REQUEST FOR PROPOSAL (RFP)

RFP #SN21002

FOR THE REQUIREMENT OF SCIENTIFIC LITERATURE SEARCH SERVICES FOR THE PATENTED MEDICINE PRICES REVIEW BOARD (PMPRB)

Bid Submissions are be submitted by email only to:

Nadia Laneve

Nadia.laneve@pmprb-cepmb.gc.ca

It is essential that the bid submission include the RFP reference number.

Closing Date and Time: July 9, 2021 at 2:00 PM EDT

RFP Issue Date: May 27, 2021

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

Nadia Laneve
Chief, Administrative Services
Nadia.laneve@pmprb-cepmb.gc.ca

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PART 1 - GENERAL INFORMATION

1.1 Introduction

The bid solicitation is divided into seven parts plus attachments and annexes, as follows:

- Part 1 General Information: provides a general description of the requirement;
- Part 2 Bidder Instructions: provides the instructions, clauses and conditions applicable to the bid solicitation and states that the Bidder agrees to be bound by the clauses and conditions contained in all parts of the bid solicitation;
- Part 3 Bid Preparation Instructions: provides Bidders with instructions on how to prepare their bid;
- Part 4 Evaluation Procedures and Basis of Selection: indicates how the evaluation will be conducted, the evaluation criteria that must be addressed in the bid, and the basis of selection;
- Part 5 Certifications and Additional Information: includes the certifications and additional information to be provided;
- Part 6 Resulting Contract Clauses: includes the clauses and conditions that will apply to any resulting contract.

The Attachments to the RFP include:

- Attachment 1 Bid Submission Form.
- Attachment 2 Technical Criteria,

The Annexes the RFP and Part 6 include:

- Annex A Statement of Work,
- Annex A1: Report Template'
- Annex B Basis of Payment and Pricing Schedule,
- Annex C Security Requirements Check List,
- Annex D Non-Disclosure Agreement

The list of suppliers being invited to bid on this bid solicitation is provided within Article 1.2 Summary. This list will not be updated if additional suppliers request copies of the bid solicitation.

1.2 Summary

- a) The purpose of this Request for Proposal (RFP) is to select a supplier to enter into a Contract(s) with the Patented Medicine Prices Review Board (PMPRB) to provide Scientific Literature Search services. The resulting Contractor would review appropriate references concerning patented medicines specified by the PMPRB and provide a report prescribed in the Statement of Work (Annex A) and Annex A1: Report Template.
- b) This process is intended to result in the award of two (2) contracts (valid from the date of contract award until 12 months after the date of contract), plus two (2) one-year option periods exercised at PMPRB's sole discretion.
- c) It is PMPRB's intention to ensure as much as possible an equitable work distribution is achieved based on factors such as expertise and staffing. This may include the issuance of alternate requests for services between the two (2) contractors to result in approximately equitable number of drug reviews and could be rotational, dependent on the available limitation of expenditure.

1.3 Security Requirements

THIS DOCUMENT CONTAINS A SECURITY REQUIREMENT.

At the date of contract award, the following conditions must be met:

SECURITY REQUIREMENT FOR CANADIAN SUPPLIER: PWGSC FILE No.

- The Contractor/Offeror must, at all times during the performance of the Contract/Standing Offer, hold a valid Facility Security Clearance at the level of **Reliability Status**, with approved Document Safeguarding at the level of **PROTECTED A**, issued by the Contract Security Program (CSP), Public Works and Government Services Canada (PWGSC).
- The Contractor/Offeror personnel requiring access to CLASSIFIED/PROTECTED information, assets or sensitive site(s) must EACH hold a valid personnel security screening at the level of Reliability Status, granted or approved by the CSP, PWGSC.
- 3. The Contractor MUST NOT utilize its Information Technology systems to electronically process, produce or store any sensitive CLASSIFIED/PROTECTED information until the CSP, PWGSC has issued written approval. After approval has been granted, these tasks may be performed at the level of **PROTECTED A.**.
- 4. Subcontracts which contain security requirements are NOT to be awarded without the prior written permission of the CSP, PWGSC.
- 5. The Contractor/Offeror must comply with the provisions of the:
 - (a) Security Requirements Check List and security guide (if applicable), attached at Annex
 - (b) Contract Security Manual (Latest Edition).

1.4 Statement of Work

The Work to be performed is detailed under Article 6.2 of the resulting contract clauses under Part 6.

1.5 Debriefings

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 through teleconference.

1.6 Trade Agreements

The requirement is subject to the provisions of the Canadian Free Trade Agreement (CFTA), Canada-Chile Free Trade Agreement, Canada-Colombia Free Trade Agreement, Canada-Honduras Free Trade Agreement, Canada-Korea Free Trade Agreement (CKFTA), Canada-Panama Free Trade Agreement, Canada-Peru Free Trade Agreement (CPFTA), World Trade Organization Agreement on Government Procurement (WTO-AGP), the North American Free Trade Agreement (NAFTA), the Canada-European Union Comprehensive Economic and Trade Agreement (CETA).

1.7 Insurance Requirements

The Contractor must obtain and maintain an appropriate level of professional liability insurance coverage. It is the sole responsibility of the Contractor to decide whether or not any insurance coverage is necessary for its own protection or to fulfill its obligations under the contract and to ensure compliance with required federal, provincial or municipal law. Any such insurance must be provided and maintained by the Contractor at its own expense.

PART 2 - BIDDER INSTRUCTIONS

2.1 Standard Instructions, Clauses and Conditions

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

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.

The <u>2003</u> (2020-05-28) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

The Office of the Procurement Ombudsman (OPO) was established by the Government of Canada to provide an independent avenue for suppliers to raise complaints regarding the award of Contracts under \$25,000 for goods and under \$100,000 for services. Canadian suppliers have the option of raising issues or concerns regarding the solicitation, or the award resulting from it, with the OPO by contacting them by telephone at 1-866-734-5169 or by email at boa.opo@boa-opo.gc.ca. You can also obtain more information on the OPO services available to you at their website at www.opo-boa.gc.ca.

2.2 Submission of Bids

Bids must be submitted only to the Contracting Authority by the date, time and place indicated below: Nadia Laneve

Chief, Administrative Services, Corporate Services Branch Patented Medicine Prices Review Board / Government of Canada

Nadia.laneve@pmprb-cepmb.gc.ca

Due to the nature of the bid solicitation, bids transmitted by any other method will not be accepted.

2.3 Enquiries - Bid Solicitation

All enquiries must be submitted in writing to the Contracting Authority no later than seven (7) calendar days before the bid closing date. Enquiries received after that time may not be answered.

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 PMPRB 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 PMPRB determines that the enquiry is not of a proprietary nature. PMPRB 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 PMPRB.

2.4 Improvement of Requirement During Solicitation Period

Should bidders consider that the specifications or Statement of Work contained in the bid solicitation could be improved technically or technologically, bidders are invited to make suggestions, in writing, to the Contracting Authority named in the bid solicitation. Bidders must clearly outline the suggested improvement as well as the reason for the suggestion. Suggestions that do not restrict the level of competition nor favour a particular bidder will be given consideration provided they are submitted to the Contracting Authority at least seven (7) calendar days before the bid closing date. Canada will have the right to accept or reject any or all suggestions.

2.5 Applicable Laws

Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario.

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.

PART 3 – BID PREPARATION INSTRUCTIONS

3.1 Bid Preparation Instructions

PMPRB requests that Bidders provide their bid in separate electronic files by email and clearly named as follows:

Section I: Technical Bid
Section II: Financial Bid

Section III: Certifications and Additional Information

Prices must appear in the financial bid only. No prices must be indicated in any other section of the bid.

3.2 Section I: Technical Bid

In their technical bid, bidders should demonstrate their understanding of the requirements contained in the bid solicitation and explain how they will meet these requirements. Bidders should demonstrate their capability and describe their approach in a thorough, concise and clear manner for carrying out the work.

Part 4, Evaluation Procedures, Part 5 Certifications and Additional Bid information and the Attachments and Annexes to this RFP contain additional instructions that bidders should consider when preparing their technical bid.

The technical bid consists of the following:

- a) Bid Submission Form: Bidders are requested to include the Bid Submission Form Attachment 1 of this document with their bids. It provides a common form in which bidders can provide information required for evaluation and contract award, such as a contact name, the Bidder's Procurement Business Number, the Bidder's status under the Federal Contractors Program for Employment Equity, etc. Using the form to provide this information is not mandatory, but it is recommended. If PMPRB determines that the information required by the Bid Submission Form is incomplete or requires correction, PMPRB will provide the Bidder with an opportunity to do so through a rectification process.
- b) **Technical Submission and Compliance:** The technical bid should address clearly and in sufficient depth the points that are subject to the evaluation criteria against which the bid is evaluated. This requires substantiation of the compliance of the Bidder and its services with the specific requirements of Attachment 2. The substantiation must not simply be a repetition of the requirement(s) but must explain and demonstrate how the Bidder will meet the requirements and carry out the required Work. Simply stating that the Bidder or its proposed solution or product complies is not sufficient. Where PMPRB determines that the substantiation is not complete, the Bidder will be considered non-responsive and disqualified. The substantiation may refer to additional documentation submitted with the bid this information can be referenced in an added column on the grids provided in Attachment 2, entitled, "Bidder's Response", where Bidders are requested to indicate where in the bid the reference material can be found, including the title of the document, and the page and paragraph numbers; where the reference is not sufficiently precise, PMPRB may request that the Bidder direct PMPRB to the appropriate location in the documentation.

- c) Technical Submission Structure: Bidders should also note that the format and structure of Attachment 2 is the preferred structure for bid submission and as much as possible should adhere to this structure. In order to facilitate the evaluation of the bid, PMPRB requests that bidders address and present topics in the order of the evaluation criteria under the same headings. To avoid duplication, bidders may refer to different sections of their bids by identifying the specific paragraph and page number where the subject topic has already been addressed.
- d) **For Previous Similar Projects:** Where the bid must include a description of previous similar projects:
 - (i) a project must have been completed by the Bidder itself (and cannot include the experience of any proposed sub-contractor or any affiliate of the Bidder);
 - (ii) a project must have been completed by the bid closing date;
 - (iii) each project description must include, at minimum, the name and either the telephone number or e-mail address of a customer reference; and
 - (iv) if more similar projects are provided than requested, PMPRB will decide in its discretion which projects will be evaluated. A project will be considered "similar" to the Work to be performed under any resulting contract if the project was for the performance of work that closely matches the Resource Category Equivalencies in Part 4. Work will be considered to "closely match" if the work in the provided project is described in at least 50% of the points of responsibility listed in the description of the given Resource Category.

