

Patented Review Board

Conseil d'examen Medicine Prices du prix des médicaments brevetés

## **REQUEST FOR PROPOSAL (RFP)**

## **RFP #160002**

## FOR THE REQUIREMENT OF

## SCIENTIFIC LITERATURE SEARCH SERVICES

## FOR THE

## PATENTED MEDICINE PRICES REVIEW BOARD

### Bid Submission envelopes are to be delivered only to the following address:

Patented Medicine Prices Review Board (PMPRB) 333 Laurier Avenue West, Suite 1200 Ottawa, ON K1P 1C1 Attention: Nadia Laneve

It is essential that the outside of each bid submission envelope include the following information: the RFP reference number, and the name of the contact person: Nadia Laneve

## Closing Date and Time: Monday, March 2, 2016 @ 12:00 PM EDT

RFP Issue Date: January 22, 2016

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Attachment 3.1: Bid Submission Form

#### List of Attachments to Part 4 (Evaluation Procedures and Basis of Selection):

Attachment 4.1: Mandatory Technical Criteria Attachment 4.1.1: Report Template Attachment 4.2: Point-Rated Technical Criteria

## 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;

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: includes the certifications to be provided;

Part 6 Security, Financial and Other Requirements: includes specific requirements that must be addressed by bidders; and

Part 7 Resulting Contract Clauses: includes the clauses and conditions that will apply to any resulting contract.

The Annexes include the Statement of Work, the Basis of Payment, the Security Requirements Checklist and attachments.

#### 1.2 Summary

1.2.1 This bid solicitation is being issued to satisfy the requirement for Scientific Literature Search services for the Patented Medicine Prices Review Board (PMPRB). The bidder would review appropriate references concerning patented medicines specified by the PMPRB and provide a report prescribed in the Statement of Work (Annex A).

It is intended to result in the award of 2 contracts for 1 year period, plus 4 irrevocable options allowing Canada to extend the term of the contracts.

**1.2.2** There are security requirements associated with this requirement. For additional information, consult Part 6 - Security, Financial and Other Requirements, and Part 7 - Resulting Contract Clauses. For more information on personnel and organization security screening or security clauses, bidders should refer to the

Industrial Security Program (ISP) of Public Works and Government Services Canada (http://ssi-iss.tpsgc-pwgsc.gc.ca/index-eng.html) website".

**1.2.3** The requirement is subject to the provisions of the World Trade Organization Agreement on government Procurement (WTO-AGP), the North American Free Trade Agreement (NAFTA), and the Agreement on Internal Trade (AIT)."

#### 1.3 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 in person.

## 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> 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> (2015-07-03) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

#### 2.2 Submission of Bids

Bids must be submitted only to Patented Medicine Prices Review Board (PMPRB) by the date, time and place indicated on page 1 of the bid solicitation.

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

#### 2.3 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, Canada will inform the Bidder of a time frame within which to provide the information. Failure to comply with Canada'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 *Financial Administration Act*, 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</u> <u>Superannuation Act</u> (PSSA), R.S., 1985, c. P-36, and any increases paid pursuant to the <u>Supplementary Retirement 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</u> <u>Act</u>, R.S., 1985, c. C-17, the <u>Defence Services Pension 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</u> <u>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 <u>Contracting Policy Notice: 2012-2</u> and the <u>Guidelines on the Proactive</u> <u>Disclosure of Contracts</u>.

#### 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.

#### 2.4 Enquiries - Bid Solicitation

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

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

## 2.5 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.

### 2.6 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 10 days before the bid closing date. Canada will have the right to accept or reject any or all suggestions.

## 2.7 Basis for Canada's Ownership of Intellectual Property

The Patented Medicine Prices Review Board has determined that any intellectual property rights arising from the performance of the Work under the resulting contract will belong to Canada, on the following grounds: the main purpose of the contract, or of the deliverables contracted for, is to deliver a component or subsystem that will be incorporated into a complete system at a later date, as a prerequisite to the planned transfer of the complete system to the private sector, through licensing or assignment of ownership, for purposes of commercial exploitation.

## **PART 3 - BID PREPARATION INSTRUCTIONS**

#### 3.1 Bid Preparation Instructions

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

Section I: Technical Bid (4 hard copies)

Section II: Financial Bid (1 hard copies)

Section III:Certifications not included in the Technical Bid (1 hard copies)

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

Canada requests that Bidders follow the format instructions described below in the preparation of their bid:

- (a) use 8.5 x 11 inch (216 mm x 279 mm) paper;
- (b) use a numbering system that corresponds to the bid solicitation.

In April 2006, Canada issued a policy directing federal departments and agencies to take the necessary steps to incorporate environmental considerations into the procurement process <u>Policy on Green Procurement (http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/politique-policy-eng.html).</u> To assist Canada in reaching its objectives, Bidders should:

- use 8.5 x 11 inch (216 mm x 279 mm) paper containing fibre certified as originating from a sustainably-managed forest and containing minimum 30% recycled content; and
- 2) use an environmentally-preferable format including black and white printing instead of colour printing, printing double sided/duplex, using staples or clips instead of cerlox, duotangs or binders.

#### 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.

The technical bid should address clearly and in sufficient depth the points that are subject to the evaluation criteria against which the bid will be evaluated. Simply repeating the statement contained in the bid solicitation is not sufficient. In order to facilitate the evaluation of the bid, Canada 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.

