 01, Interpretation, "Canada", "Crown", "Her Majesty" or "the Government", is deleted in its entirety and replaced with the following:

"Canada", "Crown", "Her Majesty" or "the Government"
means Her Majesty the Queen in right of Canada as represented by the Minister of National Defence and any other person duly authorized to act on behalf of that minister or, if applicable, an appropriate minister to whom the Minister of National Defence has delegated his or her powers, duties or functions and any other person duly authorized to act on behalf of that minister.

6.3.2 Warranty – Amendment to General Conditions 2010A

A. Section 09, paragraph 1, of General Conditions 2010A, which forms part of the Contract will not apply to Work with a specified expiry date. The following paragraph replaces section 9, paragraph 1, General Conditions 2010A for Work with a specified expiry date:

(a) Despite inspection and acceptance of the Work by or on behalf of Canada and without restricting any other provision of the Contract or any condition, warranty or provision implied or imposed by law, the Contractor warrants that the Work conforms to the specifications until the expiration date required by the Requirement. The Contractor must, upon the request of Canada, replace at its own expense including costs of returns and delivery of replacement Work as soon as possible any supplies that fail to conform or that deteriorates prior to the expiration date required by the Requirement.

(b) If full replacement is not available in a timeframe acceptable to Canada, then Canada may, in addition to and without prejudice to any other remedy available, choose from one of the following options for the quantity and Contract value of the Work affected: D

(i) Full and immediate reimbursement;

(ii) Equivalent full credit against future purchases under the Contract; or

(iii) Partial replacement and partial reimbursement or partial credit.

6.4 Term of Contract

6.4.1 Period of the Contract

A. The requested contract period from contract award until 30 June 2025.

6.4.2 Delivery Date

A. The initial requirement must be received within 12 weeks from contract award.

B. All optional requirement delivery dates will be specified as and when requested.

6.4.3 Delivery Points

A. Delivery of the requirement will be made to delivery point(s) specified at Annex A of the Contract.

6.5 Authorities

6.5.1 Contracting Authority

A. The Contracting Authority for the Contract is:

[Contact information to be detailed in the resulting contract]
Name: _____
Title: _____
Organization: _____
Address: Department of National Defence
101 Colonel By Drive
Ottawa ON K1A 0K2
Telephone: _____
E-mail: _____

B. The Contracting Authority is responsible for the management of the Contract and any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor must not

perform work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from anybody other than the Contracting Authority.

6.5.2 Technical Authority

A. The Technical Authority for the Contract is:

[Contact information to be detailed in the resulting contract]
Name: _____
Title: _____
Organization: _____
Address: Department of National Defence (DND)
101 Colonel By Drive
Ottawa ON K1A 0K2
Telephone: _____
E-mail: _____

B. The Technical Authority is the representative of the department or agency for whom the Work is being carried out under the Contract and is responsible for all matters concerning the technical content of the Work under the Contract. Technical matters may be discussed with the Technical Authority; however, the Technical Authority has no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

6.5.3 Contractor's Representative

[Contact information to be detailed in the resulting contract]
Name: _____
Title: _____
Address: _____
_____
_____
Telephone: _____
E-mail: _____

6.6 Payment

6.6.1 Basis of Payment – Firm Price

A. In consideration of the Contractor satisfactorily completing all of its obligations under the Contract, the Contractor will be paid a firm price, as specified in Annex B. Customs duties are included and Applicable Taxes are extra.

B. Canada will not pay the Contractor for any design changes, modifications or interpretations of the Work, unless they have been approved, in writing, by the Contracting Authority before their incorporation into the Work.

6.6.2 Method of Payment – Multiple Payments

A. Canada will pay the Contractor upon completion and delivery of the Work in accordance with the payment provisions of the Contract if:

(i) an accurate and complete invoice and any other documents required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;

(ii) all such documents have been verified by Canada;

(iii) the Work delivered has been accepted by Canada.

6.6.3 Electronic Payment of Invoices - Contract

A. The Contractor accepts to be paid using any of the following Electronic Payment Instrument(s):

[List to be updated in the resulting contract]

(i) Visa Acquisition Card;

(ii) MasterCard Acquisition Card;

(iii) Direct Deposit (Domestic and International);

(iv) Wire Transfer (International Only); and

(v) Large Value Transfer System (LVTS) (Over $25M).

6.7 Invoicing Instructions

A. The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.

B. Each invoice must be supported by:

(i) A description of the Work delivered; and

(ii) A breakdown of the cost elements.

