Health Canada Santé Canada

Reference Number: 1000050887

LETTER OF INVITATION

To: **Medical/Scientific Researchers**

Subject: **Providing Third-Party Scientific Review and Evaluation Services to Health Canada's (HC) Therapeutic Products Directorate (TPD)**

The Therapeutic Products Directorate of the Health Products and Food is the federal authority that regulates pharmaceutical drugs and medical devices for human use. Through strict regulation and high standards, TPD scientists review the safety, efficacy and quality of new pharmaceuticals and medical devices before they are authorized for sale in Canada.

We are issuing this Letter of Invitation (LOI) as a means of gathering information to determine the extent to which there exists both interest and capacity within the medical/scientific research community to become part of our inventory list of qualified external scientific experts to provide scientific evaluation and advisory services to TPD and/or participate as a *volunteer* (no monetary compensation) on Scientific Advisory Committees and/or Panels.

BACKGROUND:

Before a therapeutic product is authorized for sale in Canada, the manufacturer/sponsor must provide TPD with substantive scientific evidence of its safety, efficacy, and quality, as required by regulations. This evidence is reviewed by skilled scientists to determine whether the potential risks from the product are acceptable when balanced against the positive effects for the product's proposed use. If the product shows evidence of being safe and effective when used under specified conditions, the product is granted market authorization.

For drugs, this assessment involves the review of ten to hundreds of volumes of clinical (human studies), pre-clinical (animal studies) and chemistry and manufacturing data. Medical Device applications are significantly smaller in size, but still entail a review of evidence of a device's clinical safety and effectiveness as well as assurance of quality, and the conformity to recognized standards. There has been an increased emphasis on the need for external expert advice given the increased complexity of product submissions, the need to resolve difficult and complex risk/benefit questions and the need to reach timely regulatory decisions.

To further its commitment to conduct timely reviews of drugs and devices, TPD is enhancing its use of qualified and experienced external scientific experts to provide third-party evaluation services and/or independent reviews and recommendations to complement TPD's internal scientific capacity.

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At this time, TPD is seeking input from professionals with medical and/or scientific evaluation expertise with respect to human health, capable of and interested in supporting the TPD's requirement to meet regulatory performance targets for drug reviews, medical device reviews and Reconsideration Panel. The TPD is also seeking information on the existing capacity of medical and scientific researchers to participate as volunteers on Scientific Advisory Committees and/or Panels, to provide guidance and advice as required.

In responding to this LOI, Respondents should note the following four (4) areas of service in which they have both the capacity and interest.

Pharmaceutical Scientific Evaluation Services:

These services include the review, assessment, testing, and provision of recommendations, reports, analyses, and opinions on previous studies and information provided by manufacturers and information/materials and other items regarding therapeutic products.

TPD reviews pharmaceuticals carefully to assess their safety, efficacy and quality before authorizing them to be sold in Canada. Pharmaceuticals include prescription and non-prescription drugs, disinfectants, sanitizers with disinfectant claims, as well as low-risk products such as sunscreens, antiperspirants and toothpaste.

Medical Device Scientific Evaluation Services:

These services include the review, testing, and provision of recommendations, reports, analyses, and opinions on previous studies and information provided by the manufacturer, testing data, and other related items regarding new medical devices.

The definition of "Medical Devices" in the *Food and Drugs Act* covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or physical condition. Medical devices are monitored and evaluated by TPD to assess their safety, effectiveness and diagnostic and therapeutic quality before being authorized for sale in Canada.

Scientific Advisory Committees/Scientific Advisory Panels:

TPD has a number of existing scientific advisory bodies and plans to create more. The mandates of these bodies is to provide TPD with recommendations on regulatory issues generated from single drug submissions and/or from classes of drugs or devices anywhere along the continuum of scientific activities from drug/device development to post-marketing risk issues. The bodies help develop guidelines and provide recommendations on issues directly from a particular submission.