The technical bid consists of the following:

- i. Bid Submission Form: Bidders are requested to include the Bid Submission Form – Attachment 3.1 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. If Canada determines that the information required by the Bid Submission Form is incomplete or requires correction, Canada will provide the Bidder with an opportunity to do so.
- **ii. Security Clearance:** Bidders are requested to submit the following security information for each of the proposed resources with their bids on or before the bid closing date:

#### **SECURITY INFORMATION:**

Name of individual as it appears on security clearance application form:

Level of security clearance obtained:

Validity period of security clearance obtained:

Security Screening Certificate and Briefing Form file number:

If the Bidder has not included the security information in its bid, the Contracting Authority will provide the Bidder with an opportunity to submit the security information during the evaluation period. If the Bidder has not submitted the security information within the period set by the Contracting Authority, its bid will be declared non-responsive.

iii. Substantiation of Technical Compliance: The technical bid must substantiate the compliance with the specific articles of Attachments 4.1 and 4.2 which is the requested format for providing the substantiation. 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 Canada 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 the "Bidder's Response" column of Attachments 4.1 and 4.2, 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, Canada may request that the Bidder direct Canada to the appropriate location in the documentation.

- iv. For Proposed Resources: The technical bid must include résumés for the resource as identified in Attachment 4.1. Technical bid must demonstrate that each proposed individual meets the qualification requirements described (including any educational requirements, work experience requirements, and professional designation or membership requirements). With respect to the proposed resources:
  - A. Proposed resources may be employees of the Bidder or employees of a subcontractor, or these individuals may be independent contractors to whom the Bidder would subcontract a portion of the Work
  - B. For educational requirements for a particular degree, designation or certificate, Canada will only consider educational programmes that were successfully completed by the resource by the time of bid closing.
  - C. For requirements relating to professional designation or membership, the resource must have the required designation or membership by the time of bid closing and must continue, where applicable, to be a member in good standing of the profession or membership throughout the evaluation period and contract period. Where the designation or membership must be demonstrated through a certification, diploma or degree, such document must be current, valid and issued by the entity specified in this solicitation. If the entity is not specified, the issuer must be an accredited or otherwise recognized body, institution or entity.
  - D. For work experience, Canada will not consider experience gained as part of an educational programme, except for experience gained through a formal cooperative programme at a post-secondary institution.

- E. For any requirements that specify a particular time period (e.g., 2 years) of work experience, Canada will disregard any information about experience if the technical bid does not include the relevant dates (month and year) for the experience claimed (i.e., the start date and end date). Canada will evaluate only the duration that the resource actually worked on a project or projects (from his or her start date to end date), instead of the overall start and end date of a project or a combination of projects in which a resource has participated.
- F. For work experience to be considered by Canada, the technical bid must not simply indicate the title of the individual's position, but must demonstrate that the resource has the required work experience by explaining the responsibilities and work performed by the individual while in that position. In situations in which a proposed resource worked at the same time on more than one project, the duration of any overlapping time period will be counted only once toward any requirements that relate to the individual's length of experience.
- v. Customer Reference Contact Information: The Bidder must provide customer references who must each confirm, if requested by Canada the information required by the facts identified in the Bidder's bid, as required by Attachment 4.1. For each customer reference, the Bidder must, at a minimum, provide the name, the telephone number and e-mail address for a contact person. Bidders are also requested to include the title of the contact person. If there is a conflict between the information provided by the customer reference and the bid, the information provided by the customer reference will be evaluated instead of the information in the bid. If the named individual is unavailable when required during the evaluation period, the Bidder may provide the name and contact information of an alternate contact from the same customer.
- vi. **Corporate Profile:** The Bidder is requested to provide a corporate profile, which should include an overview of the Bidder and any subcontractors, and/or authorized agents of the Bidder that would be involved in the performance of the Work on the Bidder's behalf. The Bidder is requested to provide a brief description of its size, corporate structure, years in business, business activities, major customers, number of employees and their geographic presence. This information is requested for information purposes only and will not be evaluated.

## Section II: Financial Bid

**3.1.1** Bidders must submit their financial bid in accordance with the Annex B. The total amount of Applicable Taxes must be shown separately. Unless otherwise

indicated, Bidders must include a single, firm, all-inclusive hourly rate in Canadian dollars in each cell requiring an entry in the pricing tables.

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, software, peripherals, cabling and components required to meet the requirements of the bid solicitation and the associated costs of these items is the sole responsibility of the Bidder.

#### Section III: Certifications

Bidders must submit the certifications required under Part 5 that have not been included in the Technical Bid.

#### Section IV: Additional Information

**3.1.2** The Company Security Officer (CSO) must ensure through the <u>Industrial</u> <u>Security Program (ISP)</u> 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.

#### **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 Canada will evaluate the bids.
  - a. In addition to any other time periods established in the bid solicitation:
    - i. Requests for Clarifications: If Canada 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 Canada. Failure to meet this deadline will result in the bid being declared non-responsive.
    - ii. **Requests for Interviews**: If Canada wishes to interview the Bidder and/or any or all of the resources proposed by the Bidder to fulfill the requirements of the bid solicitation, the Bidder will have 5 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 at a location specified by Canada.
    - iii. Requests for Further Information: If Canada 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:
      - A. verify any or all information provided by the Bidder in its bid; or
  - B. 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 Canada within 5 working days of a request by the Contracting Authority.

iv. **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

## 4.1.1.1 Mandatory Technical Criteria

Each bid will be reviewed to determine whether it meets the mandatory requirements of the bid solicitation. Any element of the bid solicitation that is identified specifically with the words "must" or "mandatory" is a mandatory requirement. Bids that do not comply with each and every mandatory requirement will be considered non-responsive and be disqualified. The Mandatory evaluation criteria are described in Attachment 4.1- Mandatory Technical Criteria.

## 4.1.1.2 Point Rated Technical Criteria

Each bid will be rated by assigning a score to the rated requirements, which are identified in the bid solicitation by the word "rated" or by reference to a score. Bidders who fail to submit complete bids with all the information requested by this bid solicitation will be rated accordingly. The rated requirements are described in Attachment 4.2 – Point-Rated Technical Criteria.

### 4.1.2 Financial Evaluation

### 4.1.2.1 Mandatory Financial Criteria

Unless otherwise specified in the RFP, the financial evaluation will be conducted by calculating the Total Bid Price using the Pricing Tables completed by the bidders. The Bidder must provide firm, all inclusive, hourly rates for the Categories of Personnel being proposed in accordance with the bid solicitation, which includes an initial contract period and option periods. The price of the bid will be evaluated in Canadian dollars, Applicable Taxes excluded, FOB destination, Canadian customs duties and excise taxes included.