3.3 Section II: Financial Bid

- a) Bidders must submit their financial bid in Canadian funds and in accordance with the pricing schedule referenced and detailed in Annex B Basis of Payment and Pricing Schedule. Unless otherwise indicated, Bidders must include a single, firm, all-inclusive per review rate or per hour rate in Canadian dollars in each cell requiring an entry in the pricing tables.
- b) Bidders must submit their price and rates with the total amount of Harmonized Sales Tax (HST) must be shown separately, as applicable.
- c) When preparing their financial bid, Bidders should review clause 4.1.2, Financial Evaluation, of Part 4 of the bid solicitation; and article 6.7, Payment, of Part 6 of the bid solicitation.
- a) All Costs to be Included: The financial bid must include all costs for the requirement described in the bid solicitation for the entire Contract Period, including any option periods. The identification of all necessary equipment required to meet the requirements of the bid solicitation and the associated costs of these items is the sole responsibility of the Bidder.
- b) Blank Prices: Bidders are requested to insert "\$0.00" for any item for which it does not intend to charge or for items that are already included in other prices set out in the tables. If the Bidder leaves any price blank, PMPRB will treat the price as "\$0.00" for evaluation purposes and may request that the Bidder confirm that the price is, in fact, \$0.00. No Bidder will be permitted to add or change a price as part of this confirmation. Any Bidder who does not confirm that the price for a blank item is \$0.00 will be declared non-responsive.

3.3.1 Price Breakdown

In their financial bids, Bidders should provide a price breakdown for the price quoted in response to the pricing schedule detailed in Annex B Basis of Payment and Pricing Schedule using all tables provided.

3.3.1.2 Applicable Taxes

The price breakdown must not include the Applicable Taxes.

3.3.1.3 Exchange Rate Fluctuation

<u>C3011T</u> 2013-11-06 Exchange Rate Fluctuation - 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

In Section III of their bid, bidders should provide the certifications required under Part 5 and, as applicable, any associated additional information.

3.5 Additional Information

The Company Security Officer (CSO) must ensure through the Industrial Security Program (ISP) that the Bidder and proposed individual(s) hold a valid security clearance at the required level, as indicated in Part 6 – Security, Financial and Other Requirements at the time of contract award.

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 and financial evaluation criteria.
- b) An evaluation team composed of representatives of PMPRB and PMPRB's retained advisors will evaluate the bids.
- c) In addition to any other time periods established in the bid solicitation:
 - i. **Requests for Clarifications:** If PMPRB seeks clarification or verification from the Bidder about its bid, the Bidder will have 2 working days (or a longer period if specified in writing by the Contracting Authority) to provide the necessary information to PMPRB. Failure to meet this deadline will result in the bid being declared non-responsive.
 - ii. **Request for Further Information:** If PMPRB requires additional information in order to do any of the following pursuant to the Section entitled "Conduct of Evaluation" in 2003, Standard Instructions Goods or Services Competitive Requirements:
 - 1. verify any or all information provided by the Bidder in its bid; or
 - 2. contact any or all references supplied by the Bidder (e.g., references named in the résumés of individual resources) to verify and validate any information submitted by the Bidder.

The Bidder must provide the information requested by PMPRB within 5 working days of a request by the Contracting Authority.

iii. **Extension of Time:** If additional time is required by the Bidder, the Contracting Authority may grant an extension in his or her sole discretion.

4.1.1 Technical Evaluation

Except where expressly provided otherwise, the experience described in the bid must be the experience of the Bidder itself (which includes the experience of any companies that formed the Bidder by way of a merger but does not include any experience acquired through a purchase of assets or an assignment of contract). The experience of the Bidder's affiliates (i.e., parent, subsidiary or sister corporations), sub-Bidders, or suppliers will not be considered. However, joint venture bids are permitted.

4.1.1.1 Joint-Venture Experience

a) Where the Bidder is a joint venture with existing experience as that joint venture, it may submit the experience that it has obtained as that joint venture.

- b) A joint venture bidder may rely on the experience of one of its members to meet any given technical criterion of this bid solicitation.
- c) Joint venture members cannot pool their abilities with other joint venture members to satisfy a single technical criterion of this bid solicitation. However, a joint venture member can pool its individual experience with the experience of the joint venture itself. Wherever substantiation of a criterion is required, the Bidder is requested to indicate which joint venture member satisfies the requirement. If the Bidder has not identified which joint venture member satisfies the requirement, the Contracting Authority will provide an opportunity to the Bidder to submit this information during the evaluation period. If the Bidder does not submit this information within the period set by the Contracting Authority, its bid will be declared non-responsive.
- d) Any Bidder with questions regarding the way in which a joint venture bid will be evaluated should raise such questions through the Enquiries process as early as possible during the bid solicitation period.

Technical proposals will be evaluated and scored in accordance with the following Mandatory and Point-Rated evaluation criteria and formulae.

Definitions

For the purpose of the Mandatory Evaluation Criteria and Rated Evaluation Criteria, the following definitions and project information specifications apply:

A) Project Descriptions:

In response to these Mandatory and Point-Rated Evaluation Criteria, where a criterion evaluates the experience of the Proposed Resources through written project descriptions, for demonstration, the Bidder is to provide written project descriptions of the experience of the identified Proposed Resource in providing the identified services and deliverables or using the identified toolsets. The Proposed Resource's experience may have been obtained outside of the Bidder's organization. For clarity, demonstration must consist of more than a repetition of the text of the evaluation criteria.

Bidders are to clearly describe:

- i. The project title
- ii. The client organization name
- iii. The start and end dates of the Bidder or Resource engagement.
- iv. The Client contact information such as Name, Title, Email address and Telephone Number.
- v. The services and deliverables provided by the Proposed Resource, such as description of the Proposed Resource's role in undertaking the tasks and delivering the services identified in the criterion within the context of the overall project.

A response that is lacking in detail and does not clearly demonstrate the experience of the Proposed Resource would not substantively address all requirements in the criterion (i.e., the response solely repeats the text of the criterion or provides minimal description and does not explain or fully describe the role of the Proposed Resource and the activities or outcomes of their work or is missing demonstration of one or more of the elements listed in the criterion).

4.1.1.1 Mandatory Technical Criteria

Refer to Attachment 2 - Technical Criteria.

4.1.1.2 Point Rated Technical Criteria

Refer to Attachment 2 – Technical Criteria. Point-rated technical criteria not addressed will be given a score of zero.

4.1.1.3 References

If a reference check is performed, PMPRB will conduct the reference check in writing by e-mail. PMPRB will send all email reference check requests to contacts supplied by all the Bidders on the same day using

the email address provided in the bid. PMPRB will not award any points unless the response is received within five working days of the date that PMPRB's email was sent.

On the third working day after sending out the reference check request, if PMPRB has not received a response, PMPRB will notify the Bidder by email, to allow the Bidder to contact its reference directly to ensure that it responds to PMPRB within five working days. If the individual named by a Bidder is unavailable when required during the evaluation period, the Bidder may provide the name and email address of an alternate contact person from the same customer. Bidders will only be provided with this opportunity once for each customer, and only if the originally named individual is unavailable to respond (i.e., the Bidder will not be provided with an opportunity to submit the name of an alternate contact person if the original contact person indicates that he or she is unwilling or unable to respond). The Bidder will have 24 hours to submit the name of a new contact. That contact will again be given five (5) working days to respond once PMPRB sends its reference check request.

Wherever information provided by a reference differs from the information supplied by the Bidder, the information supplied by the reference will be the information evaluated.

Points will not be allocated and/or a Bidder will not meet the mandatory experience requirement (as applicable) if (1) the reference customer states he or she is unable or unwilling to provide the information requested, or (2) the customer reference is not a customer of the Bidder itself or a client of the resources. Nor will points be allocated or a mandatory met if the customer is itself an affiliate or other entity that does not deal at arm's length with the Bidder.

Whether or not to conduct reference checks is discretionary. However, if PMPRB chooses to conduct reference checks for any given rated or mandatory requirement, it will check the references for that requirement.

4.1.1.4 Interviews

PMPRB may wish to interview the Bidder and/or the Bidder's proposed resource(s) to verify the information provided within the Bidder's proposal against the requirements of the bid solicitation. The Bidder will have two (2) working days following notice by the Contracting Authority to make any necessary arrangements (at the Bidder's sole cost) for the interview to take place virtually as specified by PMPRB. Wherever information provided during the interview differs from the information supplied by the Bidder, and identifies statements within the bid to be untrue PMPRB may declare a bid non-responsive during the bid evaluation period.

4.1.2 Financial Evaluation

The price of the bid will be evaluated in Canadian dollars, Applicable Taxes excluded, FOB destination, Canadian customs duties and excise taxes included.

(a) Mandatory Financial Criteria

i. Formulae in Pricing Tables

If the pricing tables provided to Bidders include any formulas, PMPRB may re-input the prices provided by Bidders into a fresh table, if PMPRB believes that the formula may no longer be functioning properly in the version submitted by a Bidder.

ii. Substantiation of Professional Services Rates

In PMPRB's experience, Bidders will from time to time propose rates at the time of bidding for one or more categories of resources that they later refuse to honour, on the basis that these rates do not allow them to recover their own costs and/or make a profit. When evaluating the rates for professional services bid, PMPRB may, but will have no obligation to, require price support for any rates proposed (either for all or for specific resource categories). Examples of price support that PMPRB would consider satisfactory include:

a. Documentation (such as billing records) that shows that the Bidder has recently provided and invoiced another customer (with whom the Bidder deals at arm's length) for services

similar to the services that would be provided by the relevant resource category, where those services were provided for at least one month and the fees charged are equal to or less than the rate offered to PMPRB (to protect the privacy of the customer, the Bidder may black out the customer's name and personal information on the invoice submitted to PMPRB);

- A signed contract between the Bidder and an individual qualified (based on the
 qualifications described in this bid solicitation) to provide services under the relevant
 resource category, where the amount payable under that contract by the Bidder to the
 resource is equal to or less than the rate bid for that resource category;
- c. A signed contract with a sub-Contractor who will perform the work under any resulting contract, which provides that the required services will be provided at a rate that is equal to or less than the rate bid for the relevant resource category (and where the resource meets all the qualifications described in this bid solicitation); or
- d. Details regarding the salary paid to and benefits provided to the individuals employed by the Bidder qualified (based on the qualifications described in this bid solicitation) to provide services under the relevant resource category, where the amount of compensation, when converted to a per review or hourly rate (as applicable), is equal to or less than the rate bid for that resource category.

