Health Canada
Santé Canada

Contact: Denise Quesnel, Therapeutic Products Directorate
Telephone No.: (613) 957-1482

THERAPEUTIC PRODUCTS DIRECTORATE

ADVISORY COMMITTEE ON MANAGEMENT

TERMS OF REFERENCE

The Therapeutic Products Directorate Advisory Committee on Management is a forum for obtaining advice, and a sounding board for management issues relevant to the Therapeutic Products Directorate. The Committee will be asked for advice on areas such as cost recovery, performance, continuous quality improvement, and other Directorate management initiatives. Decision-making responsibility remains with the management of the Therapeutic Products Directorate. From time to time, the Committee may be consulted by other sections of Health Canada as well.

1. MANDATE

To provide the Director General and the management team of the Therapeutic Products Directorate with informed feedback, recommendations, and advice regarding general management issues and initiatives from representatives of the stakeholders served by the Directorate. Specifically:

- to provide feedback and input respecting the Strategic Framework for the Therapeutic Products Directorate, and on the direction of drug regulation in Canada in general;

- to review and provide advice on overall priorities and frameworks for programmes such as regulatory review, cost recovery, and the Quality Initiative;

- to review and provide advice on specific activities related to cost recovery, performance and performance targets, service standards, quality, and other management issues;

- to regularly review performance against targets in all areas of the Therapeutic Products Directorate, and to provide feedback on the impact of performance variances.

2. MEMBERSHIP

The members of the Committee are drawn from persons nominated by stakeholder groups, such as industry, health professions, academia, and consumers. Members are selected by the

Director General, Therapeutic Products Directorate. The membership of the Committee as a whole is intended to reflect an appropriate blend of gender, regional, ethnic, and language representation. The following sectors are considered for representation:

- innovator drug industry
- over-the-counter drug industry (including cosmetics)
- biotechnological drug industry
- generic drug industry
- complementary medicines industry
- pharmacists
- physicians
- hospital pharmacists
- nurses
- naturopaths/herbalists/homeopaths
- Deans of Pharmacy
- Deans of Medicine
- consumer groups (2)

The Committee is chaired by a member external to the Therapeutic Products Directorate. The Chair is chosen by the Director General, Therapeutic Products Directorate.

3. REPORTING STRUCTURE

The Committee reports to the Director General, Therapeutic Products Directorate, who is a member and acts as the Executive Secretary to the Committee.

4. OPERATIONS

Secretariat functions are provided by the Policy Bureau, Therapeutic Products Directorate.

The Committee meets three times per year. Additional meetings may be held at the discretion of the Chair, in consultation with the Director General.

All members of the Committee have equal status during discussion. Therapeutic Products Diectorate staff (other than the Director General) may not serve as members of the Committee, but provide Secretariat support and respond to questions and provide information at the call of the Chair.

At the recommendation of the Committee, and with the approval of the Chair, interested parties or concerned members of the public may be invited to make representations to the Committee in writing or in person, or may be granted observer status for discussion of a particular agenda item, or for an entire meeting.

5. PROPOSED TENURE/LIFE CYCLE

The Chair is appointed for a two to three year term. A single extension to the individual's term of office may be considered, to a maximum total period of six years. In the absence of the Chair, the members will select a Vice-Chair from among the themselves.

Members are appointed for a term of two to three years. They may be reappointed for a further term to a maximum of six years. The Director General will endeavour to ensure that appointments of Members are scheduled to allow for continuity and systematic rotation of membership.

An individual may withdraw from service on the Committee at any time upon written notification to the Executive Secretary. Membership may be terminated at any time upon written notification from the Executive Secretary.

6. SECURITY CLEARANCE AND CONDUCT

All Committee members are required to undergo a security clearance to the level of "enhanced reliability".

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.

Confidential or protected documents leaving Health Canada must be securely stored at all times, and must be returned to Health Canada. All members are expected to protect and maintain as confidential any trade secret or privileged information divulged during the work of the Committee. Members must not discuss this information with persons not on the Committee, or divulge information obtained from the work of the Committee, including presentations made to it, until such time as this information has been officially released for public distribution.

7. COMPENSATION

Non-industry Members will be compensated for travel expenses according to federal government policy. Honoraria will only be paid if membership on the committee results in economic hardship. Specific contractual arrangements will be made should additional work be offered or assigned to committee members.