C. Invoices must be distributed as follows:

(i) The original and one (1) copy must be forwarded to the address shown on page 1 of the Contract for certification and payment.

(ii) One (1) copy must be forwarded to the Contracting Authority identified under the section entitled "Authorities" of the Contract.

6.8 Certifications and Additional Information

6.8.1 Compliance

A. Unless specified otherwise, the continuous compliance with the certifications provided by the Contractor in its bid or precedent to contract award, and the ongoing cooperation in providing additional information are conditions of the Contract and failure to comply will constitute the Contractor in default. Certifications are subject to verification by Canada during the entire period of the Contract.

6.9 Packaging

A. Packaging for the Work must clearly indicate on packing slips and on the outside of outer packages and cartons, as applicable, the following:

(i) On each package and carton:

(a) Contractor's Name; and
(b) Manufacturer's Brand Name;

(ii) On each package, carton, vial, ampoule, bottle, and pre-filled syringe (if applicable) the following:

(a) Drug Identification Number (DIN) and NATO Stock Number (NSN) (if applicable);
(b) Global Trade Identification Number (GTIN) (if applicable);
(c) Lot Number; and
(d) Expiry Date.

(iii) Identify the carton(s) which contain the packing slip. If the Contractor will use the GTIN, then Bar codes on shipping package (i.e., shrink wrapped product), secondary and primary package, including variable data, must comply with GS1 standards and the Canadian Automated Identification of Vaccine Products process (if applicable);

(iv) The Contractor must identify partly packed carton(s) and box (es).

(v) Packaging is to be in accordance with good commercial standards to ensure safe arrival at destination. In addition to the Contract Requirement, the Contractor must ensure that all goods are properly labeled and packaged in compliance with the Biologics and Genetic Therapies Directorate (BGTD) Regulations.

(vi) Over the period of the Contract, the Contractor may offer other packaging options consistent with emerging technology. Canada retains the right to refuse such offerings.

6.10 Shipping Instructions

A. Goods must be consigned to the destination specified in the Contract and delivered:

(i) Delivered Duty Paid (DDP) Petawawa, Ontario, Incoterms 2000 for shipments from a commercial contractor.

6.11 Maintenance of Temperature During Transportation and the Use of Cold Chain Monitors.

A. Throughout the shipping process, the product must remain in temperature controlled and monitored conditions in accordance with the recommended storage conditions on the product monograph: “15 °C to 30°C”. The Contractor must maintain the ampoules at or between “+15C to +30°C”; as stated on the product label and/or in accordance with temperature conditions supported by stability data throughout transport from the Contractor to the Department of National Defence. The Contractor must provide evidence to that effect from the data analysis of the temperature monitoring device/carrier logs as applicable.

6.12 Delivery of Dangerous Goods/Hazardous Products

A. The Contractor must mark dangerous goods/hazardous products material which is classed as dangerous / hazardous as follows:

(i) Shipping container - in accordance with the *Transportation of Dangerous Goods Act*, 1992, c.34; and

(ii) Immediate product container - in accordance with the *Hazardous Products Act*, R.S., 1985,c. H-3.

B. The Contractor must provide bilingual Material Safety Data Sheets, indicating the NATO Stock Number as follows:

(i) two (2) hard copies:

(a) one (1) copy to be enclosed with the shipment, and

(b) one (1) copy to be mailed to:
National Defence Headquarters
MGen George R. Pearkes Building
101 Colonel By Drive
Ottawa, Ontario K1A 0K2
Attention: LCdr Julie Nadeau, J4 Med Mat

(ii) one (1) copy sent by email to the following address: MSDS-FS@FORCES.GC.CA in word processing format (i.e. MS Word or WordPerfect).

C. The Contractor will be responsible for any damages caused by improper packaging, labelling or carriage of goods/products.

D. The Contractor must ensure they adhere to all levels of regulations regarding dangerous goods/hazardous products as set forth by federal, provincial and municipal laws and by-laws.

E. The Contractor must contact the consignee (i.e. Supply Depot Traffic Section) at least 48 hours before shipping dangerous goods/hazardous products in order to schedule a receiving time.

6.13 Dangerous Goods / Hazardous Products - Labelling and Packaging Compliance

A. The Contractor must ensure proper labelling and packaging in the supply and shipping of dangerous goods/hazardous products to the Government of Canada.

B. The Contractor will be held liable for any damages caused by improper packaging, labelling or carriage of dangerous goods/hazardous products.