Once PMPRB requests substantiation of the rates bid for any resource category, it is the sole responsibility of the Bidder to submit information (either the information described in the examples above, or other information that demonstrates that it will be able to recover its own costs based on the rates it has proposed) that will allow PMPRB to determine whether it can rely, with confidence, on the Bidder's ability to provide the required services at the rates bid, while, at a minimum, recovering its own costs. Where PMPRB determines that the information provided by the Bidder does not demonstrate the Bidder's ability to recover its own costs in providing the relevant resource, PMPRB may declare the bid non-compliant, if the rate bid is at least 30% lower than the median price bid by compliant Bidders for the first year of the resulting contract for the relevant resource(s). Only the Per Review or Hourly Rates of bids that are technically responsive will be considered.

(b) Financial Proposal Score

The Bidder must provide fixed/firm, all-inclusive Per Review rates and Hourly Rates for the initial contract period and option period(s) using the tables attached at Annex B Basis of Payment and Pricing Schedule.

The Financial evaluation will be conducted only on proposals that are technically responsive by using these rates to calculate the Total Financial Score.

Per Review Rates and Hourly Rates proposed for Option Period(s) must not be lower than the rates proposed for the Initial Contract Period. Failure to abide with these conditions will result in a proposal being considered non-responsive.

Rate Evaluation

The Overall Evaluation Cost will be determined using the formulas specified within Annex B, Basis of Payment and Pricing Schedule.

4.2 Basis of Selection

- (a) A bid must comply with the requirements of the bid solicitation and meet all mandatory criteria and the minimum pass mark for the point-rated criteria to be declared responsive.
- (b) The Technical and Financial proposals will initially be scored separately. The Overall Score will be determined by combining the Bidder's Technical Score and Financial Score in accordance with the following weights:

Technical Score	=	70%
Financial Score	=	30%
Overall Score	=	100%

The Bidder with the **highest combined technical and financial score** as calculated in the **Summary of Evaluation Process** table below, will be recommended for contract award.

SUMMARY OF EVALUATION PROCESS			
Mandatory Evaluation Criteria	Compliant / N	lon-compliant	
M1. Bidder's Experience	Yes / No		
M2. Bidder's Point of Contact	Yes / No		
M3. Bidder's Resource Team Leads	Y	Yes / No	
M4. Bidder's Minimum Literature Access	Y	es / No	
M4. Bidder's Sample Report	Y	es / No	
Point-Rated Evaluation Criteria	Maximum Point Value	Minimum Score Required	
R1. Bidder's Sample Report Evaluation	30		
R2. Reporting Standard Methodology and Approach	80		
R3. Bidder's Resource Team	50		
R4. Bidder's Resource Capacity	20		
R5. Bidder's Resource Management Approach	40		
TOTAL TECHNICAL SCORE:	220	132 (60%)	
TECHNICAL SCORE Bidder's Total Technical Score (Weighted) 220 x 70	/70		
FINANCIAL SCORE Cost x 30 Bidder's Overall Evaluation Cost	/30		
BIDDER TOTAL Weighted Financial Score SCORE (/70)	/100	Top Ranked Bidder represents Best Value	

- (c) Bidders should note that all contract awards are subject to PMPRB's internal approvals process, which includes a requirement to approve funding in the amount of any proposed contract. Despite the fact that the Bidder may have been recommended for contract award, a contract will only be awarded if internal approval is granted according to PMPRB's internal policies. If approval is not granted, no contract will be awarded.
- (d) If more than one Bidder is ranked first because of identical overall scores, then the Bidder with the highest technical score will become the top-ranked Bidder. The Bidder with the second highest score will be the second ranked Bidder.
- (e) Notification of Evaluation Results: All Bidders will be notified in writing regarding the outcome of the RFP process. This notice will include the following information:
 - Solicitation Number;
 - Company name of winning Bidder(s);
 - o Total points scored of winning Bidder(s) (for multiple resource requirements only)
 - Total value of contract awarded;
 - Total points scored per individual Bidder (Note: Bidders will only receive their own total points scored and not the score of the other Bidders).

PART 5 – CERTIFICATIONS AND ADDITIONAL INFORMATION

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

The certifications provided by Bidders to PMPRB are subject to verification by PMPRB at all times. Unless specified otherwise, PMPRB 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.

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 Requested with the Bid

Bidders should submit the following completed certifications as part of their bid. If any of these required certifications is not completed and submitted as requested, the Contracting Authority will so inform the Bidder and provide the Bidder with a time frame within which to meet the requirement. Failure to comply with the request of the Contracting Authority and meet the requirement within that time period will that time period will render the bid non-responsive.

5.1.1 Integrity Provisions - Declaration of Convicted Offences and Required Documentation

The Bidder will complete the corresponding section within Attachment #1 Bidder Form and provide the information requested in accordance with the <u>Ineligibility and Suspension Policy</u> (http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html), and Article 2.1 of Part 2 Bidder Instructions.

Integrity Provisions – List of Names

If applicable, during this procurement process, the Bidder must immediately inform PMPRB in writing of any changes affecting the list of names.

The Bidder should provide:

For Corporations: The List of the names of all current directors or, for a privately owned corporation, the names of the owners of the corporation;

For Sole Proprietors, including sole proprietors bidding as joint ventures: The complete list of the names of all owners; or

For Partnerships: Suppliers that are a partnership do not need to provide a list of names.

If the list of names has not been received in the procurement process by the time the evaluation of bids or offers is completed, or has not been received in the procurement process where no bid/offer will be submitted, the Contracting Authority will inform the supplier of a time within which to provide the information. Providing the required names is a mandatory requirement for award of a contract agreement. Failure to provide the list of names within the time specified will render a bid or offer non-responsive, or the supplier otherwise disqualified for award of a contract agreement.

During the evaluation of bids or offers, a supplier must, within 10 working days, inform the Contracting Authority in writing of any changes affecting the list of names submitted further to section 17(a).

During performance of a contract or real property agreement, a supplier has a continuing obligation to inform the Registrar of Ineligibility and Suspension in writing, within 10 working days, of:

Any charge, conviction or other circumstance relevant to the policy with respect to itself, its affiliates and its first-tier subcontractors; and

Any change affecting the list of names submitted further to section 17(a).

PMPRB may verify information provided by a supplier at any time during the period of a contract agreement or the period during which any other instrument (e.g., standing offer, supply arrangement) is

valid. PMPRB may request additional information, including validations from a third party, consent forms and other evidentiary elements, proving such matters as identity and eligibility to contract agreement with PMPRB. The supplier must provide the requested information within the time specified. Failure to do so may render the supplier ineligible to contract agreement with PMPRB.

Provision of additional information: The supplier must provide any further information relevant to the policy, including certifications and third-party validations, by the time so requested by PMPRB or the Contracting Authority.

5.2.1. Federal Contractors Program for Employment Equity - Bid Certification

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#).

PMPRB 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.

Former Public Servant

Contracts awarded to former public servants (FPS) in receipt of a pension or of a lump sum payment must bear the closest public scrutiny, and reflect fairness in the spending of public funds. In order to comply with Treasury Board policies and directives on contracts awarded to FPSs, bidders must provide the information required below before contract award. If the answer to the questions and, as applicable the information required have not been received by the time the evaluation of bids is completed, PMPRB will inform the Bidder of a time frame within which to provide the information. Failure to comply with PMPRB's request and meet the requirement within the prescribed time frame will render the bid non-responsive.

Definitions

For the purposes of this clause, "former public servant" is any former member of a department as defined in the <u>Financial Administration Act</u>, R.S., 1985, c. F-11, a former member of the Canadian Armed Forces or a former member of the Royal Canadian Mounted Police. A former public servant may be:

- a. an individual;
- b. an individual who has incorporated;
- c. a partnership made of former public servants; or
- d. a sole proprietorship or entity where the affected individual has a controlling or major interest in the entity.

"lump sum payment period" means the period measured in weeks of salary, for which payment has been made to facilitate the transition to retirement or to other employment as a result of the implementation of various programs to reduce the size of the Public Service. The lump sum payment period does not include the period of severance pay, which is measured in a like manner.

"pension" means a pension or annual allowance paid under the <u>Public Service Superannuation Act</u> (PSSA), R.S., 1985, c. P-36, and any increases paid pursuant to the <u>Supplementary Retirement</u> <u>Benefits Act</u>, R.S., 1985, c. S-24 as it affects the PSSA. It does not include pensions payable pursuant to the <u>Canadian Forces Superannuation Act</u>, R.S., 1985, c. C-17, the <u>Defence Services Pension</u> <u>Continuation Act</u>, 1970, c. D-3, the <u>Royal Canadian Mounted Police Pension Continuation Act</u>, 1970, c. R-10, and the <u>Royal Canadian Mounted Police Superannuation Act</u>, R.S., 1985, c. R-11, the <u>Members of Parliament Retiring Allowances Act</u>, R.S. 1985, c. M-5, and that portion of pension payable to the <u>Canada Pension Plan Act</u>, R.S., 1985, c. C-8.

Former Public Servant in Receipt of a Pension

As per the above definitions, is the Bidder a FPS in receipt of a pension? Yes () No ()

If so, the Bidder must provide the following information, for all FPSs in receipt of a pension, as applicable:

- a. name of former public servant;
- b. date of termination of employment or retirement from the Public Service.

By providing this information, Bidders agree that the successful Bidder's status, with respect to being a former public servant in receipt of a pension, will be reported on departmental websites as part of the published proactive disclosure reports in accordance with Contracting Policy Notice: 2012-2 and the Guidelines on the Proactive Disclosure of Contracts.

Work Force Adjustment Directive

Is the Bidder a FPS who received a lump sum payment pursuant to the terms of the Work Force Adjustment Directive? **Yes** () **No** ()

If so, the Bidder must provide the following information:

- a. name of former public servant;
- b. conditions of the lump sum payment incentive;
- c. date of termination of employment;
- d. amount of lump sum payment;
- e. rate of pay on which lump sum payment is based;
- f. period of lump sum payment including start date, end date and number of weeks;
- g. number and amount (professional fees) of other contracts subject to the restrictions of a work force adjustment program.

