



**IRISH MEDICINES BOARD
MANAGEMENT COMMITTEE TERMS OF REFERENCE
AND RULES OF PROCEDURE**

**MGT-P0008-2
1 JULY 2010**

1. AUTHORITY

- 1.1 The Management Committee is established by the Board of the Irish Medicines Board (IMB).

2. MANDATE

(General)

- 2.1 The committee assists the Chief Executive in the management of the activities of the IMB.

(Functions devolved from the Board of the IMB)

- 2.2 The committee grants or amends any certificate, licence or authorisation issued as the competent authority under national and EU legislation.
- 2.3 The committee refers the suspension, revocation or refusal of applications or authorisations to the Advisory Committee for Human Medicines, the Advisory Committee for Veterinary Medicines, or the Advisory Committee for Medical Devices as appropriate.
- 2.4 In relation to medical devices for human use, the Management Committee recommends the designation of the Notified Bodies in Ireland to the Board, raises no objection to clinical investigations and authorises the placing on the market of non-CE-marked devices in specific cases of public health need.
- 2.5 The Management Committee performs licensing, authorisation and registration functions for the possession, supply, import and export of scheduled substances (precursor chemicals).
- 2.6 The committee takes decisions on public health matters, including those of a very serious and significant nature where the urgency is such that the Board cannot be convened. The Chairperson of the Board is informed of the decisions at the earliest opportunity and the Board is informed as soon as practical.
- 2.7 The committee approves decisions to prosecute an offence through the courts or to refer them to the Director of Public Prosecutions.
- 2.8 The committee carries out any other function that the Board may delegate to it.

3. COMPOSITION

- 3.1 The committee consists of the Chief Executive, the Directors as defined and the Senior Scientific Advisor.

4. MEETINGS

- 4.1 A licensing meeting is held each week and a general management meeting every second week. Additional meetings may be held at the discretion of the Chief Executive.
- 4.2 Members may participate in meetings by telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting.
- 4.3 Meetings are chaired by the Chief Executive. In the absence of the Chief Executive, one of the directors is nominated by him/her to chair the meeting.
- 4.4 The committee may act in the absence of one or more members. If members cannot attend all or part of a meeting, they should notify the Secretary to the Board in advance of the meeting.
- 4.5 The quorum for meetings is one half of the membership plus one.
- 4.6 The agenda is established by the Chief Executive and circulated with related papers before the meeting. Separate agendas are prepared for the licensing and general management meetings.
- 4.7 Each member of the committee present has one vote. Decisions are made by consensus or by a majority of the votes of the members present. If there is an equal division of votes, the chairperson has a casting vote.
- 4.8 Any employee of the IMB or other person may be invited to attend for particular items at the discretion of the Chief Executive but they are not entitled to vote.

5. MINUTES OF MEETINGS

- 5.1 Minutes of each meeting are prepared by the Secretary to the Board. Separate minutes are prepared for the licensing and general management meetings.

- 5.2 The minutes indicate the names of the attendees, and in respect of each item on the agenda:
- the documents submitted to the committee,
 - a summary record of the proceedings,
 - the decisions taken or the conclusions reached by the committee.
- 5.3 Draft minutes are sent to members after the meeting. They are adopted at the following meeting and are signed by the chairperson.

6. URGENT DECISIONS

- 6.1 Between meetings, it may be necessary to take urgent decisions for the proper functioning of the IMB. Normally, urgent decisions will be taken by convening a meeting of at least five members or by written procedure (usually e-mail).
- 6.2 A full report on the outcome of the urgent business and the decisions taken shall be presented at the next general meeting of the committee.

7. WRITTEN PROCEDURE

- 7.1 The Chairperson may initiate a written procedure for decisions.
- 7.2 Draft written decisions are sent to the members who are requested to respond with their agreement or comments within a specified period of time, usually 10 days.
- 7.3 The quorum must be reached for any decision taken by written procedure.
- 7.4 A full report on the outcome of the procedure and the decision taken is presented at the next general meeting of the committee.

8. REPORTING

- 8.1 The Chief Executive reports to the Board at each Board meeting, and includes in the report any request to the Board for decisions to be taken on matters arising from the Management Committee meetings.

9. GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

- 9.1 The names of the committee members and their professional qualifications are made public.
- 9.2 Members of the committee may not have a financial or other beneficiary interest in any industry regulated by the IMB. Members will make an annual declaration of financial or other beneficiary interest and a declaration under the Ethics in Public Office Act.
- 9.3 Members of the committee will abide by the IMB's Code of Conduct.
- 9.4 Members of the committee are required not to disclose information received by them while performing their duties, even after their duties have ceased.

10. DEVOLVED FUNCTIONS

(General)

- 10.1 The members of the Management Committee, while retaining responsibility for assisting the Chief Executive in the management of the activities of the IMB, will devolve many of the day-to-day activities to appropriately-qualified staff of the IMB.

(Licensing)

- 10.2 The Management Committee devolves the following licensing activities to appropriately-qualified staff of the IMB:
 - Issuing of variations to licences or authorisations
 - Issuing of certificates
 - Determining the classification of products
 - Issuing of controlled drugs licences
 - Issuing of GMP certificates
 - Issuing of approvals for contract testing laboratories

11. LEGAL ISSUES

- 11.1 The committee may avail of legal advice from the IMB's solicitor on any issues which may arise.

12. GENERAL PROVISIONS

- 12.1 These terms of reference and rules of procedure are approved by the Board and the committee, and are made public.