IRISH MEDICINES BOARD

TERMS OF REFERENCE AND RULES OF PROCEDURE OF THE BOARD OF THE IRISH MEDICINES BOARD

MGT-P0007-4
1 JULY 2010

1. AUTHORITY

1.1 The Board is established by the Irish Medicines Board Act, 1995 ('the Act').

1.2 The seal of the Board is authenticated by the signature of the Chairperson or another member of the Board authorised by it to act in that behalf, and by the signature of an officer of the Board authorised by it to act in that behalf.

2. MANDATE

(Statutory)

2.1 The Board is responsible for the discharge of the functions specified in Section 4 of the Act (see Appendix 1).

(Strategic)

2.2 The Board approves the three-year strategic plan and reviews performance against the plan.

(Reserved functions)

2.3 The Board takes decisions relating to very significant and serious public health matters.

2.4 Through its Audit Committee, the Board approves the internal financial controls and the financial audit function. The Board appoints the internal financial auditor.

2.5 The Board approves the investment policy, major investments, capital projects and the terms of major contracts.

2.6 Significant acquisitions and the disposal or retirement of assets above a threshold set by the Board is subject to Board approval.

2.7 The Board approves the annual budget, monitors expenditure and supervises the preparation and submission of the annual statutory accounts.

2.8 The Board makes an annual report on the activities of the Irish Medicines Board (IMB), including a financial statement, to the Minister for Health and Children. The report is published.

2.9 The Board selects and appoints the Chief Executive, with the consent of the Minister for Health and Children. The terms of office and the remuneration of the Chief Executive are determined by the Minister for Health and Children, after consultation with the Board and with the consent of the Minister for Finance. The Board, through its Remuneration Committee, conducts a process of annual performance appraisal of the Chief Executive.

(General)

2.10 The Board ensures that the procurement rules include competitive tendering for purchases above an approved threshold and ensures compliance with national guidelines and EU directives.

2.11 The Board approves the Code of Conduct applicable to employees, Board and committee members and nominated experts.

3. COMPOSITION

3.1 The Board of the IMB consists of nine members appointed by the Minister for Health and Children for a term of five years, which may be renewed.

3.2 If a member resigns, the resignation takes effect from the date on the letter of resignation or the date of receipt by the Minister for Health and Children of the letter, whichever is the later.

3.3 Members of the Board may be paid travelling and subsistence allowances as approved by the Minister for Health and Children, with the consent of the Minister for Finance.

4. CHAIRPERSON

4.1 The Chairperson is appointed by the Minister for Health and Children from among the members of the Board, for the term of office of the Board. The term expires on the expiry of the term of office of the Board or when the Chairperson ceases to be a member of the Board. A person re-elected to the Board may be re-appointed as Chairperson by the Minister.

4.2 If the Chairperson resigns, the resignation takes effect at the start of the next meeting of the Board after it is informed by the Minister of the resignation.

4.3 The Chairperson is responsible for the efficient conduct of the business of the Board, in particular by:

- providing an effective leadership to the Board and giving a strategic direction to the Irish Medicines Board,

- planning the work of the Board with the Chief Executive and the secretary to the Board,
- monitoring, together with the secretary to the Board, that the rules of procedure are respected
- ensuring that at the beginning of each meeting, any potential conflict of interest is declared regarding any particular item to be discussed by the Board,
- aiming to achieve consensus on issues discussed by the Board, and
- reporting on the activities of the Board, as appropriate.

4.4 The Chairperson of the Board is paid remuneration and allowances for expenses as approved by the Minister for Health and Children, with the consent of the Minister for Finance.

5. MEETINGS

5.1 Meetings of the Board are held at least six times a year. Meetings are normally held on the last Wednesday of the month. The dates of the meetings are agreed on an annual basis by the Board.

5.2 Members may participate in meetings by telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting.

5.3 Meetings are chaired by the Chairperson. In his/her absence, or if the office of the Chairperson is vacant, the members of the Board choose a Chairperson from among themselves.

5.4 The Board may act in the absence of one or more members. Members who cannot attend all or part of a meeting should notify the secretary to the Board in advance of the meeting.

5.5 The quorum for meetings is five.

5.6 Where a member does not attend Board meetings for a period of six consecutive months, and following a failure to satisfactorily resolve the matter, the Chairperson will write to the Minister for Health and Children about the member's non-attendance. Until the matter is resolved, the quorum will be reduced by one.