For all contracts awarded during the lump sum payment period, the total amount of fees that may be paid to a FPS who received a lump sum payment is \$5,000, including Applicable Taxes.

5.2 Certifications Precedent to Contract Award and Additional Information

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 provided may render the bid non-responsive.

5.2.1. Status and Availability of Resources

The Bidder certifies that, should it be awarded a contract as a result of the bid solicitation, every individual proposed in its bid will be available to perform the Work as required by PMPRB's representatives and at the time specified in the bid solicitation or agreed to with PMPRB's representatives. If for reasons beyond its control, the Bidder is unable to provide the services of an individual named in its bid, the Bidder may propose a substitute with similar qualifications and experience. The Bidder must advise the Contracting Authority of the reason for the substitution and provide the name, qualifications and experience of the proposed replacement. For the purposes of this clause, only the following reasons will be considered as beyond the control of the Bidder: death, sickness, maternity and parental leave, retirement, resignation, dismissal for cause or termination of an agreement for default.

If the Bidder has proposed any individual who is not an employee of the Bidder, the Bidder certifies that it has the permission from that individual to propose his/her services in relation to the Work to be performed and to submit his/her résumé to PMPRB. The Bidder must, upon request from the Contracting Authority,

provide a written confirmation, signed by the individual, of the permission given to the Bidder and of his/her availability.

5.2.2. Education and Experience

The Bidder certifies that all the information provided in the résumés and supporting material submitted with its bid, particularly the information pertaining to education, achievements, experience and work history, has been verified by the Bidder to be true and accurate. Furthermore, the Bidder warrants that every individual proposed by the Bidder for the requirement is capable of performing the Work described in the resulting contract.

PART 6 - RESULTING CONTRACT CLAUSES

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

6.1 Security Requirements

THIS DOCUMENT CONTAINS A SECURITY REQUIREMENT

Security:

The Contractor will be required to hold a Designated Organizational Screening clearance at the time of contract award. Resource team members will be required to hold valid Reliability security clearances at contract award. The Product monograph drafts may at times be business sensitive but not protected. Contractors will be required to provide a Confidentiality and Non-Disclosure Agreement.

6.1.1 The following security requirements apply and form part of the Contract.

SECURITY REQUIREMENT FOR CANADIAN SUPPLIER:

PWGSC FILE # [Insert File Number]

[Insert Security Clauses from CISD]

6.2 Statement of Work

The Contractor must perform the Work in accordance with the Statement of Work at Annex A.

6.3 Standard Clauses and Conditions

All clauses and conditions identified in the Contract by number, date and title are set out in the <u>Standard Acquisition Clauses and Conditions Manual</u> (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

2035 (2020-05-28), General Conditions – Higher Complexity - Services apply to and form part of the Contract.

6.3.2 Supplemental General Conditions

<u>4007 (</u>2010-08-16), Supplemental Condition - Canada to Own Intellectual Property Rights in Foreground Information apply to and form part of the Contract.

6.4 Term of Contract

6.4.1 Period of the Contract

The "Contract Period" is the entire period of time during which the Contractor is obliged to perform the Work, which includes:

- a) The "Initial Contract Period", which begins on the date the Contract is awarded and ends 12 months later; and
- b) the period during which the Contract is extended, if PMPRB chooses to exercise any options set out in the Contract.

6.4.2 Option to Extend the Contract

The Contractor grants to PMPRB the irrevocable option to extend the term of the Contract by up to two (2) 12-month periods under the same conditions. The Contractor agrees that, during the extended period

of the Contract, it will be paid in accordance with the applicable provisions as set out in Annex B, Basis of Payment and Pricing Schedule.

PMPRB may exercise this option at any time by sending a written notice to the Contractor at least 15 calendar days before the expiry date of the Contract. The option may only be exercised by the Contracting Authority, and will be evidenced for administrative purposes only, through a contract amendment.

6.4.4 Inspection and Acceptance

The Project Authority is the Inspection Authority. All reports, deliverable items, documents, goods and all services rendered under the Contract are subject to inspection by the Inspection Authority or representative. Should any report, document, good or service not be in accordance with the requirements of the Statement of Work and to the satisfaction of the Inspection Authority, as submitted, the Inspection Authority will have the right to reject it or require its correction at the sole expense of the Contractor before recommending payment.

Should any of the Contractor's personnel at any time be unable to provide services, the Contractor will be responsible for providing replacement personnel at the same cost who will be of similar or greater ability and attainment, and whom will be acceptable to the Project Authority.

Under no circumstance will the Contractor allow the performance of services by a replacement resource that has not been authorized by the Project Authority.

6.4.5 Termination on Thirty Days' Notice

Canada reserves the right to terminate the Contract at any time in whole or in part by giving thirty (30) calendar days written notice to the Contractor.

In the event of such termination, Canada will only pay for costs incurred for services rendered and accepted by Canada up to the date of the termination. Despite any other provision of the Contract, there will be no other costs that will be paid to the Contractor as a result of the termination.

6.4.6 Delivery Points

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

The Contracting Authority for the Contract is:

Name: Guillaume Couillard

Title: Director, Regulatory Affairs & Outreach Branch

Telephone: 613-288-9635

E-mail address: Guillaume.couillard@pmprb-cepmb.gc.ca

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 Project Authority

The Project Authority for the Contract is:

Name: Dianne Breau

Title: A/Chief, Scientific Analysis

E-mail address: Dianne.breau@pmprb-cepmb.gc.ca

The Project 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 Project Authority. However, the Project 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

___(to be completed at contract award)____

6.6 Proactive Disclosure of Contracts with Former Public Servants

By providing information on its status, with respect to being a former public servant in receipt of a <u>Public Service Superannuation Act (PSSA)</u> pension, the Contractor has agreed that this information will be reported on departmental websites as part of the published proactive disclosure reports, in accordance with <u>Contracting Policy Notice</u>: 2012-2 of the Treasury Board Secretariat of Canada.

6.7 Payment

6.7.1 Basis of Payment

In consideration of the Contractor satisfactorily completing all of its obligations under the Contract, the Contractor will be paid _____(to be completed at contract award)_____, the firm per hour rate in accordance with the basis of payment and pricing schedule, in Annex B, applicable Taxes are extra.

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

6.7.2 Limitation of Expenditure

- a) PMPRB's total liability to the Contractor under the Contract must not exceed \$ _____(to be completed at contract award)____, applicable Taxes are extra.
- b) No increase in the total liability of Canada or in the price of the Work resulting from any design changes, modifications or interpretations of the Work, will be authorized or paid to the Contractor unless these design changes, modifications or interpretations have been approved, in writing, by the Contracting Authority before their incorporation into the Work. The Contractor must not perform any work or provide any service that would result in Canada's total liability being exceeded before obtaining the written approval of the Contracting Authority. The Contractor must notify the Contracting Authority in writing as to the adequacy of this sum:
 - i. when it is 75% committed, or
 - ii. four months before the contract expiry date, or
 - iii. as soon as the Contractor considers that the contract funds provided are inadequate for the completion of the Work,

whichever comes first.

c) If the notification is for inadequate contract funds, the Contractor must provide to the Contracting Authority a written estimate for the additional funds required. Provision of such information by the Contractor does not increase Canada's liability.

6.7.3 Terms of Payment

Canada will pay the Contractor on a monthly basis for work performed during the month covered by the invoice in accordance with the payment provisions of the Contract if:

- a) 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.
- b) all such documents have been verified by PMPRB;

c) the Work performed has been accepted by PMPRB.

6.8 Invoicing Instructions

The Contractor must submit invoices in accordance with the information required in Section 12 of 2035, General Conditions https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual/3/2035/18#invoice-submission. Invoices cannot be submitted until all work identified in the invoice is completed.

The original invoice must be forwarded to the Project Authority identified under the section entitle "Authorities" of the Contract, no later than 30 calendar days after the end of a monthly period.

6.9 Compliance

The continuous compliance with the certifications provided by the Contractor in its bid and the ongoing cooperation in providing additional information are conditions of the Contract. Certifications are subject to verification by PMPRB during the entire period of the Contract. If the Contractor does not comply with any certification, fails to provide the additional information, or if it is determined that any certification made by the Contractor in its bid is untrue, whether made knowingly or unknowingly, PMPRB has the right, pursuant to the default provision of the Contract, to terminate the Contract for default.

6.10 Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario.

6.11 Insurance

The Contractor must obtain and maintain an appropriate level of professional liability insurance coverage. It is the sole responsibility of the Contractor to decide whether or not any insurance coverage is necessary for its own protection or to fulfill its obligations under the Contract and to ensure compliance with required federal, provincial or municipal law. Any such insurance must be provided and maintained by the Contractor at its own expense.

6.12 Priority of Documents

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.

- a) the Articles of Agreement;
- b) the supplemental general conditions 4007 Canada to Own Intellectual Property Rights in Foreground Information (2010-08-16);
- c) the general conditions 2035 (2020-05-28), General Conditions Higher Complexity Services;
- d) Annex A, Statement of Work;
- e) Annex B, Basis of Payment and Pricing Schedule;
- f) Annex C, Security Requirements Check List;
- g) Annex D, Non-Disclosure Agreement
- h) the Contractor's bid dated _____ (insert date of bid).

ATTACHMENT 1 - BID SUBMISSION FORM

Bid Submission Form for the Patented Medicine Prices Review Board (PMPRB) RFP Reference Number SN21002			
A. GENERAL INFORMATION			
Bidder's full legal name			
	Name		
	Title		
Authorized Representative of Bidder for evaluation purposes (e.g.,	Address		
clarifications)	Telephone #		
	Fax #		
	Email		
Bidder's Procurement Business Number (PBN)			
[see the Standard Instructions 2003]			
Jurisdiction of Contract: Province in Canada the Bidder wishes to be the legal jurisdiction applicable to any resulting contract (if other than as specified in solicitation)			
Integrity Provisions See the Article in Part 5 of the bid solicitation entitled Integrity Provisions – Declaration of Convicted Offences and Required Documentation	Has the Bidder provided the required information, in accordance with the <i>Ineligibility and Suspension Policy</i> (http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html), 2003 (2020-05-28) Standard Instructions - Goods or Services - Competitive Requirements: Section 01 (2016-04-04) Integrity provisions, Article 2.1 of Part 2 Bidder Instructions, and Part 5 Certifications and Additional Information? Yes \[\] No \[\]		
	If Yes, indicate the section or page number of the proposal where this information can be found:		

Bid Submission Form for the Patented Medicine Prices Review Board (PMPRB) RFP Reference Number SN21002				
	Is the Bidder a FPS in receipt of a pension as defined in the bid solicitation? Yes No If yes, provide the information required by the Article in Part 5 entitled "Former Public Servant Certification"			
Former Public Servants See the Article in Part 5 of the bid solicitation entitled Former Public Servant Certification for a definition of "Former Public Servant".	Is the Bidder a FPS who received a lump sum payment under the terms of a work force reduction program? Yes No I If yes, provide the information required by the Article in Part 5 entitled "Former Public Servant Certification"			
	(a) Is subject to FCP-EE and has a valid certification number as follows: (and has not been declared an Ineligible Contractor by HRSD).			
Status and Availability of Resources	Does the Bidder certify section 5.2.1 Status and Availability of Resources? Yes No			
Education and Experience	Does the Bidder certify section 5.2.2 Education and Experience? Yes No			
Security Clearance Level of Bidder [include both the CISD security clearance number, level and the date it was granted]				
Security Clearance Level of Bidder's Individual Resources [add	i.			

