TERMS OF REFERENCE
WORKING GROUP ON INTERNATIONAL THERAPEUTIC CLASS COMPARISION

MANDATE

The mandate of the Working Group (WG) is to develop a methodology for appropriately identifying comparable medicines in comparator countries listed in the *Patented Medicine Regulations, 1994* (Regulations).

DELIVERABLES

1. Parameters to guide the selection of comparable medicines

2. A methodology and rationale for identifying drugs that meet the parameters, including sources of data to be used

3. Considerations/rationales as to when comparators may appropriately be added/deleted from the initial list.

REPORTS &TIMEFRAME

- Status/progress report in February 2008
- Final report to the Board by the end of April 2008

MEMBERSHIP

The Working Group (WG) shall be composed of 8 to 10 members including:

- At a minimum, one member of the PMPRB's Human Drug Advisory Panel (HDAP)
- Clinical pharmacologist(s) or pharmacist(s)
- Practicing clinician(s)
- International pharmaceutical expert(s)
- Representative(s) of international regulatory bodies/International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)[1]

[1] The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.

- Representative(s) of the pharmaceutical industry
- Representative(s) of a public drug plan
- Consumers

A key consideration will be expertise relative to the domestic and international drug markets, drug regulation, and international drug formularies.

The names of the Working Group members will be publicly available on PMPRB's Web site.

ORGANIZATION AND STRUCTURE

Each member of the WG will have equal status. A Chairperson will be nominated during the first meeting of the WG...The Chairperson's responsibilities include keeping the team focused on the exercise; maintaining open and effective communication; and ensuring issues and thoughts are raised and recorded. The PMPRB Staff will provide Secretariat services.

CONFIDENTIALITY OF WORKING GROUP DELIBERATIONS

The deliberations of the WG are confidential and members are expected to respect the confidentiality of any materials provided by the PMPRB Staff and/or collected by the WG as during the course of its work.

MEETINGS

- An initial face-to-face meeting of the Working Group in November 2007 to confirm the terms of reference and work plans
- Monthly teleconference/videoconference meetings (meetings 1-2 hours with clear agenda), as needed
- A face-to-face meeting in February 2008 to finalize the report
- If requested, a presentation of the final report to the Board in May 2008

LOCATION OF MEETINGS

WG meetings will take place on PMPRB premises in Ottawa, unless availability of space or other rationale necessitates off-site meetings.