

Terms of Reference

Expert Advisory Committee on Veterinary Natural Health Products

The Expert Advisory Committee on Veterinary Natural Health Products issues (EAC-vNHP) is selected from professional and scientific communities to provide expert advice and to make recommendations to the Health Products and Foods Branch (HPFB, the Branch), through the Veterinary Drugs Directorate (VDD). Issues of interest related to the safety, quality and efficacy of veterinary natural health products (vNHPs), and matters of a scientific nature regarding the implementation of the new regulatory framework for vNHPs may be referred to the EAC-vNHP by the Branch. The collective expertise from the EAC-vNHP may assist the Branch in making decisions on the administration of these questions; however final responsibility and decision making authority remains with the Branch.

The committee will also provide a mechanism to involve the public providing them with the opportunity to have their views heard by experts who can discuss their input and incorporate it into the advice provided to the Branch. Incorporating the views of citizens and stakeholders is critical for effective regulation in the public interest.

Health Canada, through the HPFB, is Canada's federal authority responsible for the regulation of health products and food. The Expert Advisory Committee on Veterinary Natural Health Products (EAC-vNHP) is being established as part of a series of measures to ensure that the decision-making at Health Canada and at the Health Products and Food Branch (HPFB) in particular, is more open, transparent and accountable to stakeholders and the public.

Mandate

The mandate of the EAC-vNHP is to provide the Branch with timely expert advice and recommendations on questions on the safety, quality, efficacy, claims, use, and regulation of vNHPs. This may include matters of a scientific nature regarding the implementation of the new regulatory framework for vNHPs. Questions referred to the EAC-vNHP by the Branch may be from a broad range of issues, but will focus on scientific areas where detailed or difficult evaluation is required.

Such issues referred for advice and recommendation may include, but not be limited to, the following:

1. Providing advice, as required, to implement the new regulatory environment;
2. Establishing criteria for submissions regarding safety, efficacy, quality and health claims;
3. Defining clear inclusion criteria for proper classification of products as animal feeds or vNHPs;
4. Establishing specific requirements for product labelling;
5. Evaluating data sources used to establish safety, efficacy, quality and health claims;
6. Providing advice on specific issues related to reported adverse reactions, incidents and effects;
7. Evaluating critical situations concerning the safety of a product or ingredient;
8. Advising on research needed to support regulatory decisions;
9. Establishing appropriate guidelines for Good Manufacturing Practices for various vNHP classes;

Governance

The Branch is represented on the Committee by the Assistant Deputy Minister (ADM), HPFB, or its delegate, who acts as the Executive Secretary to the committee. The committee provides its advice to the ADM, HPFB in the form of a report which includes a summary of the public input. It is understood that the Branch always retains all decision-making authority and responsibilities.

Membership

The committee is comprised of 10-14 individuals. Membership of the EAC-vNHP should include, but is not limited to, the following areas of expertise: vNHPs, veterinary medicine, relevant medical sciences, and practice of healthcare. The committee should also represent a cross section of the following groups: health professionals, consumers, industry, and research/academia sectors. If members are part of a professional association then they are required to be in good standing.

Health Canada staff will not serve as members of the committee. However, a non-Health Canada federal employee may be a member of this committee, as long as the employee is acting in an independent capacity and is not representing the government.

Nomination of Members

Members and Chairpersons of the committee are appointed by the ADM or by the DG VDD for a two- **or three-** year term which may be extended to a maximum total period of six consecutive years. The Executive Secretary in consultation with the Chair will appoint a member of the EAC-vNHP to be the media spokesperson when circumstances warrant this.

In appointing advisory board member, the Branch will consider, in addition to the required expertise, experience, and good professional standing of members: affiliations and interests, demonstrated ability to keep an open mind and demonstrated ability to exercise independent judgement. In considering whom to recruit to an advisory body, HPFB may consult with Health Canada staff, consult with other government organizations, consult with external organizations, associations or experts, consult with the chair and members already on the advisory body or ask the public for suggestions. HPFB is committed to diversity and inclusiveness and membership of the committee will strive to reflect an appropriate proportion of gender, regional, ethnic and language representation for Canada.

Security Clearance

As a condition of appointment, all members must undergo a security clearance to the "reliability status" level.

Affiliations and interest

To be considered for appointment, potential members of the committee must complete the  [Affiliations and Interests Declaration Form for Advisory Body Members](#). It is incumbent upon the member to update their statement in writing, should their personal situation change.

A person with a direct financial interest in the outcome of a review of a regulated product may be a member of an advisory body such as this one, whose broader mandate encompasses matters of policy, management or program development. However, such a member may not participate in any discussion, formulation of advice, or recommendations by the advisory body to the Branch relating to the review.

In addition to direct financial interests, potential members must disclose a number of other affiliations and interests in the Declaration Form. It is recognized that a member(s) who have such other relevant affiliations and interests may have valuable input to offer based on their expertise or experience.