Bid Submission Form for the Patented Medicine Prices Review Board (PMPRB) RFP Reference Number SN21002				
I .	litional resources on another ue, if required)	ii.		
i.	Name of Individual as it appears on security clearance application:			
ii.	Level of security clearance obtained and expiry date:	iii.		
iii.	Security Screening Certificate and Briefing Form file number			
	urance Requirement: Bidder certifies has provided the red	quired Insurance documentation as specified within the RFP.		
		w, I confirm that I have read the entire bid solicitation including the to the bid solicitation and I certify that:		
1.	1. The Bidder considers itself and its products able to meet all the mandatory requirements described in the bid solicitation;			
2.	The Bidder certifies all information	and certifications provided within this Bid Submission Form;		
3.	This bid is valid for the period requ	uested in the bid solicitation;		
4.	All the information provided in the	bid is complete, true and accurate; and		
5.	5. If the Bidder is awarded a contract, it will accept all the terms and conditions set out in the resulting contract clauses included in the bid solicitation.			
Signature of Authorized Representative of Bidder:				

ATTACHMENT 2 – TECHNICAL CRITERIA

Mandatory Evaluation Criteria:

The Mandatory Evaluation Criteria listed below will be evaluated on a simple Pass/Fail (i.e., compliant/non-compliant) basis. Bids that fail to meet one of the Mandatory Evaluation Criteria will be deemed non-compliant and given no further consideration.

Bids must demonstrate compliance with all of the Mandatory Evaluation Criteria as described in the Criteria and must provide the necessary documentation to support compliance in order to be evaluated on the basis of the Point-Rated Evaluation Criteria.

MANDATORY EVALUATION CRITERIA

M1. Bidder's Experience

The Bidder must demonstrate the completion of six (6) projects similar* to those described within the Statement of Work. It is the Bidder's responsibility to demonstrate how these projects are similar to the PMPRB's statement of work. *Similar may include medical, pharmaceutical, scientific, therapeutic product and / or device review and evaluation.

M2. Bidder's Point of Contact

The Bidder must identify a Point of Contact for PMPRB and demonstrates the Point of Contact's experience managing a similar requirement and team to that described within the Statement of Work.

M3. Bidder's Resource Team Leads

The Bidder must demonstrate that two (2) proposed resource team members each meet the following minimum qualifications:

- The resource has a degree in pharmacy from a CCAPP-Accredited Pharmacy Program or an equivalent degree as assessed by the Pharmacists' Gateway Canada program for international pharmacists;
- b. The resource has a current license to practice as a pharmacist in a Canadian jurisdiction, which must be proven by provision of the resource's licence number;
- c. The resource has a minimum of five (5) years of demonstrated clinical pharmacy experience;
- d. The resource has a minimum of two (2) years of demonstrated experience providing research, analysis and reporting of information of scientific literature.
- e. The resource has experience searching grey literature.

M4. Bidder's Minimum Literature Access

The Bidder must demonstrate its ability to access the following literature resources:

- a. Access to Medline (e.g., Ovid Medline or PubMed) to facilitate primary literature searching;
- b. Access to original reports in the periodical literature and a method of obtaining primary periodical literature, including reprints;
- c. Access to a minimum of two on-line secondary information sources such as RxTx, UpToDate, Dynamed, BMJ Best Practice, or Micromedex; and
- d. Access to relevant grey literature publications where appropriate (e.g., health technology assessments, regulatory agency reports, clinical trial registry reports).

Point Rated Evaluation Criteria:

Bids meeting all Mandatory Evaluation Criteria will be further evaluated and point rated against the following Point-Rated Evaluation Criteria, using the evaluation factors and weighting indicators specified for each criterion.

Bids must meet a minimum pass mark of 60% cumulatively over all of Point-Rated Evaluation Criteria (R1-R5). Bids which fail to obtain the required minimum number of points specified will be declared non-responsive. Each point rated technical criterion should be addressed separately.

Scoring Guide for Point Rated Criteria

Scoring Guide (out of 10)			
Score	Description		
10 = Excellent	Response is complete and exceeds the requirements.		
8 = Good	Response substantially meets all and exceeds some of the requirements.		
7 = Satisfactory Response substantially meets all of the requirements.			
5 = Fair Response meets most of the requirements.			
3 = Marginal Response meets only some of the requirements.			
1 = Poor Response is insufficient. Information provided is too vague and does not clearly explain how requirements are/will be met.			
0 = Not relevant No relevant response or simple statement of compliance with no substantiation consideration.			

For illustrative purposes only the Scoring Guide would be used in the following manner:

For a criterion weighted to 20 points, "Good" (8 points) on the Scoring Guide, would be weighted to 16 points out of the Maximum Point Value of 20 points.

Point Rated Criteria:

POINT-RATED EVALUATION CRITERIA	WEIGHT	Demonstrated Experience	
R1. Bidder's Sample Reports			
a. the sample reports used as part of the delivery of services in the six (6) projects proposed in M1; and b. A sample report prepared using PMPRB format, as shown in Annex A1: Report Template. This sample report is for a pre-selected drug and indication as detailed below: i. For Imfinzi for treatment of locally advanced or metastatic urothelial cancer (information up to 2018) that has progressed on platinum-based therapy. For the six (6) reports in R1.a) the Bidder should demonstrate the similarity of these project's reports to the requirement as stated in the Statement of Work. It is the Bidder's responsibility to show how these reports are similar to what is required within the Statement of Work. For the sample report in R1. b) The Bidder should demonstrate an understanding of the requirements and report accuracy within the sample report. It is the Bidder's responsibility to show all information for all sections of the sample report using the PMPRB format (Annex A1: Report Template).	40 points	A maximum of 40 points will be awarded in accordance with the scoring guide and weighted as 20 points for the six (6) sample reports from the projects proposed in M1.and 20 points for the sample report provided in R1.	
R2. Standard Methodology and Approach			
The Bidder should describe its standard Methodology and Approach, incorporating the following: a. A description of the Standard Methodology and Approach that was used to deliver the services identified in the six (6) projects identified in M1 and	70 points	A maximum of 60 points will be awarded for R2, where each sub-factor a) to c) is scored using the Scoring Guide for Point Rated Criteria and a) is weighted out of 30 points, b) is weighted out of 20 points and c) is weighted out of 20 points.	

POINT-RATED EVALUATION CRITERIA	WEIGHT	Demonstrated Experience
the sample report identified in R1. The description should incorporate the Bidder's: i. literature search strategy from the sample reports, ii. Identification and description of the summary of identified literature, iii. A critical appraisal of results and conclusions or recommended actions (where applicable) based on evidence identified. iv. Identify that the literature search is undertaken using secondary retrieval systems such as EMBASE, CINAHL, International Pharmaceutical Abstracts, Google Scholar or other relevant indexing systems. v. Identification of relevant primary literature. vi. Identification of tertiary literature such as subscription databases used to augment or contextualize the information identified in a literature search. b. Incorporation of an understanding of PMPRB's requirement as part of the methodology that will be used to provide the service as described in the Statement of Work. c. Description of how this standard approach will be used to complete the deliverables for PMPRB's requirements. This should include a description of the sources of primary, secondary and tertiary information that the resource team will access.		

POINT-RATED EVALUATION CRITERIA	WEIGHT	Demonstrated Experience
For the two (2) resources proposed in M.3, the Bidder should demonstrate: a. The resource's clinical pharmacy experience in excess of the five (5) years of demonstrated experience in M.3; b. The resource' experience providing research, analysis and reporting of information of scientific literature in excess of the two (2) years of demonstrated experience in M.3; c. Each resource's demonstrated experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates: i. Drug reviews; ii. Critical appraisal and literature evaluation; iii. Adherence to Best practices;	WEIGHT 50 points	A maximum of 50 points will be awarded as 25 points for each of the two (2) resources proposed in M3. For a. Up to 8 points will be awarded as two (2) points per additional year of experience in excess of the five (5) years of demonstrated experience in M.3. (e.g., six (6) years of demonstrated experience overall will achieve two (2) points) For b. Up to 8 points will be awarded as four (4) points per additional year of experience in excess of the two (2) years of demonstrated experience in M.3. (e.g., three (3) years of demonstrated experience overall will achieve four (4) points) For c. 9 points will be awarded where the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates all three (3) of the items listed under c. 7 points will be awarded where the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates two (2) of the three (3) items listed under c. 3 points will be awarded where the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates one (1) of
		demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates two (2) of the three (3) items listed under c. 3 points will be awarded where the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the
		Statement of Work and incorporates one (1) of the three (3) items listed under c. 0 points will be awarded where the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates none of the three (3) items listed under c.