5.7 The agenda for the Board meeting is established by the Chairperson in consultation with the Chief Executive and the secretary to the Board and is circulated with related papers in advance of the meeting.

5.8 Each member of the Board present has one vote. Board decisions are made by consensus or by a majority of votes of the members present. If there is an equal division of votes, the Chairperson has a casting vote.

5.9 The Chief Executive attends the meetings of the Board but is not entitled to vote.

5.10 Any other employee of the IMB or other person may be invited to attend for particular items of business at the discretion of the Chairperson but they are not entitled to vote.

6. MINUTES OF MEETINGS

6.1 Minutes of each meeting are prepared by the secretary to the Board.

6.2 The minutes indicate the names of attendees and in respect of each item on the agenda:

- the documents submitted to the Board,
- a summary record of the proceedings,
- the decisions taken or the conclusions reached by the Board.

6.3 Draft minutes are sent to members before the next meeting. They are adopted at the following meeting and signed by the Chairperson.

7. URGENT DECISIONS

7.1 Between meetings, it may be necessary for the Board to take urgent decisions for the proper functioning of the IMB. Urgent decisions may be taken by convening an extraordinary meeting, by telephone, by telephone conference or by video-conference. In each case, the quorum must be reached.

7.2 A full report on the outcome of the urgent business and the decisions taken are presented at the next general meeting of the Board.

8. WRITTEN PROCEDURE

8.1 The Chairperson may initiate a written procedure for decisions.

8.2 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.

8.3 The quorum must be reached for any decision taken by written procedure.

8.4 A full report on the outcome of the procedure and the decision taken is presented at the next general meeting of the committee.

9. COMMITTEES

9.1 The structure of the Board and the committees is shown in Appendix 2.

9.2 The Board may appoint such committees from time to time as it sees fit, to advise it in relation to the performance of its functions.

9.3 The Board may appoint to a committee, persons who have a special knowledge and experience related to the purpose of the committee. The appointment of a person to a committee is subject to such terms and conditions as the committee may determine.

9.4 The Board may at any time dissolve a committee.

9.5 The acts of a committee are subject to confirmation by the Board unless the Board dispenses with the necessity for confirmation.

9.6 The Board may regulate the procedure of committees but, subject to any such regulation, committees may regulate their own procedure.

9.7 Reports on the proceedings of the committees are submitted to the Board.

9.8 The Board has established the following committees: Audit Committee, Management Committee and Remuneration Committee.

9.9 The Act has established the Advisory Committee on Human Medicines, the Advisory Committee on Veterinary Medicines and the Advisory Committee on Medical Devices to advise the Board under Section 9 of the Act.

10 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

10.1 The names of the Board members and their professional qualifications are made public.

10.2 Members of the Board will make an annual declaration of financial or other beneficiary interest in any industry regulated by the IMB, and will make a declaration under the Ethics in Public Office Act.

10.3 At each meeting, members will declare any financial or other beneficiary interest in any agenda item. When a member is unable to participate in a meeting due to a conflict of interest, he or she must inform the secretary to

the Board in advance of the meeting in writing. They will withdraw from the meeting while the item is considered and will not vote or act as a member in relation to it.

10.4 Members of the Board will abide by the Code of Conduct.

10.5 Members of the Board are required not to disclose information received by them while performing their duties, even after their duties have ceased.

11 DEVOLVED FUNCTIONS

(Chief Executive)

11.1 The Chief Executive is appointed by the Board to manage and control the administration and business of the Board. The Board acts through, and its functions are performed in its name by, the Chief Executive or other officer of the Board duly authorised by the Chief Executive.

(Management Committee)

11.2 The licensing, authorisation and registration functions of the Board are devolved to the Management Committee. Details of the licensing, authorisation and registration functions are given in Appendix 3.

11.3 The Management 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.

11.4 In relation to medical devices for human use, the Management Committee recommends the designation of the Notified Bodies in Ireland to the Board, grants permission for clinical investigations and approves the placing on the market of non-CE-marked devices in specific cases of public health need.

11.5 The Management Committee may take decisions on public health matters including very significant and serious matters where the urgency is such that the Board cannot be convened. The Chairperson is informed of the decisions at the earliest opportunity and the Board as soon as practical.

