

**TERMS OF REFERENCE
WORKING GROUP ON THERAPEUTIC IMPROVEMENT**

MANDATE

The mandate of the Working Group (WG) is to develop definitions or parameters relating to “breakthrough/substantial improvement,” “moderate improvement,” and “little or no improvement,” along with supporting evidence requirements and sources.

DELIVERABLES

1. Clear, scientifically/clinically-based definitions (either as a full statement or component parameters) for “breakthrough/substantial improvement,” “moderate improvement,” and “little or no improvement” relative to other clinically equivalent drug products available in Canada and used to treat the same disease and/or condition.
2. Thresholds of scientific/clinical evidence, with rationale, to evaluate therapeutic improvement associated with each of the definitions above.
3. Other considerations and/or circumstances which may be appropriate to take into account, including the degree of significance or weight each should be accorded.

REPORTS & TIMEFRAME

- Status/progress report in November 2007
- Final report to the Board by the end of January 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)
- 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, pharmaceutical drug pipeline, and the review of scientific and clinical evidence.

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

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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 September 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 January 2008 to finalize the report
- If requested, a presentation of the final report to the Board in February 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.