#### 4.2 Basis of Selection

## 4.2.1 Highest Combined Rating of Technical Merit and Price

- 1. To be declared responsive, a bid must:
  - a. comply with all the requirements of the bid solicitation; and
  - b. meet all mandatory criteria; and
  - c. obtain the required minimum of 34 points overall for the technical evaluation criteria which are subject to point rating.

The rating is performed on a scale of 50 points.

- 2. Bids not meeting (a) or (b) or (c) will be declared non-responsive.
- 3. The selection will be based on the highest responsive combined rating of technical merit and price. The ratio will be 70 % for the technical merit and 30 % for the price.
- 4. To establish the technical merit score, the overall technical score for each responsive bid will be determined as follows: total number of points obtained / maximum number of points available multiplied by the ratio of 70 %.
- 5. To establish the pricing score, each responsive bid will be prorated against the lowest evaluated price and the ratio of 30%.
- 6. For each responsive bid, the technical merit score and the pricing score will be added to determine its combined rating.
- 7. Neither the responsive bid obtaining the highest technical score nor the one with the lowest evaluated price will necessarily be accepted. The responsive bid with the highest combined rating of technical merit and price will be recommended for award of a contract.

The table below illustrates an example where all three bids are responsive and the selection of the contractor is determined by a 60/40 ratio of technical merit and price, respectively. The total available points equals 135 and the lowest evaluated price is \$45,000 (45).

		Bidder 1	Bidder 2	Bidder 3
Overall Technical Score		115/135	89/135	92/135
Bid Evaluated Price		\$55,000.00	\$50,000.00	\$45,000.00
Calculations	Technical Merit Score	115/135 x 60 = 51.11	89/135 x 60 = 39.56	92/135 x 60 = 40.89
Calculations	Pricing Score	45/55 x 40 = 32.73	45/50 x 40 = 36.00	45/45 x 40 = 40.00
Combined Rating		83.84	75.56	80.89
Overall Rating		1st	3rd	2nd

#### Basis of Selection - Highest Combined Rating Technical Merit (60%) and Price (40%)

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

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

### 5.1 Certifications Required with the Bid

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

#### 5.1.1 Declaration of Convicted Offences

As applicable, pursuant to subsection Declaration of Convicted Offences of section 01 of the Standard Instructions, the Bidder must provide with its bid, a completed <u>Declaration Form (http://www.tpsgc-pwgsc.gc.ca/ci-if/formulaire-form-eng.html),</u> to be given further consideration in the procurement process.

#### 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 specified will render the bid non-responsive.

#### 5.2.1 Integrity Provisions – List of Names

Bidders who are incorporated, including those bidding as a joint venture, must provide a complete list of names of all individuals who are currently directors of the Bidder.

Bidders bidding as sole proprietorship, as well as those bidding as a joint venture, must provide the name of the owner(s).

Bidders bidding as societies, firms or partnerships do not need to provide lists of names.

## 5.2.2 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 (http://www.labour.gc.ca/eng/standards\_equity/eq/emp/fcp/list/inelig.shtml) available from Employment and Social Development Canada (ESDC) - Labour's website.

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

#### 5.2.3 Additional Certifications Precedent to Contract Award

#### 5.2.3.2 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 Canada's representatives and at the time specified in the bid solicitation or agreed to with Canada'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 Canada. 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. Failure to comply with the request may result in the bid being declared non-responsive.

#### 5.2.3.4 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 - SECURITY, FINANCIAL AND OTHER REQUIREMENTS

#### 6.1 Security Requirements

1. Before award of a contract, the following conditions must be met:

- (a) the Bidder must hold a valid organization security clearance as indicated in Part 7- Resulting Contract Clauses;
- (b) the Bidder's proposed individuals requiring access to classified or protected information, assets or sensitive work site(s) must meet the security requirements as indicated in Part 7 - Resulting Contract Clauses;
- (c) the Bidder must provide the name of all individuals who will require access to classified or protected information, assets or sensitive work sites;
- 2. Bidders are reminded to obtain the required security clearance promptly. Any delay in the award of a contract to allow the successful Bidder to obtain the required clearance will be at the entire discretion of the Contracting Authority.
- 3. For additional information on security requirements, Bidders should refer to the <u>Industrial Security Program (ISP)</u> of Public Works and Government Services Canada (<u>http://ssi-iss.tpsgc-pwgsc.gc.ca/index-eng.html</u>) website.

## **PART 7 - RESULTING CONTRACT CLAUSES**

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

#### 7.1 Statement of Work

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

### 7.2 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</u> <u>Manual(https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual)</u> issued by Public Works and Government Services Canada.

#### 7.2.1 General Conditions

<u>2035</u>2015-07-03, General Conditions - Higher Complexity - Services, apply to and form part of the Contract.

#### 7.3 Security Requirements

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

- The Contractor/Offeror must, at all times during the performance of the Contract/Standing Offer/Supply Arrangement, hold a valid Designated Organization Screening (DOS), issued by the Canadian Industrial Security Directorate (CISD), Public Works and Government Services Canada (PWGSC).
- 2. The Contractor/Offeror personnel requiring access to PROTECTED information, assets or sensitive work site(s) must EACH hold a valid **RELIABILITY STATUS**, granted or approved by CISD/PWGSC.
- 3. The Contractor/Offeror MUST NOT remove any PROTECTED information or assets from the identified work site(s), and the Contractor/Offeror must ensure that its personnel are made aware of and comply with this restriction.
- 4. Subcontracts which contain security requirements are NOT to be awarded without the prior written permission of CISD/PWGSC.
- 5. The Contractor/Offeror must comply with the provisions of the:
  - 1. Security Requirements Check List and security guide (if applicable), attached at Annex C;

- 2. Industrial Security Manual (Latest Edition).
- **7.3.2** The Company Security Officer (CSO) must ensure through the <u>Industrial</u> <u>Security Program (ISP)</u> that the Contractor and individual(s) hold a valid security clearance at the required level.