11.6 The Management Committee approves decisions to prosecute an offence through the courts or to refer it to the Director of Public Prosecutions.

12. LEGAL ISSUES

12.1 The IMB retains the services of a solicitor to address all legal issues raised.

13. GENERAL PROVISIONS

13.1 These terms of reference and rules of procedure are adopted by the Board and are made public.

Appendix 1 Principal functions of the Board

Section 4 of the Irish Medicines Board Act 1995, as amended by the Irish Medicines Board (Miscellaneous Provisions) Act, 2006.

(a) The licensing of the manufacture, preparation, importation, distribution and sale of medicinal products,

(b) To exercise the powers conferred on the competent authority by Directive No. 2001/83/EEC of 6 November 2001,[1]

(c) To exercise the powers conferred on the supervisory authority by Regulation (EC) No. 726/2004 of 31 March 2004,[2]

(d) To exercise the powers conferred on the competent authority by Directive 2001/82/ EC of 6 November 2001,[3]

(e) To exercise the powers specified in the Control of Clinical Trials Acts, 1987 and 1990,

(f) To establish and administer a service for obtaining and assessing information as regards the safety, quality and efficacy of medicinal products,

(g) To establish and administer a service for obtaining and assessing reports on any adverse effects of medicinal products in use in the State,

(h) To advise the Minister and others concerned as to the precautions or restrictions, if any, subject to which medicinal products may be marketed or continued in use in the State,

(i) To arrange for the collection and dissemination of information relating to medicinal products including, in particular, information concerning the pharmacological classification and the therapeutic efficacy of such products,

(j) To furnish, whenever it is so requested by the Minister, advice to the Minister in relation to the certification for export or any other purpose of medicinal products manufactured in the State,

(k) To establish and administer a service –

    (i) for the receipt of applications form persons proposing to export any description of medicinal products, cosmetic products, veterinary medicinal products or medical devices

(ii) for the issue to such persons of certificates containing any statement relating to such description of such products or devices as the Board considers appropriate after having regard to –

(I) the law (whether under any enactment or rule of law or otherwise) in the State which is for the time being applicable to such description of such products or devices, and

(II) the law (whether under any enactment or rule of law of otherwise) in the place to which such description of such products or devices is to be exported which is for the time being applicable to such description of such products or devices,

(l) If so requested, to advise the Minister or others concerned on such matters relating to medical devices as may be referred to it and are connected with the functions or activities of, or the services provided by the Board,

(m) To furnish, whenever it so thinks fit or is so requested by the Minister, advice to the Minister in relation to any matter connected with the functions or activities of, or the services provided by, the Board,

(n) To perform such additional functions as considered appropriate by the Minister for Health and Children and the Minister for Agriculture, Food & Forestry,

(o) To exercise the powers conferred on the competent authority by Council Directive 98/79/EC of the 27th October[4], 1998 and the European Communities,

(p) To exercise the powers conferred on the competent authority by Council Directive 90/385/EEC of 20 June 1990[5] and the European Communities (Active Implantable Medical Devices) Regulations, 1994 (S.I. No. 253 of 1994) and Council Directive 93/42/EC of June 1993[6] and the European Communities (Medical Devices) Regulations, 1994 (S.I. No. 252 of 1994),

(q) To exercise, subject to subsection (5), the powers specified in section 14(1) of the Misuse of Drugs Act 1977 (as amended by section 7 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006),

(r) The authorisation of persons under section 24 of the Misuse of Drugs Act 1977 (as amended by section 9 of the Irish Medicines Board (Miscellaneous Provisions Act 2006),

(s) To exercise the powers conferred on the competent authority by Directive 2001/20/EC of 4 April 2001,[7]

(t) To exercise the powers conferred on the competent authority by Council Directive 76/768/EEC of 27 July 1076,[8] as amended, Commission Directive 95/17/EC of 19 June 1995[9] and the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004),

(u) To exercise the powers conferred on the competent authority by Directive 2004/23/EC of 31 March 2004,[10]

(v) To perform such other functions as are conferred on the Board by this or any other enactment (including any statutory instrument made thereunder).

---

[1]Directive No. 2001/83/EEC of 6 November 2001 on the Community code relating to medicinal products for human use.

[2]Regulation (EC) No. 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[3]Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products.

[4]Council Directive 98/79/EC of the 27 October, 1998 and the European Communities Regulations, 2001 of the European Parliament and of the Council of 27th October 1998 on in vitro diagnostic medical devices.

