

TERMS OF REFERENCE

Working Group on “Making” and “Marketing” (ss. 85(2) of the *Patent Act*) Project

PREAMBLE

One of the issues the Board is considering in the review of its Excessive Price Guidelines (Guidelines) is the definition of the “costs of making and marketing the medicine” (subsection 85(2) of the *Patent Act*). Given the technical nature of this issue, PMPRB has contracted an economist, Dr. Donald McFetridge, to write a report on this subject. The report will include the development of a conceptual/theoretical framework, definitions of/or parameters for “making” and “marketing”, and data needed to quantify such costs along with possible public and confidential sources of such data. (Note: Any information provided by a patentee to the PMPRB is confidential under section 87 of the *Patent Act*.)

MANDATE

The mandate of the Working Group is to act as a reference/advisory group and provide both feedback on Dr. McFetridge’s report and any other insights into the concepts of costs of making and marketing a patented medicine.

DELIVERABLES

1. To review and provide comments on Dr. McFetridge’s draft report
2. To provide any other views on the question of definitions, data needs and data sources for making and marketing costs

MEETING AND TIMEFRAME

The Working Group will meet once only, face-to-face, in Ottawa in early May 2008. The meeting will take place on PMPRB premises in Ottawa, unless availability of space or other circumstances necessitate an off-site meeting.

MEMBERSHIP

The Working Group shall be composed of 12 to 14 members including:

- Forensic accountant(s)
- Market economist(s)
- Tax expert (e.g., tax lawyer and/or representative from the Canada Revenue Agency)
- Up to two representatives of the innovative pharmaceutical industry
- Up to two representatives of the biotechnology industry
- Up to two representatives of the generic pharmaceutical industry
- One representative of federal/provincial/territorial governments
- One representative of private insurers

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- One consumer representative

SECRETARIAT

Board Staff member

ORGANIZATION AND STRUCTURE

A senior PMPRB staff person will chair the meeting of the Working Group. Dr. McFetridge’s draft report will be provided to members at least one week prior to the meeting. Minutes of the meeting will be taken by the Secretariat and provided to all members for approval.

CONFIDENTIALITY OF THE WORKING GROUP’S DELIBERATIONS

The deliberations of the Working Group are confidential, and members are expected to respect the confidentiality of any materials provided to them during the course of this work.