#### 7.4 Term of Contract

#### 7.4.1 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:

- i. The "Initial Contract Period", which begins on the date the Contract is awarded and ends one year later ; and
- ii. the period during which the Contract is extended, if Canada chooses to exercise any options set out in the Contract.

#### 7.4.2 Option to Extend the Contract

The Contractor grants to Canada the irrevocable option to extend the term of the Contract by up to (4) four additional (1) one year 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 the Basis of Payment.

Canada may exercise this option at any time by sending a written notice to the Contractor at least 30 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.

#### 7.5 Authorities

#### 7.5.1 Contracting Authority

The Contracting Authority for the Contract is:

Ginette Tognet Director, Regulatory Affairs and Outreach Branch Patented Medicine Prices Review Board 333 Laurier Avenue West, Suite 1400 Ottawa, ON K1P 1C1 Telephone: 613-954-8297 Ginette.tognet@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.

## 7.5.2 Project Authority

The Project Authority for the Contract is:

George Botulynsky Manager, Investigations Unit Patented Medicine Prices Review Board 333 Laurier Avenue West, Suite 1400 Ottawa, ON K1P 1C1 Telephone: 613-960-4575 George.Botulynsky@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.

## 7.6 **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</u> (PSSA) 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>: <u>2012-2</u> of the Treasury Board Secretariat of Canada.

#### 7.7 Payment

## 7.7.1 Basis of Payment

The Contractor will be reimbursed for the costs reasonably and properly incurred in the performance of the Work described in Annex A as determined in accordance with the Basis of Payment in Annex B, to a limitation of expenditure of **\$\_\_\_\_\_** (*insert the amount at contract award*). Customs duties are excluded and Applicable Taxes are extra.

### 7.7.2 Limitation of Expenditure

- Canada's total liability to the Contractor under the Contract must not exceed \$\_\_\_\_\_. (*insert the amount at contract award*) Customs duties are excluded and Applicable Taxes are extra.
- 2. 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:
  - a. when it is 75 percent committed, or
  - b. four (4) months before the contract expiry date, or
  - c. as soon as the Contractor considers that the contract funds provided are inadequate for the completion of the Work, whichever comes first.
- 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

#### 7.7.3 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 Canada;

#### 7.8 Invoicing Instructions

- 1. The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.
- 2. Invoices must be distributed as follows:

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

## 7.9 Certifications

## 7.9.1 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 Canada 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, Canada has the right, pursuant to the default provision of the Contract, to terminate the Contract for default.

### 7.10 Applicable Laws

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

### 7.11 **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 general conditions <u>2035</u>2015-07-03
- (c) Annex A, Statement of Work
- (d) Annex B, Basis of Payment;
- (e) Annex C, Security Requirements Check List;
- (f) the Contractor's bid dated \_\_\_\_\_, (to be filled at contract award)

#### 7.14 Insurance

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

## ANNEX "A"

## STATEMENT OF WORK

#### 1.0 Scope

#### 1.1 Title

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

#### 1.2 Introduction

Since the mandate requires the review of the introductory price of any new drug product introduced on the Canadian market, the PMPRB requires the expertise of Drug Information Centres in terms of research of all scientific literature and the understanding of the place in therapy of the new product under review. As a result, the PMPRB is seeking to establish up to two (2) contracts for these services.

### 1.3 Estimated Value

It is the intention of the PMPRB to establish up to two (2) contracts to fulfill this requirement. The total value of all contracts combined resulting from this RFP shall not exceed \$400,000.00, including travel and living expenses (if applicable), other expenses and all applicable taxes associated with the requirement over the one year period and the four (4) one (1) year option periods. The individual value of each contract will be determined by the evaluation results of this Request for Proposal (RFP). It is estimated that the total number of medicines to review in a year is sixty-four (64), approximately 16 per quarter (May, September, November & February)

#### **1.4 Objectives of the Requirement**

Review appropriate references concerning patented medicines specified by the PMPRB and provide a report in the prescribed format as described in the Statement of Work. The PMPRB is seeking to establish up to two (2) contracts for scientific literature services for a one year period with four (4) one (1) year option periods.

#### 1.5 Background, Assumptions and Specific Scope of the Requirement

#### Overview of the PMPRB

The Patented Medicine Prices Review Board (PMPRB) is an independent, quasijudicial 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 to wholesalers, hospitals, pharmacies or others for both human and veterinary use. The PMPRB regulates the price of each patented drug product. This includes each strength of an individual, final 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.

#### 2.0 Requirements

#### 2.1 Tasks, Activities, Deliverables and Milestones

The Contractor will:

- A. Review appropriate references concerning patented medicines specified by the PMPRB and provide a report in the prescribed format (see Attachment 4.1.1) that shall include the following information:
  - 1. The approved indication(s) for the patented medicine under review (or the proposed indication/use if the drug is not yet approved);
  - 2. The primary use of the patented medicine under review if more than one approved indication; or where appropriate, the primary use of the

individual strengths or dosage forms(generally the DIN) of the patented medicine if the therapeutic use is different for each DIN;

- **3.** The usual recommended dosage regimen for the primary use of the patented medicine under review, and for the individual DINs of the patented medicine unless specified otherwise by Board Staff;
- **4.** A list of comparable medicines for the DIN under review specifying the company, brand name, generic name, DIN, dosage form, strength and ATC code for each.

Comparable medicines must be considered CLINICALLY EQUIVALENT and generally have COMPARABLE DOSAGE FORMS. They must be selected in accordance with the PMPRB's Guidelines (reference PMPRB Compendium of Policies, Guidelines, and Procedures: Scientific Review Procedures, please refer to www.pmprb-cepmb.gc.ca. The contractor must indicate if the accepted use of the comparable medicine is NOT an approved indication.