POINT-RATED EVALUATION CRITERIA	WEIGHT	Demonstrated Experience			
R4. Bidder's Resource Capacity	R4. Bidder's Resource Capacity				
The Bidder should describe its capacity to provide multiple resources by identifying up to two (2) additional proposed resources that meet the minimum qualifications of M3 and are assessed against the following criteria:	20 points	A maximum of 20 points will be awarded as 10 points for each of the two (2) additional resources.			
 a. The resource's clinical pharmacy experience in excess of the five (5) years of experience in M.3; b. The resource' experience providing research, analysis and reporting of information of scientific literature in excess of the two (2) years of experience in M.3; c. Each resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates: i. Drug reviews; 		For a. Up to 4 points will be awarded as one (1) point per additional year of experience in excess of five (5) years of demonstrated minimum experience. (e.g., six (6) years of demonstrated experience overall will achieve one (1) point) For b. Up to 3 points will be awarded as three (3) point2 per additional year of experience in excess of two (2) years of demonstrated minimum experience. (e.g., three (3) years of demonstrated experience overall will achieve three (3) points.) For c. 3 points will be awarded where the Bidder			
ii. Critical appraisal and literature evaluation; iii. Adherence to Best practices;		demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates all three (3) of the items listed under c.			
		2 points will be awarded where the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates two (2) of the three (3) items listed under c.			
		1 points will be awarded where the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work and incorporates one (1) of the three (3) items listed under c.			
		0 points will be awarded where the Bidder demonstrates the resource's experience providing research, analysis and reporting of information similar/relevant to the tasks in the			

POINT	-RATED EVALUATION CRITERIA	WEIGHT	Demonstrated Experience
			Statement of Work and incorporates none of the three (3) items listed under c.
R5. Bidder's Resource Management Approach			
The Bidder should describe its resource management approach which should include:		40 points	A maximum of 40 points will be awarded in accordance wit the scoring guide and weighted as 20 points for a. and 20 points for b.
a. b.	its capacity to complete simultaneous requests and the maximum volume of requests that can be complete simultaneously; its ability to retain qualified resources; and how the Bidder ensures its resources have access to the appropriate guidelines and information to complete the research and reviews, identifying the specific sources that will be used;		For a., the Bidder will have achieved full points in accordance with the scoring guide and if there is an indication that the Bidder has the capacity to complete more than four (4) simultaneous requests.

ANNEX A - STATEMENT OF WORK

1. Scope

1.1. Title

Scientific Literature Search services for the Patented Medicine Prices Review Board.

1.2. Introduction

The Patented Medicine Prices Review Board (PMPRB) requires the expertise and services of a qualified Contractor and resources in the area of research of scientific literature. As part of the PMPRB's regulatory mandate, these services are required to inform the understanding of the place in therapy of new medicines during the review of the introductory price of any new patented medicine introduced on the Canadian market.

1.3. Objectives of the Requirement

The objective of the contract is to provide the PMPRB with drug information reports in PMPRB's prescribed format based on the review of appropriate references concerning patented medicines specified by the PMPRB as stated herein. Reports will be requested on an as required basis and will require Contractors and Contractor Resources with knowledge and experience conducting the required research as specified within this Statement of Work.

1.4. Background

The Patented Medicine Prices Review Board (PMPRB) is an independent, quasi-judicial body established by Parliament in 1987 under the <u>Patent Act</u>.

The PMPRB protects the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. It does this by reviewing the prices that patentees charge for individual patented drug products in Canadian markets. If a price appears to be excessive, the Board can hold public hearings and order price reductions and/or the offset of excess revenues. The PMPRB is also responsible for reporting on trends in pharmaceutical sales and pricing for all medicines and for reporting Research and Development (R&D) spending by patentees.

The Minister of Health is responsible for the pharmaceutical provisions of the *Patent Act* (Act) as set out in sections 79 to 103. The PMPRB is part of the Health Portfolio, which also includes Health Canada, the Public Health Agency of Canada and the Canadian Institutes of Health Research. The Health Portfolio supports the Minister of Health in maintaining and improving the health of Canadians.

Although part of the Health Portfolio, the PMPRB carries out its mandate at arm's length from the Minister of Health. It also operates independently of other bodies such as Health Canada, which authorizes the sale of drugs in Canada after their assessment for safety, efficacy and quality; federal, provincial and territorial public drug plans, which are responsible for listing reimbursement decisions for their respective plans; and the Common Drug Review, administered by the Canadian Agency for Drugs and Technologies in Health, which provides listing recommendations to participating public drug plans based on cost-effectiveness.

Jurisdiction:

Regulatory

The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada to ensure that they are not excessive. It includes sales for both human and veterinary use. The PMPRB regulates the price of each patented drug product. This includes each strength of each dosage form of a medicine.

The Board's jurisdiction is not limited to drug products for which the patent is on the active ingredient. Rather, the Board's jurisdiction also covers drugs for which the patents relate to, but are not limited to, the processes of manufacture, the delivery system or dosage form, the indication/use and any formulations.

Patented drug products are not limited to brand-name products. A number of generic companies fall under the Board's jurisdiction by virtue of being licensees selling the same drug product as the brand company or because of manufacturing or processing patents, which various generic companies also hold.

The PMPRB has no authority to regulate the prices of non-patented drugs and does not have jurisdiction over prices charged by wholesalers or pharmacies, or over pharmacists' professional fees. Also, matters such as whether medicines are reimbursed by public drug plans, their distribution and prescribing are outside the purview of the PMPRB.

Under the Act, patentees are required to inform the PMPRB of their intention to sell a new patented drug product. Upon the sale of such a patented drug product, patentees are required to file price and sales information at introduction and, thereafter, twice a year for each strength of each dosage form of each patented drug product sold in Canada.

Although patentees are not required to obtain approval of the price before a drug is sold, they are required to comply with the Act to ensure that the prices of patented drug products sold in Canada are not excessive. In the event that the Board finds, after a public hearing, that a price is or was excessive in any market, it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received.

Reporting

The PMPRB reports annually to Parliament through the Minister of Health on its activities, on trends relating to the sales and prices of medicines, and on R&D spending by patentees.

Through the National Prescription Drug Utilization Information System (NPDUIS) program, the PMPRB provides critical analyses of price, utilization and cost trends in Canada to support decision making by participating federal, provincial and territorial public drug plans.

2. Scope of the Requirement

Through a Contract Agreement the Patented Medicine Prices Review Board (PMPRB) will obtain the expertise and services of Contractor resources in terms of research of relevant scientific literature and the understanding of the place in therapy of new medicines under review to support the PMPRB's mandate. These services are to support the scientific review component of the price review process and investigations of the Regulatory Affairs and Outreach Branch at PMPRB.

Historically, there have been 60 to 80 product review requests per year, based on current guidelines, which require assessment of each new Notice of Compliance (NOC) granted. With the move to new guidelines, taking effect July 1, 2021, which require evaluation of each new Health Canada-granted indication, there is a potential for 20 to 40 additional evaluations to be required each year in addition to the historical values noted above. However, the historical values and estimates are for information purposes only and not a guarantee of work under this requirement.

The Contractor may also be required to provide ad-hoc services, as and when requested, such as:

- · providing information obtained from the Contractor's access to scientific journals; and
- update the content of the deliverable due to areas of rapid development that require further substantiation of new information.

2.1. Deliverables

The Contractor will provide knowledgeable and experienced resources that will undertake the following types of tasks and complete the following types of deliverables, with the specifics outlined at the commencement of each request by the Project Authority.

 Conduct the substantiating research required to provide, as and when requested, research services pertaining to the therapeutic area of the medicine, clinical guidelines and other relevant information for that medicine;

- Provide the reports requested by the Project Authority in the prescribed format based on the review of appropriate references concerning patented medicines specified by the PMPRB;
- Update the reports as requested by the Project Authority as edits to draft reports or to update information based on changes to substantiating information; and
- Provide information as requested by the PMPRB to support the PMPRB's mandate, relevant to the review of appropriate references concerning patented medicines, including access to relevant sources used in the review.

2.2. Tasks and Activities

The Contractor will perform the following tasks as and when required by the Project Authority:

- **2.2.1.** Review appropriate references concerning patented medicines specified by the PMPRB and provide a report in the prescribed format (see Annex A1) that will include the following information:
 - a. The approved indication(s) for the patented medicine under review (or the proposed indication/use if the drug is not yet approved);
 - b. The use(s) or indication(s) of the patented medicine as indicated in the product monograph with information specified for the individual strengths or dosage forms (generally the Drug Identification Number (DIN)) of the patented medicine if the therapeutic use is different for each DIN. Use(s) or indication(s) of interest may be identified by the Chief, Scientific Analysis or designate from time to time for these requests;
 - c. Prevalence information for the use(s) or indication(s) of the patented medicine as indicated in the product monograph, or the use(s) or indication(s) of interest as identified by the Chief, Scientific Analysis or designate.
 - d. The usual recommended dosage regimen, including the maximum approved dosage regimen, for the patented medicine under review, and for the individual DINs of the patented medicine unless specified otherwise by Board Staff;
 - e. A list of comparable medicines for the DIN under review specifying the company, brand name, generic name, DIN, dosage form, strength and the World Health Organization's Anatomic and Therapeutic Classification (ATC) code for each.
 - f. Comparable medicines must be considered clinically comparable and generally have comparable dosage forms as determined by PMPRB's Compendium of Policies, Guidelines and Procedures (http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492). The Contractor must indicate if the accepted use of the comparable medicine is NOT an approved indication.
 - g. For each comparable medicine listed, the dosage regimen that is required to produce a Clinically Comparable effect to the DIN under review when the latter is administered according to the dosage regimen identified in paragraph c above. Any references relied upon or assumptions made in determining the proposed dosage regimens must be clearly documented in the report such that it is clear how the comparable dosage regimes were derived.
 - h. A list of the references used to support the information provided in paragraphs a through f above, as well as electronic copies of pertinent references used in the review. The file name for each electronic copy should start with the reference number, followed by last name of first author, initial and year. For example: "Ref 1-Smith J 2014". Any additional references considered should be listed at the end of the report using the alphabet for numbering. The electronic copy of such information should be saved as "A- Jones E 2014". Product monographs or other like documents such as U.S. Summary of Prescribing Information will be identified by brand name (or generic name if brand unavailable) of the product and date of publication of the monograph e.g., "Ref 29–Amoxi-Clav 2019". Guidelines will be referenced by Author name followed by sponsoring organization name e.g., "Ref 1- Martin A 2019 NCCN".

- **2.2.2.** An electronic copy of the completed report and all pertinent references used in the review must be submitted to the PMPRB within 30 calendar days from the date of initial review request or as otherwise agreed upon with the PMPRB at the time the request is made. The template for the report is provided in Annex A1. The template and content of the New Medicine Scientific Review may be modified in the future given operational requirements.
- **2.2.3.** Provide on request, for specified drug product reviews:
 - a. Any further clarification or explanation of the report submitted by the Contractor as requested. There will be no additional charge to the PMPRB for this activity however time spent should be noted in the invoice report.
 - b. Copies of any additional references pertaining to the review completed, as requested.
- **2.2.4.** Provide other drug information on request (e.g., specific Medline searches), to be submitted to the PMPRB within 2 working days from the request or as otherwise agreed upon with the PMPRB at the time the request is made.
- 2.2.5. Keep a detailed record which identifies the nature of the work completed for the PMPRB including:
 - a. Drug name, number of DINs and number of comparators identified (where applicable);
 - b. Total time required to respond to each request;
 - c. Identity of pharmacist who completed the research/review;
 - d. Date work completed;
 - e. Total time spent in the month for which the invoice was submitted plus cumulative time to date.
 - f. This record will be submitted to the PMPRB on a monthly basis along with the invoice for payment.
- **2.2.6.** The Contractor will on request, give written or verbal evidence under oath before the Board in the course of any proceedings under the Patent Act respecting patented drug products which have been reviewed by the contractor.