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Reconsideration Panel:

These services include the review, assessment and provision of recommendations, analyses and opinions in the production of a report to the Director General for use in the resolution of disputes handled in the Reconsideration Panel process.

HEALTH CANADA REQUIREMENTS:

HC-TPD is attempting to ascertain the capacity and willingness of medical and scientific researchers to support TPD in:

1. Reviewing the drug and/or device information and material provided by the manufacturer and assessing the accuracy, completeness and validity of the information provided;

2. Reviewing the drug and/or device information and material provided by the manufacturer and providing a recommendation to HC-TPD on the authorization to market a drug and/or device;

3. Identifying requirements for additional information on a drug and/or device;

4. Reviewing and providing a perspective and/or opinion on correspondence between the manufacturer and HC-TPD regarding quality as in toxicity, safety, quality and/or efficacy of the drug and/or device;

5. Reviewing the decision made by HC-TPD regarding the authority to market a drug and/or device;

6. Reviewing the drug and/or device label information provided by the manufacturer assessing compliance with applicable legislation, policies and guidance;

7. Reviewing the drug and/or device product monograph provided by the manufacturer and making recommendations for revisions to the product monograph;

8. Reviewing the drug and/or device information and material provided by the manufacturer and revising and/or recommending revisions to the submission;

9. Reviewing the drug and/or device testing specifications provided by the manufacturer and revising and/or making recommendations for the revision.

10. Reviewing and providing a written perspective and/or opinion on a manufacturer's response to a Notice of Non-Compliance (for a drug)/refusal letter (for a device) issued by HC-TPD;

11. Reviewing the drug and/or device information and material provided by the manufacturer and identifying any concerns;

12. Evaluating clinical trial/investigational testing, data subsets regarding the drug and/or device and providing a report to HC-TPD about efficacy and safety;

13. Conducting a statistical analysis for the dose concentration studies on a drug, conducting statistical analysis on safety and effectiveness data for devices;

14. Evaluating and providing advice, recommendations, and/or an opinion to HC-TPD;

15. Providing expert advice for and/or participation on an HC Advisory Committee or Panel;

16. Meeting with HC-TPD personnel to discuss findings and/or recommendations;

17. In consultation with HC-TPD, developing guidelines and data requirements for the therapeutic class of products;

18. Providing content for letters to manufacturers regarding the findings of scientific reviews of a drug and/or device;

19. Reviewing information or material provided by suppliers of non-drug materials or substances used in the manufacture of drug and medical device products; and

20. Providing advice on compliance action, i.e. relating to health hazard evaluations involving drug products or medical devices;

21. Providing expert advice on Reconsideration Panel for the resolution of disputes with industry.

BASIC REQUIREMENTS FOR RESPONDENTS

HC is seeking to identify Respondents who:

- have experience conducting scientific and/or medical research regarding human health, animal toxicity studies, chemical and formulation research; and

- have at least one post-secondary Degree or Certificate from a recognized institution, in a related field.

NO COMMITMENT OR OBLIGATION

This LOI document and any responses received hereto in no way constitute a commitment or obligation on the part of Health Canada to establish a resulting contract with one or more parties to provide the services described herein.

CONFIDENTIALITY OF RESPONDENT INFORMATION

HC shall, during and after the period of the LOI, treat as confidential and not divulge, unless authorized in writing by the Respondent, any information obtained from the Respondent that has been identified by Respondents as “confidential” or “proprietary”, within their response to this LOI.

If you are interested in being qualified for our database in order to either participate in potential opportunities with Health Canada or in becoming a volunteer member of a Scientific Advisory Committee (SAC) or Scientific Advisory Panel (SAP) to provide guidance/advice, as required, please click this link to complete the required registration documents.

Online Application Form

Should you have any questions relating to this Letter of Invitation please contact Enhanced Review Capacity Unit by email at**: erci-iace@hc-sc.gc.ca**