- 5. 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 3 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.
- 6. A list of the references used to support the information provided in paragraph 1 through 5 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".
- **B.** 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 request or as otherwise negotiated with the PMPRB at the time the request is made. The template for the report is provided in Annex C. A bidder can request a sample completed report from the contract person stated on the first page of this RFP.
- **C.** In addition, for specified drug product reviews, the contractor shall provide on request:

- 1. 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.
- **2.** Copies of any additional references pertaining to the review completed, as requested.
- D. The Human Drug Advisory Panel (HDAP) meets on a quarterly basis. The Scientific Literature Search is one element that the HDAP considers. Patentees are required to file product monographs or information similar to that included in a product monograph about 14 weeks prior to the HDAP meeting. Upon receipt of the product monograph/information, the scientific literature is to commence. The scientific literature search for all medicines to be discussed at the particular HDAP meeting must be completed no later than six (6) weeks before the HDAP meeting. There are approximately sixteen (16) medicines considered at each quarterly HDAP meeting. See table below for approximate timeframes.

HDAP MEETING	Request sent for	All scientific literature
May 2, 2016	scientific literature 3.5	searches to be received
September 12, 2016	months prior to the	6 weeks before the
November 28, 2016	HDAP meeting	HDAP meeting
February 2017 (date to		
be determined)		

- **E.** The Contractor will 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 negotiated with the PMPRB at the time the request is made.
- **F.** The Contractor will keep a detailed record which identifies the nature of the work completed for the PMPRB including:
  - i. Drug name, number of DINs and number of comparators identified (where applicable);
  - ii. Total time required to respond to each request;
  - iii. Identity of pharmacist who completed the research/review;
  - iv. Date work completed;
  - v. Total time spent in the month for which the invoice was submitted plus cumulative time to date.

This record will be submitted to the PMPRB on a monthly basis along with the invoice for payment.

**G.** The Contractor shall, 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.

## 2.2 Specifications and Standards

The work is to be delivered and will be measured in accordance with the written confirmation provided by the contractor before the work was begun including any specific reference to details and qualitative and quantitative measures which will be used by the Project Authority to determine completion and satisfaction with the work.

### 2.3 Method and Source of Acceptance

All deliverables and services rendered under the contract are subject to inspection by the Project Authority 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 reject it or require correction before payment will be authorized by the Project Authority.

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

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

#### 2.4 Reporting Requirements

See details provided in the above section 2.1

#### 2.5 Contractor Project Management Control Procedures

The PMPRB individual identified in the RFP as the Project Authority shall control the work through reviews of the completed report and references.

#### 2.6 Change Management Procedures

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

## 3.0 Other Terms and Conditions of the SOW

#### 3.1 Authorities

#### The Project Authority:

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. The Project Authority is:

George Botulynsky Manager, Investigations Unit Patented Medicine Prices Review Board 333 Laurier Avenue West, Suite 1400 Ottawa, ON K1P 1C1 Telephone: 613-960-4575 George.Botulynsky@pmprb-cepmb.gc.ca

#### **Contracting Authority:**

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. The Contracting Authority is:

Ginette Tognet Director, Regulatory Affairs and Outreach Branch Patented Medicine Prices Review Board 333 Laurier Avenue West, Suite 1400 Ottawa, ON K1P 1C1 Telephone: 613-954-8297 Ginette.tognet@pmprb-cepmb.gc.ca

#### 3.2 PMPRB's Obligations

The Project Authority will:

Ensure the appropriate subject matter experts from within their organization are available to 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;

Provide the Contractor with both physical and electronic delivery addresses, to which deliverables are to be submitted.

### 3.3 Contractor's Obligations

To perform the work as per 2.1 of the Task, Activities, Deliverable and Milestones

### 3.4 Location of Work, Work Site and Delivery Point

The work will be performed at the Contractor's location.

### 3.5 Language of Work

All deliverables are to be provided in English.

### 4.0 Expected Start and Completion Dates

The services of the Contractor will be required for a period of approximately one year upon contract award. The expected completion date of this project is March 31, 2017. The Crown reserves the right to extend the period of the contract by up to four (4) additional one (1) year periods.

## ANNEX "B"

## **BASIS OF PAYMENT**

The Supplier's hourly rate for the proposed Categories of Personnel are as follows:

#### **CONTRACT PERIOD:**

Table "A1" –		Contract award to	March 31, 2017
А	В	С	D (BxC)
Category of Personnel Insert rows as required	Hourly Rate(s)	Level of Effort/Number of Hours Required	Total Costs for Professional Fees TAXES NOT INCLUDED
1.	\$		\$
2.	\$		\$
	\$		

## **OPTION PERIODS:**

Table "A2" – Option Period 1		April 1, 2017 – March 31, 2018	
A B		С	D (BxC)
Category of Personnel Insert rows as required	Hourly Rate(s)	Level of Effort/Number of Hours Required	Total Costs for Professional Fees TAXES NOT INCLUDED
1.	\$		\$
2.	\$		\$
	\$		

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Table "A3" – Option Period 2		April 1, 2018 – Ma	arch 31, 2019
А	В	С	D (BxC)
Category of Personnel Insert rows as required	Hourly Rate(s)	Level of Effort/Number of Hours Required	Total Costs for Professional Fees TAXES NOT INCLUDED
1.	\$		\$
2.	\$		\$
	\$		

Tahla	"Δ3" -	- Ontion	Period 2
rable	- AS	- Option	Period Z



Table	" <b>Δ4</b> "	- Option	Period 3
Iabic	~ ~		

April 1, 2019 – March 31, 2020

А	В	С	D (BxC)
Category of Personnel Insert rows as required	Hourly Rate(s)	Level of Effort/Number of Hours Required	Total Costs for Professional Fees TAXES NOT INCLUDED
1.	\$		\$
2.	\$		\$
	\$		