2.3. Specifications and Standards

The Chief, Scientific Analysis or designate will provide details on qualitative and quantitative measures of the work to be completed and the Contractor will provide the deliverables of this work in accordance with these details and measures. The Chief, Scientific Analysis or designate will use these same details and measures to determine completion and satisfaction with the work.

2.3.1. Deliverable Format

All document-based deliverables will be delivered in electronic format, compatible with the PMPRB's standard desktop software, currently, Microsoft Office Suite (including Word, Excel, and PowerPoint) or Portable Document Format, as specified by PMPRB at the time of request.

The Contractor may be required to adapt its work to ensure compatibility with the technology within PMPRB.

2.3.2. Deliverable Acceptance

In meeting its obligations under the Contract, the Contractor will ensure that all deliverables submitted and services rendered are in conformity with any instructions issued by the PMPRB Project Authority.

Payment will be made upon receipt of an invoice, and as accepted by the PMPRB Project Authority, based on the terms of payment specified within the Contract . The payment terms may be rates provided per review or by hourly payments based on the level of effort to complete the specified deliverables.

Should any deliverable or service provided not be to the satisfaction of the PMPRB Project Authority, as submitted, the PMPRB Project Authority will have the right to reject it or require correction by the Contractor at no charge to PMPRB before any payment will be authorized to the Contractor.

2.4. Method and Source of Acceptance

All deliverables and services rendered under the contract are subject to inspection by the Chief, Scientific Analysis or a designated representative. Should any deliverable not be to the satisfaction of the Project Authority, as submitted, the Project Authority will reserve the right to verify the accuracy and completeness, reject it or require correction before payment will be authorized by the Project Authority.

2.5. Project Management Control Procedures

The PMPRB individual identified as the Project Authority will oversee the work delivered through reviews of the completed reports and references.

In addition to the timely submission of all deliverables and fulfillment of obligations specified within the Contract, it is the responsibility of the Contractor to facilitate and maintain regular communication with the PMPRB Project Authority.

Communication is defined as all reasonable effort to inform all parties of plans, decisions, proposed approaches, and results of work, to ensure that the work is progressing well and in accordance with expectations. Communication may include (but is not limited to) phone calls, electronic mail, and meetings.

The Contractor will respond to inquiries from the PMPRB Project Authority, Chief, Scientific Analysis or designate within one (1) business day.

Additionally, the Contractor will immediately bring to the attention of the PMPRB Project Authority any issues, problems, or areas of concern in relation to any work completed under the Contract, as they arise, in order to proactively seek a mutual resolution to these concerns, before they escalate.

Change Management Procedures

Any proposed changes to the specifications and scope of the work will be mutually discussed and agreed upon by the Contractor and Contracting Authority in the form of a written contract amendment.

3. Additional Information

3.1. Authorities

Contracting Authority

The Contracting Authority for the Contract is:

Name: Nadia Laneve

Title: Chief, Administrative Services

Organization: Patented Medicine Prices Review Board

Address: 333 Laurier Avenue West, Suite 1400, Ottawa, ON K1P 1C1

Telephone: 613-288-9575

E-mail address: nadia.laneve@pmprb-cepmb.gc.ca

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 or Contractor's Resources 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.

Project Authority

The Project Authority and Chief, Scientific Analysis or designate for the Contract will be identified at the time of Contract award.

The Project 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 Project Authority; however, the Project 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.

3.2. PMPRB's Obligations

As required for the completion of work, PMPRB will provide:

- a. Access to the appropriate subject matter experts from within their organization for the Contractor to discuss and provide content, source, and/or reference material, as well as to facilitate cooperation with other representatives of their organization as required;
- b. Identification of the product to be reviewed, a copy of the product monograph (as applicable), and any additional instructions regarding the scope of the review at time of review request.
- c. Electronic delivery addresses, to which deliverables are to be submitted.

3.3. Contractor's Obligations

Unless otherwise specified, the Contractor must use its own equipment, software (including word processing software), scientific literature search subscriptions and databases for the performance of this Statement of Work.

In fulfilling the terms and conditions of the Contract, the Contractor shall:

- a. Provide a mutually agreed-upon principal Point of Contact for the Contractor, who will be actively involved in, and responsible for, all activities undertaken;
- b. Provide a finalized work plan and schedule and will obtain PMPRB's approval, prior to the commencement of any work issued against the Contract;
- c. Complete assigned work according to pre-defined schedules and standards and as per this Statement of Work;
- d. Provide quality assurance and monitoring on all deliverables;
- e. As required, liaise with the PMPRB Project Authority and any stakeholders identified by the PMPRB Project Authority for meetings, project reviews and other related project management activities.

3.4. Location of Work, Work Site and Delivery Point

It is anticipated that the work will be conducted at the Contractor's work site(s) and will be in accordance with local, provincial and federal health guidelines.

3.5. Meetings

The Contractor's resources may be required to attend meetings via teleconference or videoconference as requested by the Project Authority. These meetings may be annual meetings to address the Contract.

3.6. Language of Work

The Contractor will ensure that all verbal and written communication with PMPRB is in English, at a minimum.

The language of all reports and documents will be in English.

3.7. Constraints/Special Requirements

The services of the Contractor must be completed within a strict timeline to meet the PMPRB's commitments. The Contractor may be required to conduct work outside of its normal operating hours in order to meet associated deadlines. All services rendered will be subject to remuneration in accordance with the rates and prices set out in Annex B Basis of Payment and Pricing Schedule (note there is no provision for overtime under this Contract). Notwithstanding, the Contractor is responsible for the organization of its resources to ensure the timely completion of the work.

3.8. Travel and Living

PMPRB will not pay any travel or living expenses associated with performing the Work as there is no requirement for travel anticipated under this Contract. The Contractor is responsible for all costs related to local transportation and any travel expenses.

4. Project Schedule

4.1. Expected Start date and Level of Effort

The Contractor's services will be required for a period of one (1) year with two (2) one-year option periods exercised at PMPRB's sole discretion.

5. Required Resources

The Contractor will provide Resources to complete the Tasks and Deliverables stated herein. These Resources must meet the following qualifications, at a minimum:

- a. The resource has a degree in pharmacy from a CCAPP-Accredited Pharmacy Program or an equivalent degree as assessed by the Pharmacists' Gateway Canada program for international pharmacists;
- b. The resource has a current license to practice as a pharmacist in a Canadian jurisdiction;
- c. The resource has a minimum of five (5) years of clinical pharmacy experience;
- d. The resource has a minimum of two (2) years of experience providing research, analysis and reporting of information of scientific literature;
- e. The resource has experience searching grey literature.

The Contractor's Resources should also have experience providing research, analysis and reporting of information similar/relevant to the tasks in the Statement of Work that incorporates drug reviews, critical appraisals and literature evaluation and should have experience adhering to best practices.

6. Applicable Documents and Glossary

6.1. Relevant Terms, Acronyms and Glossaries

Term/Acronym	<u>Definition</u>
Clinically Comparable	The result of a review in accordance with the PMPRB's Compendium of Policies, Guidelines and Procedures. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492
Comparable Dosage Forms	As defined within the PMPRB's Compendium of Policies, Guidelines and Procedures http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492
Contracting Authority	The Contracting Authority will be the sole authority on behalf of Canada for the administration and management of this Contract. Any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor is not to perform work in excess of or outside the scope of the Contract based on written requests from any government personnel other than the Contracting Authority.
Contractor	The qualified supplier awarded a Contract pursuant to the competitive selection process.

Term/Acronym	<u>Definition</u>
DIN	Drug Identification Number
Chief, Scientific Analysis	The officer or employee of the Crown authorized by PMPRB, as a PMPRB contact concerning matters related to tasks and deliverables.
NCR	National Capital Region.
NOC	Notice of Compliance
Personal Information	Has the meaning as set out in the <i>Privacy Act</i> .
Project Authority	The officer or employee of the Crown who is authorized by the Minister to perform any of the Project Authority's functions as described in the Articles of Agreement. The Project Authority or his/her delegate is responsible for all matters concerning the technical content of the work as specified in the Contract.
Resource	Means personnel (whether employed or subcontracted) of the Contractor, qualified by the PMPRB to provide Services under the Contract.
sow	Statement of Work.

ANNEX A1: REPORT TEMPLATE

NEW MEDICINE SCIENTIFIC REVIEW (DIC Name)

PROTECTED

PRODUCT: Drug Name (generic name)- Company name

INDICATION(S):
ATC CODE:

DIN FORM STRENGTH

- 1 BACKGROUND
 - 1.1 ATC Classification
 - 1.2 NOC Status
 - 1.3 Disease Background
 - 1.4 Pharmacology and Pharmacokinetics
- 2 CLINICAL TRIALS
 - 2.1 Comparative Clinical Trials

Author and Study Design	Patient Population	Interventions	Outcomes

2.2 Non-Comparative Clinical Trials

Author and Study Design	Patient Population	Interventions	Outcomes

2.3 Any additional clinical information should also be provided in tabular format.

3 COMPARATORS

- 3.1 4th Level ATC
- 3.2 Clinical Trials
- 3.3 Guidelines
- 3.4 Expert Opinions
- 3.5 Comparator Summary
- 3.6 Other Considerations

4 COMPARABLE DOSAGE REGIMENS

5 REFERENCES CONSIDERED

A list of the references used to support the information provided above, as well as electronic copies of pertinent references.

- 1.
- 2.
- 3.

6 ADDITIONAL REFERENCES CONSIDERED

List of any additional references considered as well as electronic copies of additional references considered.

- Α
- В
- С

ANNEX B - Basis of Payment and Pricing Schedule

At Bid submission, the Bidder should complete the attached pricing tables below and include this completed Annex B in its financial bid.

Any volumetric data included in the pricing schedule is 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.