C. The Contractor must clearly mark all merchandise labels with the percentage of volume that is a hazardous item. Failure to do so will result in the Contractor being held responsible for damages caused in the movement of goods/products by government vehicles or government personnel.

D. The Contractor must adhere to all applicable laws regarding dangerous goods/hazardous products.

6.14 Product Recall or Withdrawal

A. In the event of a recall or a withdrawal of Work, the Contractor must notify the Contracting Authority and the Department of National Defence and must collect and destroy the delivered, recalled, or withdrawn Work at their own cost.

B. The Contractor must, upon the request of Canada, replace as soon as possible any recalled or withdrawn Work at their own cost.

C. If full replacement is not available in a timeframe acceptable to Canada, then Canada or the Identified User may, in addition to and without prejudice to any other remedy available, choose from one of the following options for the quantity and Contract value of the Work affected:

(i) Full and immediate reimbursement;

(ii) Equivalent full credit against future purchases under the Contract; or

(iii) Partial replacement and partial immediate reimbursement or partial credit under the Contract.

6.15 Product Dating

A. All Work supplied must have a shelf life of no less than 20 months remaining upon arrival at DND Central Medical Equipment Depot (CMED).

6.16 Notice of Anticipated Shortage

A. The Contractor must notify the Contracting Authority when it becomes aware of a potential problem, delay, or event that may lead to a shortage of any of the orders. Such notice must include a description of the nature of the problem or delay or event, the anticipated impact on the requirements of the Contract, the steps being taken by the Contractor to rectify the situation or to minimize the impact on this Contract, and the expected date by which the shortage will be fully corrected.

B. For the purpose of this clause "shortage" is defined as the inability to meet an Order in full.

6.17 Inability to Supply

A. In the event that the Contractor is unable to supply the Work in accordance with the terms and conditions of the Contract, whether as the result of drug discontinuation or for any other reason, the Contractor will provide a substitute product acceptable to Canada at a price no greater than firm unit price specified in Annex A.

B. Should the Department of National Defence be required to purchase the Work from an alternate source at a higher price, the Contractor must reimburse the Department of National Defence for the difference between the price paid to the alternate source and the firm unit price specified in Annex A.

C. Should the Department of National Defence be required to purchase the Work from an alternate source, Canada reserves the right to adjust the final total estimated quantity in the Contract.

6.18 Canada's Special Access Program

A. As required by Health Canada's Special Access Program in order to facilitate importation/shipment, the container is to include the following label: "URGENTEMERGENCY DRUG", and must include a copy of the following document: *-Letter of Authorization* Issued by Health Canada's Special Access Program.

B. For Schedule II narcotics under the United States *Controlled Substances Act (DEA Number 9801)*, and for Schedule I controlled drugs as per *Canada's Controlled Drugs and Substances Act (1996, c. 19), Part VII, Schedule I, Section 16: "Fentanyls, their salts, derivatives, and analogues and salts of derivatives and analogues,..."*, this shipment must also include copies of the following documents:

(i) Export Permit issued by the United States Drug Enforcement Agency; and

(ii) Import Permit issued by Health Canada's Office of Controlled Substances.

6.19 Applicable Laws

A. The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario [or as specified by the bidder in its bid, if applicable].

6.20 Priority of Documents

A. If there is a discrepancy between the wording of any documents that appear on the list, the wording of the document that first appears on the list has priority over the wording of any document that subsequently appears on the list:

(i) The Articles of Agreement;

(ii) The General Conditions 2010A (2020-05-28), General Conditions - Goods (Medium Complexity);

(iii) Annex A, Requirement

(iv) Annex B, Basis of Payment;

(v) the Contractor's bid dated [date to be specified in the resulting contract], as clarified on [date to be specified in the resulting contract, if required], and as amended on [date to be specified in the resulting contract, if required].

6.21 Defence Contract

A. The Contract is a defence contract within the meaning of the *Defence Production Act*, R.S.C. 1985, c. D-1 (http://laws-lois.justice.gc.ca/eng/acts/d-1/), and must be governed accordingly.

B. Title to the Work or to any materials, parts, work-in-process or finished work must belong to Canada free and clear of all claims, liens, attachments, charges or encumbrances. Canada is entitled, at any time, to remove, sell or dispose of the Work or any part of the Work in accordance with section 20 of the *Defence Production Act*.