April 1, 2020 – March 31, 2021

А	В	С	D (BxC)
Category of Personnel Insert rows as required	Hourly Rate(s)	Level of Effort/Number of Hours Required	Total Costs for Professional Fees TAXES NOT INCLUDED
1.	\$		\$
2.	\$		\$
	\$		

Bidder total tendered price to perform the work from contract award to March 31, 2017	\$
Bidder total tendered price for Optional period 1 - April 1, 2017 to March 31, 2018	\$
Bidder total tendered price for Optional period 2 - April 1, 2018 to March 31, 2019	\$
Bidder total tendered price for Optional period 3 - April 1, 2019 to March 31, 2020	\$
Bidder total tendered price for Optional period 4 - April 1, 2020 to March 31, 2021	\$
Total value of tables "A1", "A2", "A3", "A4" and "A5"	
TOTAL HST	
Bidder total tendered price inclusive of optional periods.	\$

# ANNEX "C"

## SECURITY REQUIREMENTS CHECK LIST

							which are not the second se			
-	Governmen		Bouvernement			Cont	ract Number / Numéro du con	trat		
<b>T</b>	of Canada	c	lu Canada		160002					
						Security C	lassification / Classification de Unclassified	: sécuri	té	
							Unclassified			
		1.151	SI TE DE VÉRIEIO	ECURITY REQUIREMEN CATION DES EXIGENCE	TS CHE	CK LIST (SRC	E)			
PART A - CON	TRACT INFOR	MAT	ON / PARTIE A	- INFORMATION CONTRAC	S RELA	TIVES A LA S	ECURITE (LVERS)			
1. Originating G	Sovernment De	partm	ent or Organizatio	on /	TOECCE		or Directorate / Direction géné	irale or	Direct	tion
			mental d'origine	Patented Medicine Price	s Review E		tory Affairs and Outreach	1000 01	. 0100	
<ol><li>a) Subcontra</li></ol>	act Number / Nu	iméro	du contrat de so	us-traitance 3. b) Na	me and A	ddress of Subco	ntractor / Nom et adresse du s	sous-tra	aitant	
4. Priof Departs	tion of Mark / I	Trade un	description du tra							
	rature search serv		description du tra	ivair.						
Sciencing man	aure adarch sen	10es								
E a) USU the ev	methes an ender		to Controlled C							
Le fournis	seur aura-t-il ar	iccess toès à	to Controlled Go des marchandis	20057 es contrôlées?				$\checkmark$	No	Yes
				nilitary technical data subject	to the ex	a dalama af the T		_ <u></u>	Non	U Oui
Regulation	ns?	luueaa	to unclassified fi	ninary technical data subjec	t to the ph	ovisions of the 1	echnical Data Control	$\checkmark$	No	Yes
Le fournis	seur aura-t-il ad	cès à	des données teo	niques militaires non class	ifiées qui :	sont assuletties :	aux dispositions du Règlement	, Ŀ	Non	U Oui
sur le cont	trôle des donné	es tec	hniques?			,				
<ol><li>Indicate the</li></ol>	type of access	requir	ed / Indiquer le ty	/pe d'accès requis						
6. a) Will the su	applier and its e	mplay	ees require acce	ss to PROTECTED and/or C	LASSIFIE	ED information of	assets?		No	Yes
Le fournise	seur ainsi que l	es em	ployés auront-ils	accès à des renseignement	s ou à des	s biens PROTÉG	ÉS et/ou CLASSIFIÉS?		Non	✓ Oui
(Specity th (Práciser l	he level of accer le niveau d'acci	SS USI	ng the chart in Qu utilisant lo tablea	Jestion 7. c) u qui se trouve à la question	7 *					
6, b) WII the su	polier and its e	molov	ees (e.a. cleaner	s maintenance personnel) r	7.C) equire and	ness to restricted	access areas? No access to		Ma	- New
PROTECT	TED and/or CLA	ASSIF	IED information of	or assets is permitted.				$ \langle  $	No Non	Ves Oui
Le fournise	seur et ses emp	olayés	(p. ex. nettoyeur	s, personnel d'entretien) aur	ont-ils acc	cès à des zones	d'accès restreintes? L'accès		NOT	
a des rens	seignements ou	à des	biens PROTEG	ÉS et/ou CLASSIFIÉS n'est	pas autori	isé.				
<li>c) is this a co S'anit-il d'i</li>	un contrat de m	eroro	telivery requirem	ent with no overnight storag on commerciale sans entrep	e?	26.00			No	Yes
		-			<u> </u>		-	Ŀ	Non	L Oui
7. a) Indicate th		hation	that the supplier	will be required to access / I	ndiquer le	type d'informati	on auquel le fournisseur devra	avoir a	accès	
	Canada	1		NATO / OTAN			Foreign / Étranger	r 🗌	1	
7. b) Release re	estrictions / Res	triotio	ne relative à le r	17.00	_					
		ALL CRO	is relatives a la t	Illusion						
No release res	strictions		is relatives a la t	All NATO countries			No release restrictions		7	
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PART A (con	tinued) / PARTIE A (suite)		-		
8. Will the sup	plier require access to PROTECTED	and/or CLASSIFIED COMSEC	information or assets?		No Yes
Le fourniss	eur aura-t-il accès à des renseigneme	nts ou à des biens COMSEC d	ésignés PROTÉGÉS et/ou	CLASSIFIÉS?	✓ Non Oui
	ate the level of sensitivity:				
	native, indiquer le niveau de sensibilit plier require access to extremely sens				
Le fourniss	eur aura-t-il accès à des renseigneme	itive INFOSEC information or a nts ou à des biens INFOSEC d	ISSEIS? 9 noture extrêmement délic	Coto:	✓ No Yes
Lu luuli	car adia-tra acces a des renseigneme	its of a des plena INPOSEC 0	e nature extremement dead	ate? .	Non LOui
	s) of material / Titre(s) abrégé(s) du m	atériel :			
	Number / Numéro du document :				
PART B - PER	SONNEL (SUPPLIER) / PARTIE B -	PERSONNEL (FOURNISSEU	R)		
10. a) Personr	nel security screening level required / I	viveau de contrôle de la sécurit	é du personnel requis		
	RELIABILITY STATUS	CONFIDENTIAL	SECRET	TOP SECR	)ET
1	COTE DE FIABILITÉ	CONFIDENTIEL	SECRET	TRÈS SEC	
	TOP SECRET-SIGINT	NATO CONFIDENTIAL			
	TRÈS SECRET – SIGINT	NATO CONFIDENTIAL	NATO SECRET NATO SECRET		OP SECRET RÈS SECRET
	SITE ACCESS		L NATO SCORET		RED DEURET
	ACCÉS AUX EMPLACEMENTS				
	ACCES NOX EMPERCEMENTS				
	Special comments:				
	Commentaires spéciaux :				
	NOTE: If multiple levels of screening	are identified, a Security Classifi	cation Guide must be provid	ed	
	REMARQUE : Si plusieurs niveaux (	le contrôle de sécurité sont reo	uis, un guide de classificat	on de la sécurité doit être i	loumi.
10. b) May uns	creened personnel be used for portion	is of the work?			No Ver
	onnel sans autorisation sécuritaire per		lu travail?		Non Oui
	vill unscreened personnel be escorted				No Yes
Dans l'a	ffirmative, le personnel en question se	ra-t-il escorté?			Non Oui
PART C - SAF	EGUARDS (SUPPLIER) / PARTIE C	MESURES DE PROTECTION	COUDNIESELIDI		
INFORMATIO	ON / ASSETS / RENSEIGNEMEN	TS / BIENS	(FOURNISSEUR)		
in vision	ASSETS / RENSEIGNEMEN	137 BIENS			
11. a) Will the	supplier be required to receive and st	TRANSPORTECTED and/or CLAS	RIEIED information or once	to on the site of	
premise	s?	IN PROTECTED and/or CEAS	SIFIED Information or asse	as on its site or	✓ No Yes Non Oui
Le fourn	isseur sera-t-il tenu de recevoir et d'er	treposer sur place des renseio	nements ou des biens PRO	DTÉGÉS et/ou	
CLASSI	FIÉS?			12020 000	
11. b) Will the	supplier be required to safeguard COI	ASEC information or assets?			V No Yes
Le iourn	isseur sera-t-il tenu de protéger des re	inseignements ou des biens Co	DMSEC?		Non Oui
PRODUCTIO	N				
11. c) Will the p	roduction (manufacture, and/or repair a	nd/or modification) of PROTECT	ED and/or CLASSIFIED ma	terial or equipment	Yes
l es insta	the supplier's site or premises?	a production distribution other of	and a still start the start		Non Oui
et/ou CL	ilations du fournisseur serviront-elles à ASSIFIÉ?	a producción (rabrication et/ou re	eparation et/ou modification)	de materiel PROTEGE	
INFORMATIO	N TECHNOLOGY (IT) MEDIA / SU	PPORT RELATIF À LA TECHN	OLOGIE DE L'INFORMATI		
				Sec (1)	
	No. I was a second s				
11. d) Will the s	upplier be required to use its IT systems on or data?	to electronically process, produ	ce or store PROTECTED ar	d/or CLASSIFIED	VN0 Yes
Le fourni	sseur sera-t-il tenu d'utiliser ses propres	sustàmos informatiques pour in	tion produine ou chadren dies	den al a constat d	Non Oui
renseion	ements ou des données PROTÉGÉS e	Vou CLASSIFIÉS?	ator, produire ou stocker ele	curoniquement des	
11. e) Will there	be an electronic link between the suppl	ier's IT systems and the occurry	nent department or anonco?		No Yes
Disposer	a-t-on d'un lien électronique entre le sys	tème informatique du fournisser	r et celui du ministère ou de	Tagence	Non Qui
gouverne	mentale?				
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		Unclassifi	ed		Canadä
					Sundu