Committee members are expected to conduct themselves in an appropriate manner, *i.e.*, the use of their positions cannot be reasonably construed to be for their private gain or that of any other person, company, or organization.

In keeping with the  [Privacy Act](#), a completed Affiliations and Interests Declaration Form for Advisory Body Members is confidential. The HPFB will not make public any information in the form without the member's permission. However, as a condition of membership, advisory body members will allow the Branch to publish on its Web site a Summary of Expertise, Experience, and Affiliations and Interests, which will be based on the

complete Declaration Form. Advisory body members will be asked to review the content of the Summary for Accuracy before its release.

Confidentiality

Every member of the Committee may be requested to sign a confidentiality agreement before participating in an advisory body, as a member, invited guest, observer, or resource person. The agreement prohibits the disclosure of any protected information received through participation in the committee, including information received orally or in writing.

The HPFB will mark information according to the level to which it is protected under the  Policy. The Chairperson will ensure that everyone participating in the meeting, telephone discussion, e-mail exchange, or in another form of communication has received clear instructions on the confidentiality of the proceedings.

Responsibilities of members

Members of the EAC-vNHP have a responsibility to Canadians to offer their independent and objective advice to the HPFB. Members are appointed as individuals on the basis of their individual expertise, and they are not to represent their firms, organizations, or associations. They are to serve in the best interest of all Canadians.

Specific responsibilities include:

- being available and prepared to participate in meetings;
- being available and prepared to attend a public input activity related to the committee's mandate, if necessary;
- considering information that is relevant to the Committee's mandate, this may include information that the Branch has received from the public during a public input process, for instance, through meetings, interviews, public forums, or in writing;
- participating in discussions before the committee prepares its report to the HPFB;
- notifying a Branch official and the Chair of any changes in the status of their affiliations and interests relevant to the EAC-vNHP mandate,
- making a verbal statement of affiliations and interests at the beginning of a meeting, if asked by the Branch or the Chair of the advisory body.

As qualified experts, members - based on their expertise and declared affiliations and interests - may be asked to participate in an EAC-vNHP sub-committee; to represent the committee's viewpoint at other HPFB advisory body meetings; or to participate in branch initiatives as an external advisor.

As well, in the event expert advice and public input is sought on a specific issue with respect to a specific product or class of products, matters which are not within the mandate of the EAC-vNHP, select members may be asked to join a one-time expert committee which would be supplemented with additional scientific expertise.

Responsibilities of the Chairperson

In addition to all the responsibilities of a committee member, the Chair is responsible for the following:

- overseeing and chairing meetings;
- consulting with the Executive Secretary to determine how public input will be sought and deciding if all, or part of, a meeting should be held in private, in consultation with and subject to particular requests from the Branch;
- providing input to the Executive Secretary on the selection of members;
- consulting with the Executive Secretary to end the appointment of a member;
- consulting with the Executive Secretary to determine whether to limit the participation of a member in a meeting, depending on the nature of the person's affiliations or interests;
- coordinating the work of the committee;

- facilitating discussion among members in answering the Branch's questions before preparing advice or recommendations for the Branch;
- ensuring that all members agree with, or note their disagreement with, the advice in the report to the Branch;
- preparing and delivering the report to the Branch; and
- supporting, in any other way, the EAC-vNHP's mandate.

If the Chair is unavailable, the Co-chair assumes the role of Chair.

Responsibilities of the Executive Secretary

The Executive Secretary is the designated Federal Official who provides leadership and strategic advice in the management of the committee and works closely with the Chair and Secretariat. In particular, the Executive Secretary is responsible for preparing and delivering to the EAC-vNHP members, the Branch response to the committee's report.

Responsibilities of the Secretariat

The secretariat, which is provided by Health Canada and is housed in the HPFB's VDD, acts as a liaison between committee members and the Branch, as a resource for members and works closely with the Chair. In addition, the secretariat:

- coordinates preparation of the meeting agendas and minutes, records of proceedings and reports, and maintains any information about the committee, its mandate, or work that may be posted on the Health Canada Web site;
- coordinates the processes for the Affiliations and Interests Declaration Form for members and security clearance;
- coordinates preparation of information for the EAC-vNHP and marks it according to the level to which it is protected under the *Government Security Policy*;
- maintains a list of forward agenda items and nominees;
- coordinates requests for travel reimbursement;
- helps to prepare the committee member designated as media spokesperson, if appropriate;
- monitors and evaluates the efficiency and effectiveness of the committee; and
- carries out additional duties as appropriate in support of the committee.

The secretariat receives guidance from a working group with representation from within the HPFB.