6.22 Excess Goods

A. The quantity of goods to be delivered by the Contractor is specified in the Contract. The Contractor remains liable for any shipment in excess of that quantity whether the excess quantity is shipped voluntarily or as a result of an error by the Contractor. Canada will not make any payment to the Contractor for goods shipped in excess of the specified quantity. Canada will not return the said goods to the Contractor unless the Contractor agrees to pay for all the costs related to the return, including but not limited to administrative, shipping and handling costs. Canada will have the right to deduct such costs from any invoice submitted by the Contractor.

One (1) of the following two (2) options will be inserted in the resulting contract, as applicable:

Option 1: A2000C (2006-06-16) when the contract is to be with a Canadian-based supplier; or

6.23 Foreign Nationals (Canadian Contractor)

A. The Contractor must comply with Canadian immigration requirements applicable to foreign nationals entering Canada to work temporarily in fulfillment of the Contract. If the Contractor wishes to hire a foreign national to work in Canada to fulfill the Contract, the Contractor should immediately contact the nearest Service Canada regional office to enquire about Citizenship and Immigration Canada's requirements to issue a temporary work permit to a foreign national. The Contractor is responsible for all costs incurred as a result of non-compliance with immigration requirements.

Option 2: A2001C (2006-06-16) when the contract is to be with a foreign-based supplier.

6.23 Foreign Nationals (Foreign Contractor)

A. The Contractor must comply with Canadian immigration legislation applicable to foreign nationals entering Canada to work temporarily in fulfillment of the Contract. If the Contractor wishes to hire a foreign national to work in Canada to fulfill the Contract, the Contractor should immediately contact the nearest Canadian Embassy, Consulate or High Commission in the Contractor's country to obtain instructions, information on Citizenship and Immigration Canada's requirements and any required documents. The Contractor is responsible to ensure that foreign nationals have the required information, documents and authorizations before performing any work under the Contract in Canada. The Contractor is responsible for all costs incurred as a result of non-compliance with immigration requirements.

6.24 Insurance - No Specific Requirement

A. The Contractor is responsible for deciding if insurance coverage is necessary to fulfill its obligation under the Contract and to ensure compliance with any applicable law. Any insurance acquired or maintained by the Contractor is at its own expense and for its own benefit and protection. It does not release the Contractor from or reduce its liability under the Contract.

6.25 Dispute Resolution

A. The parties agree to maintain open and honest communication about the Work throughout and after the performance of the Contract.

B. The parties agree to consult and co-operate with each other in the furtherance of the contract and promptly notify the other party or parties and attempt to resolve problems or differences that may arise.

C. If the parties cannot resolve a dispute through consultation and cooperation, the parties agree to consult a neutral third party offering alternative dispute resolution services to attempt to address the dispute.

D. Options of alternative dispute resolution services can be found on Canada's Buy and Sell website under the heading "Dispute Resolution".

ANNEX A - STATEMENT OF REQUIREMENT

1. TITLE

1.1 Doxycycline Hyclate for Injection, 100mg

2. OBJECTIVE

2.1 The Strategic Medical Countermeasures Program (SMCP) on behalf of the Canadian Forces Health Services Group (CF H Svcs Gp), Department of National Defence (DND), has a requirement for Doxycycline injectable for the treatment of Canadian Armed Forces (CAF) members who may have been exposed to bacterial biological warfare agents.

3. SPECIFICATIONS

REQUIREMENT	SPECIFICATION
Active ingredient	Alpha-6-deoxy-5-oxytetracycline
Dose/strength (unit)	100 mg
Volume	10 – 50 mL
Dosage Form	Lyophilized powder for reconstitution
Route of Administration	Intravenous
Prescribing Information	The Contractor must provide a copy of the most up to date product prescribing information in English or French.
Primary packaging	The Contractor must provide a description of primary packaging to facilitate an assessment that the packaging is of adequate fit, form and function to maintain stability of the product throughout the labelled shelf-life under the recommended storage condition(s). The primary packaging must include the following: • Product name; • Strength; • Lot/batch number; and • Expiry date or Date of manufacture
Secondary packaging	Any secondary packaging must include the following: • Product name; • Strength; • Lot/batch number; and • Expiry date or Date of manufacture
Packaging Dimensions	The Contractor must provide the type, physical dimensions and quantities for each packaging level by which the product may be received. This includes primary packaging (e.g. vial, bottle, etc.), secondary packaging (e.g. box, carton, tray, etc.), tertiary packaging (e.g. box, shipper, etc.) up to and including dimensions of pallet(s).
Physicochemical characteristics	Light yellow crystalline powder for reconstitution. Preservative-free.