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Contract Number / Numéro du contrat

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PART C - (continued) / PARTIE C - (suite) For users completing the form manually use the summary chart below to indicate the category(ies) and level(s) of safeguarding required at the supplier's site(s) or premises. Les utilisateurs qui remplissent le formulaire manuellement doivent utiliser le tableau récapitulatif ci-dessous pour indiquer, pour chaque catégorie, les niveaux de sauvegarde requis aux installations du fournisseur.

For users completing the form **online** (via the Internet), the summary chart is automatically populated by your responses to previous questions. Dans le cas des utilisateurs qui remplissent le formulaire **en ligne** (par Internet), les réponses aux questions précédentes sont automatiquement saisies dans le tableau récapitulatif.

#### SUMMARY CHART / TABLEAU RÉCAPITULATIF

	Category Catégorie		otect OTÉC			SSIFIED ASSIFIÉ			NATO						COMSEC		
		A	8	с	CONFIDENTIAL	SECRET	TOP SECRET	NATO RESTRICTED	NATO CONFIDENTIAL	NATO SECRET	COSMIC TOP		TECT		CONFIDENTIAL	SECRET	TOP SECRET
					CONFIDENTIEL		TRÈS SECRET	NATO DIFFUSION RESTRENTE	NATO CONFIDENTIEL		SECRET COSMIC TRES SECRET	A	в	с	CONFIDENTICL		TRES SECRET
	Information / Assets Renseignements / Biens												_				
	Production		-										_				
	IT Media / Support Ti																
j	IT Link /		-														
l	Lien électronique			L													
	12. a) Is the description of the work contained within this SRCL PROTECTED and/or CLASSIFIED?       Image: No result of the work contained within this SRCL PROTECTED and/or CLASSIFIED?         La description du travail visé par la présente LVERS est-elle de nature PROTÉGÉE et/ou CLASSIFIÉ?       Image: No result of the work contained within the area entitled "Security Classification".         If Yes, classifier la présent formulaire en indiguant le niveau de sécurité dans la case intitulée « Classification de sécurité » au haut et au bas du formulaire.								Yes Out								
1	<ol> <li>b) Will the docur La documentat</li> </ol>									FIÉE?					[	✓ No Non	Ves Oui
	If Yes, classify this form by annotating the top and bottom in the area entitled "Security Classification" and indicate with attachments (e.g. SECRET with Attachments). Dans l'affirmative, classifier le présent formulaire en indiquant le niveau de sécurité dans la case intitulée « Classification de sécurité » au haut et au bas du formulaire et indiquer qu'il y a des pièces jointes (p. ex. SECRET avec des pièces jointes).																