Administration of the committee

Frequency and location of meetings

There will be a standing schedule of at least two meetings per year. Notices of meetings will be issued in writing by the Secretariat. Meetings will generally be held in the National Capital Region, or by teleconference. It is recommended that committee members limit the number of teleconferences to one or two a year, as the Directorate prefers that members participate in person to facilitate a more productive meeting.

Meetings will be scheduled by the VDD and will accommodate as much as possible the schedules of the EAC-vNHP members. Additional meetings may be held at the request of the Chair or the secretariat, in consultation with the Executive Secretary. These or any additional meetings may be undertaken using in-person, web-based or other communication vehicles.

Meeting agendas

EAC-vNHP members and the HPFB working group are canvassed for agenda items at least eight weeks in advance of regularly scheduled meetings. The agenda is then developed by the Chair, in collaboration with the Executive Secretary. The agenda, along with supporting meeting materials, will be provided to committee members a minimum of two weeks prior to the meeting.

Committee deliberations

Advice from the committee is in the form of recommendations. The EAC-vNHP is encouraged to reach consensus in providing advice whenever possible. Dissenting opinions will be taken into consideration by the Director General in situations where consensus is not achieved, and the number of members in disagreement and their issues will be recorded. In such cases, the EAC may also make a recommendation of further study of the issue. Decisions of the Committee are recommendations to the Director General. The committee will not provide recommendations unless a quorum is present. The quorum for the EAC-vNHP is determined to be one half of the members plus one.

Reporting

The content and approach of reporting will depend on the type of issue that the Advisory Body is advising on: Where meetings or reports address the pre or post market review of a regulated product, they may contain confidential information protected by Canadian laws and policies and international treaties. In this case they will not be published on the Web site of HPFB.

Where the advisory body is involved purely in policy, management and program development, the minutes of the meetings and the formal reports will be published on the HPFB Web site as soon as possible. Reports will be published after the committee has approved the content. Reports posted online will be available in both official languages and will comply with  [Treasury Board's Common Look and Feel Guidelines](#), Health Canada's Guidelines for Presentation of Reports and Publications, and Health Canada's Guidelines for Presentation of Public Involvement Activities and Consultations. There will be no references to comments made by individual Members or the public. The report is non-attributable.

The HPFB will also make public how the advice, combined with other information and scientific expertise, led to decision-making, as well as the consequence(s) and the next step(s).

Sub-committees and ad hoc advisors:

The EAC-vNHP may form sub-committees or working groups or seek out *ad hoc* advisors, where necessary, to assist in its work.

Sub-committee and *ad hoc* members will be selected by the DG VDD in consultation with the EAC-vNHP. Sub-committee and *ad hoc* members may be appointed for specific meetings or for the specific fields they have expertise in, for a term of up to two years. Sub-committee and *ad hoc* members may, at the discretion of the DG VDD, be re-appointed for a further term of two years for a maximum of four years.

An Ad Hoc member must follow the same rules and procedures as a core member

Invited guests

The HPFB, or the Chair in consultation with the Executive Secretary, may invite individuals with particular expertise or experience to provide input on a specific topic or agenda item. However, an invited guest may not participate in the formulation of advice or recommendations to the Branch.

Observers

The HPFB, or the Chair in consultation with the Executive Secretary, may allow individuals, organizations, or members of the general public to observe a meeting, or parts of a meeting. A limited number of federal employees may be permitted to observe a meeting, to respond to questions and provide information at the call of the Chair and the Executive Secretary.

The HPFB will assess and forward to the Chair for consideration any requests from the public to observe a meeting, or parts of a meeting, that it receives. A response will be provided to the requestor by phone or in writing as soon as a decision has been made, and will include the reasons for the decision.

Health Canada staff may actively participate in discussions, as observers, at the call of the Chair.

Indemnification of members: when serving as volunteers

All members serve on the committee on a volunteer basis. In keeping with the  [Treasury Board's Policy on the Indemnification of and Legal Assistance for Crown Servants and the Volunteers Policy](#), members are eligible for the same protection against personal civil liability as federal employees when faced with comparable risks while acting within the mandate of the committee and serving as volunteers.

Travel and expenses

Members will be reimbursed for expenses incurred during their work on the committee, such as travel and accommodation, according to  [Treasury Board's Travel Directive](#) and  [Hospitality Policy](#)

Process for resignation

An individual member may withdraw his or her membership on the EAC-vNHP at any time by providing to the Executive Secretary and to the Chair 14 days' written notice of their intention to resign. The letter should state the effective date of resignation.

Reasons for Termination

A member's failure to act according to the committee's terms of reference may give cause for termination. If this is the case, the Executive Secretary will advise the member in writing, stating the reason for the termination and the effective date.

Review of the committee

The Executive Secretary and the Chair will review the EAC-vNHP mandate, activities, terms of reference and relevance annually to ensure that it continues to meet ongoing needs. Recommendations for improvement will be considered on an ongoing basis. The Branch retains the prerogative to disband the committee following such review.