Shelf-life Documentation	Upon request, the Contractor must provide real-time stability data at the recommended storage condition to support a minimum shelf-life of 24 months. Documentation must be provided in a report and signed off by the Contractors' Quality Assurance Department.
Shelf-life upon delivery	At the time of delivery and receipt at DND location, the product must have a minimum of 20 months of its labelled shelf-life remaining.
Sterility	Sterile

4. CERTIFICATIONS

4.1 Throughout the duration of the Contract, the product must hold a Health Canada issued Notice of Compliance in accordance with Division 8 of the Canadian Food and Drug Regulations (https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-141.html#h-578215), or be authorized for sale through the Health Canada Special Access Program (SAP). The SAP application will be filed by CF H Svcs Gp.

4.2 The Contractor must provide evidence that the product has been manufactured in compliance with current Good Manufacturing Practices (cGMP) as set out in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7: https://database.ich.org/sites/default/files/Q7%20Guideline.pdf. The evidence provided must include, at a minimum, the following:

4.2.1 A Certificate of Analysis representative of the batch or lot to be delivered. Certificates must be signed by the manufacturer's Quality Assurance department; and

4.2.2 Evidence of cGMP compliance. Evidence may include, but is not limited to, a valid Health Canada Establishment License or inspection reports from the regulatory national competent authority from Canada, the United States, the United Kingdom or a member state of the European Union within the last five (5) years.

5. DELIVERY REQUIREMENTS AND SCHEDULE

5.1 **Initial Requirement:** The Contractor must supply up to 15,120 vials within 12 weeks of contract award and no later than 31 March 2022. The Contractor must provide email confirmation to DND of the confirmed total quantity to ship to DND prior to production. The Contractor must supply the fully executed Certificate of Analysis for the lot to be supplied.

5.2 **Option Requirement 1 (Year 1)**: The Contractor must supply up to 15,120 vials no later than 31 March 2023. The Contractor must provide email confirmation to DND of the confirmed total quantity to ship to DND prior to production. The Contractor must supply the fully executed Certificate of Analysis for the lot to be supplied.

5.3 **Option Requirement 2 (Year 2)**: The Contractor must supply up to 15,120 vials no later than 31 March 2024. The Contractor must provide email confirmation to DND of the confirmed total quantity to ship to DND prior to production. The Contractor must supply the fully executed Certificate of Analysis for the lot to be supplied.

5.4 **Option Requirement 3 (Year 3)**: The Contractor must supply up to 15,120 vials no later than 31 March 2025. The Contractor must provide email confirmation to DND of the confirmed total

quantity to ship to DND prior to production. The Contractor must supply the fully executed Certificate of Analysis for the lot to be supplied.

6. PACKAGING AND SHIPPING CONDITIONS

6.1 Throughout the shipping process, the product must remain in a temperature controlled environment under monitored conditions in accordance with the recommended storage conditions on the labelling, or between 15 and 25°C. The Contractor must provide evidence to that effect from the data analysis of the temperature monitoring device/carrier logs as applicable.

7. DELIVERY ADDRESS

7.1 DEPARTMENT OF NATIONAL DEFENCE
CENTRAL MEDICAL EQUIPMENT DEPOT
105 Montgomery Rd, Bldg: BB-104A
Garrison Petawawa
Petawawa ON
K8H 2X3

ANNEX B – BASIS OF PAYMENT

A. All prices are in Canadian Dollars, Applicable Taxes excluded, DDP destination, freight charges included, Canadian customs duties and excise taxes included.

B. The Contractor will be paid the following firm unit prices upon the delivery/completion of the Requirement described in Annex A.

Initial Purchase

Initial Requirement (Contract award to 31 March 2022)			
Item Description	**Quantity**	**Unit Cost (CAD)**	**Total Cost (CAD)**
Doxycycline Hyclate for injection, 100mg	Up to 15,120 vials		

Optional Requirement

Maximum number of optional vials is 45,360

Option Period 1	Item Description	Quantity	Unit Cost (CAD)	Total Cost (CAD)
1 April 2022 to 31 March 2023	Doxycycline Hyclate for injection, 100mg	Up to 15,120 vials	$	$

Option Period 2	Item Description	Quantity	Unit Cost (CAD)	Total Cost (CAD)
1 April 2023 to 31 March 2024	Doxycycline Hyclate for injection, 100mg	Up to 15,120 vials	$	$

Option Period 3	Item Description	Quantity	Unit Cost (CAD)	Total Cost (CAD)
01 April 2024 to 31 March 2025	Doxycycline Hyclate for injection, 100mg	Up to 15,120 vials	$	$