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BID SUBMISSION FORM							
Bidder's full legal name							
Authorized Representative of Bidder for evaluation purposed (e.g.	Name						
clarification)	Title						
	Address						
	Telephone #						
	Email						
Bidder's Procurement Business Number (PBN)							
[see the Standard Instructions 2003]							
Former Public Servants See the Article in Part 2 of the bid solicitation entitled Former Public Servant for a definition of "Former Public Servant"	defined in the bid Yes If yes, provide the Article in Part 2 of Servant" Is the Bidder a F sum payment put Work Force Adjut Yes If yes, provide the	<ul> <li>PS in receipt of a pension as d solicitation? No</li> <li>ne information required by the entitled "Former Public</li> <li>PS who received a lump ursuant to the terms of the ustment Directive? No</li> <li>ne information required by the entitled "Former Public</li> </ul>					
Security Clearance Level of Bidder [include both the level and the date it was granted]							
<ul> <li>On behalf of the Bidder, by signing below, I confirm the documents incorporated by reference into the bid 1. The Bidder considers itself and its products described in the bid solicitation;</li> <li>2. This bid is valid for the period requested in the 3. All the information provided in the bid is com</li> <li>4. If the Bidder is awarded a contract, it will accoresulting contract clauses included in the bid</li> </ul>	d solicitation and I c able to meet all the he bid solicitation; aplete, true and acc cept all the terms ar	ertify that: mandatory requirements urante; and					
Signature of Authorized Representative of Bidder							

# ATTACHMENT 3.1

## **ATTACHMENT 4.1**

## MANDATORY TECHNICAL CRITERIA

Attention Bidders: Write beside each of the criteria the relevant payour proposal which addresses the requirement identified in the c	• • • • •
Criteria	Reference to Bidder's Proposal
M1 Bidder Experience:	
The Bidder must demonstrate that it has expertise and experience in the offering of the services relevant to the requirements of the RFP, provide some examples.	
M2 Reporting:	
The Bidder must provide a complete report (using template provided in – Attachment 4.1.1) in the prescribed information as stated in the RFP.	
M3 Education:	
The Bidder must have accredited pharmacists who have experience in researching, analyzing and summarizing scientific literature.	

#### ATTACHMENT 4.1.1

#### **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 Pharmokinetics**

#### 2 CLINICAL TRIALS

- 2.1 Comparative Clinical Trials
- 2.2 Non-Comparative Clinical Trials

#### **3 COMPARATORS**

- 3.1 4<sup>th</sup> 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.

А

В

С

## ATTACHMENT 4.2

#### POINT-RATED TECHNICAL CRITERIA

Attention Bidders: Write beside each of the criteria the relevant page number(s) from your proposal which addresses the requirement identified in the criteria. Must obtain a minimum of 70% on the point-rated criteria (50/34) All criteria will be rated using the scoring grid below.

Point-rated criteria	Demonstrated Compliance, cross reference to Resume	Points allocated for the criteria	Score
R1 Understanding of the Requirement: The Bidder should demonstrate knowledge and understanding of both the objectives and scope of the work to be undertaken. Refer to the below scoring grid		Maximum of ten (10) points	/10
R2 Approach: The Bidder should outline the methodology and specific tasks and steps proposed to complete all aspects of the evaluation as identified in the Statement of Work. Refer to the below scoring grid		Maximum of ten (10) points	/10
R3 Resource Qualifications and Experience: The Bidder should demonstrate expertise, professional qualification and experience on similar projects. Refer to the below scoring grid		Maximum of fifteen (15) points	/15

R4 Scheduling: The Bidder should demonstrate that the organization is able to meet the deadlines describe in the RFP. Refer to the below scoring grid		Maximum fifteen (15) points	/15
	TOTAL:	Minimum amount of point required: 34	/50

<b>SCORING GRID</b>	SCORING GRID (15)									
BELOW S	TANDARD	STANDARD	ABOVE S	TANDARD						
1-3 (1-5)	4-6 (6-9)	7 (7-10)	8-9 (11-14)	10 (10-15)						
Does Not Meet Expectations	Partially Meets Expectations	Meets Expectations	More Than Meets Expectations	Exceeds Expectations						
Bidder's proposal is unsatisfactory in regard to requirement	<ul> <li>Bidder's proposal is inadequate in certain areas of the requirement and bidder would likely be ineffective in carrying out task</li> <li>Bidder's proposal covers some areas partly or inadequately</li> <li>Bidder's proposal has demonstrated difficulties that could handicap carrying out task</li> </ul>	<ul> <li>Bidder's proposal is adequate; expectations have been met</li> <li>Overall, proposal addresses requirement in sufficient manner</li> <li>Bidder may have demonstrated some weaknesses but none of major significance</li> </ul>	<ul> <li>Bidder's proposal is above average and reflects more than adequate ability to perform</li> <li>Proposal addresses requirement, without any significant exceptions, in a complete manner</li> <li>There is a more than moderate probability of success in the task</li> </ul>	<ul> <li>Bidder's proposal is exceptional and should ensure extremely effective performance</li> <li>Proposal is complete and all aspects of requirement are more than fully addressed</li> <li>No weaknesses demonstrate; there is a high probability of success in the task</li> </ul>						