[5]Council Directive 90/385/EEC of the 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

[6]Council Directive 93/42/EC of June 1993 concerning medical devices.

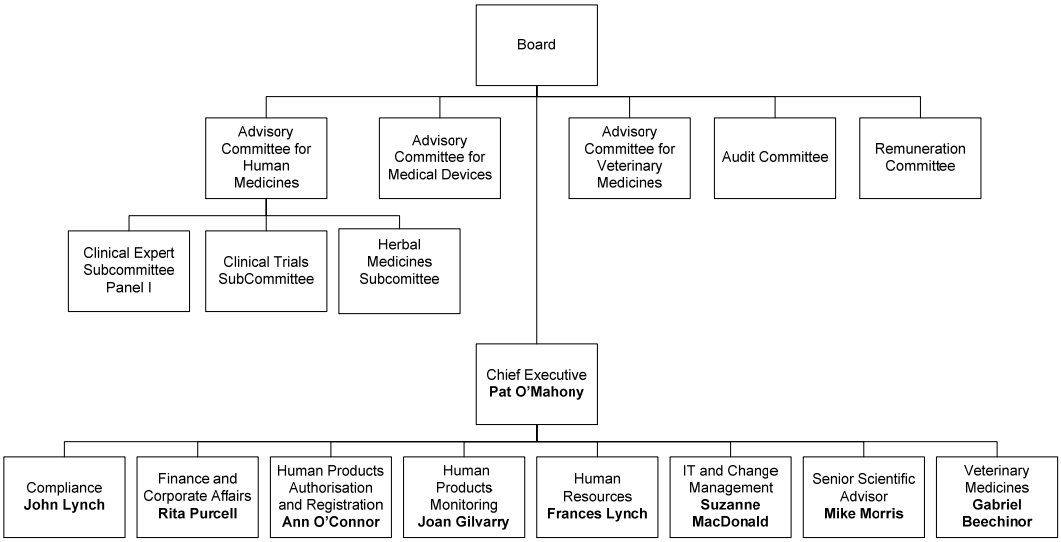
[7]Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

[8]Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

[9]Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non- inclusion of one or more ingredients on the list used for the labelling of cosmetic products.

[10]Directive 2004/23/EC of 31 March 2004 on setting the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

Appendix 2 Structure of the Board, committees and departments



Appendix 3 Licensing functions devolved to the Management Committee

Licensing functions devolved by the Board to the Management Committee	Licensing functions devolved by the Management Committee to staff	Authority to sign licences
The grant, renewal, variation and transfer of authorisations for medicinal products for human use	The variation of authorisations for medicinal products for human use	Grades IV to VI
The grant, renewal, variation and transfer of authorisations for medicinal products for veterinary use	The variation of authorisations for medicinal products for veterinary use	Grades IV to VI
The grant or amendment of authorisations to conduct clinical trials with medicinal products for human use		Grades IV to VI
The grant, renewal and variation of authorisations to manufacture medicinal products for human use	The variation of authorisations to manufacture medicinal products for human use	Grades IV to VI
The grant, renewal and variation of authorisations to manufacture medicinal products for veterinary use	The variation of authorisations to manufacture medicinal products for veterinary use	Grades IV to VI
The grant, renewal and variation of authorisations to manufacture investigational medicinal products for human use	The variation of authorisations to manufacture investigational medicinal products for human use	Grades IV to VI
The grant, renewal and variation of authorisations to distribute medicinal products for human use	The variation of authorisations to distribute medicinal products for human use	Grades IV to VI

Licensing functions devolved by the Board to the Management Committee	**Licensing functions devolved by the Management Committee to staff**	**Authority to sign licences**
*The grant of licences to import, export, possess, supply and manufacture controlled drugs	*The grant of licences to import and export controlled drugs	*Grades IV to VI
Issuing of licences and registrations for the possession, supply, import and export of scheduled substances (precursor chemicals)	Issuing of licences for the import and export of scheduled substances (precursor chemicals)	Grades IV to VI
The grant, renewal and variation of authorisations for blood establishments	The variation of authorisations for blood establishments	Grades IV to VI
The grant, renewal and variation of authorisations for tissue establishments	The variation of authorisations for tissue establishments	Grades IV to VI

*Pending the signing into law of new legislation