Travel and Living expenses are not authorized 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.

During the period of the Contract and Option period(s), for Work performed by the Contractor in accordance with the Contract, the Contractor will be paid as specified below. Options periods are only applicable if the option to extend is exercised by the PMPRB.

Estimate Calculation for Evaluation Purposes only

Table 1: Evaluation Estimate Calculation – Per Hour & Overall Estimated Evaluation Calculation

		Evaluation Estima	te Calculation	
	A	В	D (BxC)	
	Period of Contract	Hourly Rate	Evaluation Estimate for Period	Estimated Hourly Cost TAXES NOT INCLUDED
1	Initial Contract Period	\$[insert hourly rate]	100	\$
2	Option Period 1	\$[insert hourly rate]	100	\$
3	Option Period 2	\$[insert hourly rate]	100	\$
		\$		
	Total amount of			

With the exception of the rates specified above, the amounts shown as "Evaluation Estimate for Period" are used for evaluation purposes only and are not reflective of the work.

For the purpose of this Contract, payment will be made in accordance of completed deliverables accepted by the Chief, Scientific Analysis and Project Authority.

ANNEX C - SECURITY REQUIREMENTS CHECK LIST

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		LIS		ATION DES EXIGENCE							
PART A - CO	NTRACT INFOR			INFORMATION CONTRAC							
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				accès à des renseignement	s ou à	des biens PROTEC	BES et/ou CLASSIFIES?		Non	_	Ou
			ing the chart in Qu	iestion 7. c) i qui se trouve à la question	7 0)						
						access to restricted	access areas? No access to		No	$\overline{}$	1 Yes
				or assets is permitted.	cquire	access to restricted	access areas: 140 access to	~	Non		Ou
					ont-ils	accès à des zones	d'accès restreintes? L'accès		NOI		JOu
				ÉS et/ou CLASSIFIÉS n'est							
				ent with no overnight storac							
6. c) is this a	Commercial Count	ei oi	delivery requirem	ent with no overnight storag	e?				No		Ye
				ent with no overnight storag on commerciale sans entre		e de nuit?		~	No Non		
² S'agit-il	d'un contrat de m	essa	gerie ou de livrais	on commerciale sans entre	osage		on auguel le fournisseur devra	• avoir	Non		
² S'agit-il	d'un contrat de m the type of inform	essa	gerie ou de livrais	on commerciale sans entre	ndique		on auquel le fournisseur devra		Non		
² S'agit-il	d'un contrat de m	essa	gerie ou de livrais	on commerciale sans entre	ndique		on auquel le fournisseur devra		Non		
S'agit-il	d'un contrat de m the type of inform Canada	essagnation	gerie ou de livrais	on commerciale sans entre will be required to access / NATO / OTAN	ndique		T .		Non		
S'agit-il 7. a) Indicate	d'un contrat de m the type of inform Canada e restrictions / Res	essagnation	gerie ou de livraise that the supplier	on commerciale sans entre will be required to access / NATO / OTAN diffusion All NATO countries	ndique		T .		Non		
7. a) Indicate 7. b) Release No release Aucune res	d'un contrat de m the type of inform Canada e restrictions / Res restrictions triction relative	essagnation	gerie ou de livraise that the supplier	on commerciale sans entre will be required to access / NATO / OTAN diffusion	ndique		Foreign / Étrange No release restrictions Aucune restriction relative		Non		
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S'agit-il 7. a) Indicate 7. b) Release No release Aucune res à la diffusio	d'un contrat de m the type of inform Canada e restrictions / Res restrictions triction relative	essagnation	gerie ou de livraise that the supplier	on commerciale sans entre will be required to access / NATO / OTAN diffusion All NATO countries	ndique		Foreign / Étrange No release restrictions Aucune restriction relative		Non		
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TBS/SCT 350-103(2004/12)

Security Classification / Classification de sécurité

UNCLASSIFIED

Canadä



Contract Number / Numéro du contrat	
SN21002	
Security Classification / Classification de sécurité UNCLASSIFIED	

PART A (continued) / PARTIE A (suite)									
	ED and/or CLASSIFIED COMSEC information or assets?	No Yes							
	ements ou à des biens COMSEC désignés PROTÉGÉS et/ou CLASSIFIÉS?	Non LOui							
If Yes, indicate the level of sensitivity:									
Dans l'affirmative, indiquer le niveau de sens		□ Na □Vaa							
Will the supplier require access to extremely sensitive INFOSEC information or assets? Le fournisseur aura-t-il accès à des renseignements ou à des biens INFOSEC de nature extrêmement délicate? No Ve									
Le lournisseur aura-t-il acces a des renseign	sherita da a dea biena ira Gold de nature extrementent delicate:	NonOui							
Short Title(s) of material / Titre(s) abrégé(s)	u matériel :								
Document Number / Numéro du document :									
PART B - PERSONNEL (SUPPLIER) / PARTIE									
10. a) Personnel security screening level require	d / Niveau de contrôle de la sécurité du personnel requis								
RELIABILITY STATUS	CONFIDENTIAL SECRET TOP SEC	CRET							
COTE DE FIABILITÉ	CONFIDENTIEL SECRET TRÈS SE								
TOP SECRET- SIGINT	NATO CONFIDENTIAL NATO SECRET COSMIC	TOP SECRET							
TRÈS SECRET – SIGINT		TRÈS SECRET							
SITE ACCESS									
ACCÈS AUX EMPLACEMENT									
AGOEG NOX EINII ENGEMENT									
Special comments:									
Commentaires spéciaux :									
	ning are identified, a Security Classification Guide must be provided.								
	aux de contrôle de sécurité sont requis, un guide de classification de la sécurité doit êtr								
10. b) May unscreened personnel be used for p	ortions of the work? e peut-il se voir confier des parties du travail?	No Yes Non Oui							
	·								
If Yes, will unscreened personnel be escondary by the personnel of the per		No Yes Non Oui							
Dans rammative, le personner en questi	in scra-t-ii escorte:	NonOui							
PART C - SAFEGUARDS (SUPPLIER) / PART	E C - MESURES DE PROTECTION (FOURNISSEUR)								
INFORMATION / ASSETS / RENSEIGNE	MENTS / BIENS								
	d store PROTECTED and/or CLASSIFIED information or assets on its site or	No Yes							
premises?	Western BROTCOCO	└─ Non └ Oui							
Le fournisseur sera-t-il tenu de recevoir e CLASSIFIÉS?	d'entreposer sur place des renseignements ou des biens PROTÉGÉS et/ou								
OL/NOON ILO									
11. b) Will the supplier be required to safeguard	COMSEC information or assets?	No Yes							
Le fournisseur sera-t-il tenu de protéger	es renseignements ou des biens COMSEC?	Non Oui							
PROBLICTION									
PRODUCTION									
	air and/or modification) of PROTECTED and/or CLASSIFIED material or equipment	No Yes							
occur at the supplier's site or premises?	es à la production (fabrication et/ou réparation et/ou modification) de matériel PROTÉGÉ	Non Oui							
et/ou CLASSIFIÉ?	es a la production (labrication evou reparation evou modification) de materiel PROTEGE								
3434 3E (3311 1E .									
INFORMATION TECHNOLOGY (IT) MEDIA	SUPPORT RELATIF À LA TECHNOLOGIE DE L'INFORMATION (TI)								
	, ,								
11. d) Will the cumplior be required to use its IT av	stems to electronically process, produce or store PROTECTED and/or CLASSIFIED	□ No □ Yes							
information or data?	items to electronically process, produce or store PROTECTED and/or CLASSIFIED	Non Oui							
	opres systèmes informatiques pour traiter, produire ou stocker électroniquement des								
renseignements ou des données PROTÉC									
	supplier's IT systems and the government department or agency?	No Yes							
Disposera-t-on d'un lien électronique entre qouvernementale?	le système informatique du fournisseur et celui du ministère ou de l'agence	Non Oui							
gouvernementale:									
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	UNCLASSIFIED	Canadä							
		Juliuuu							



Contract Number / Numéro du contrat

Security Classification / Classification de sécurité
UNCLASSIFIED

PART C - (continue																
For users comple site(s) or premise Les utilisateurs q niveaux de sauve	es. ui re	empl	isser	nt le formulaire	e manuell	ement do	oivent utiliser		0 , .	,	` '		•			
For users comple Dans le cas des dans le tableau re	utilis	ateu	ırs q		le formula	aire en lig	ne (par Inter		ises aux	questions						aisies
Category Catégorie		OTECT OTÉC			ASSIFIED ASSIFIÉ			NATO						COMSEC		
	А	В	С	CONFIDENTIAL	SECRET	TOP SECRET	NATO RESTRICTED	NATO CONFIDENTIAL	NATO SECRET	COSMIC TOP		OTECTE ROTÉGI		CONFIDENTIAL	SECRET	TOP SECRET
				CONFIDENTIEL		TRÈS SECRET	NATO DIFFUSION RESTREINTE	NATO CONFIDENTIEL		SECRET COSMIC TRÈS SECRET	А	В	С	CONFIDENTIEL		TRES SECRET
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TBS/SCT 350-103(2004/12)

Security Classification / Classification de sécurité UNCLASSIFIED

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RFP Reference Number: SN21002

ANNEX D - NON-DISCLOSURE AGREEMENT

I,, recognize that in the course of my work as an employee or subcontractor of, I may be given access to information by or on behalf of Canada in connection with the Work, pursuant to Contract Serial No between Her Majesty the Queen in right of Canada, represented by the Minister of Public Works and Government Services and, including any information that is confidential or proprietary to third parties, and information conceived, developed or produced by the Contractor as part of the Work. For the purposes of this agreement, information include but not limited to: any documents, instructions, guidelines, data, material, advice or any other information whether received orally, in printed form, recorded electronically, or otherwise and whether or not labeled as proprietary or sensitive, that is disclosed to a person or that a person becomes aware of during the performance of the Contract.
I agree that I will not reproduce, copy, use, divulge, release or disclose, in whole or in part, in whatever way or form any information described above to any person other than a person employed by Canada or a need to know basis. I undertake to safeguard the same and take all necessary and appropriate measures, including those set out in any written or oral instructions issued by Canada, to prevent the disclosure of or access to such information in contravention of this agreement.
I also acknowledge that any information provided to the Contractor by or on behalf of Canada must be used solely for the purpose of the Contract and must remain the property of Canada or a third party, as the case may be.
I agree that the obligation of this agreement will survive the completion of the Contract Serial No.:
Signature Date