HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Terms of Reference and Rules of Procedure
Advisory Committee for Human Medicines

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CONTENTS

1 ESTABLISHMENT

1.1 The Advisory Committee for Human Medicines is established by the Irish Medicines Board Act, 1995, as amended ('the Act')[1].

2 MANDATE

2.1 The committee assists and advises the Health Products Regulatory Authority (the 'Authority')[2] in relation to any matters pertaining to public health or the safety, quality or efficacy of medicinal products for human use which may be referred to it by the Authority.

2.2 The committee advises the Authority on matters relating to the proposed refusal to grant a licence or authorisation in respect of a medicinal product or class of medicinal products, or the manufacture or wholesale of a medicinal product or class of medicinal products for human use, on any grounds relating to the safety, quality or efficacy of the product.

2.3 The committee advises the staff of the Authority on matters of public health, safety, quality or efficacy, relating to medicinal products for human use which are referred to the committee.

3 COMPOSITION

3.1 The committee consists of no fewer than six and no more than 12 members, appointed by the Minister for Health for a period not exceeding five years.

3.2 Members of the committee are paid allowances for expenses as the Authority may, with the consent of the Minister for Health and the Minister for Public Expenditure and Reform, determine.

[1] The body was originally established as the Irish Medicines Board ('the Board'); the name was changed to Health Products Regulatory Authority by the Health (Pricing and Supply of Medical Goods) Act 2013.

[2] 'The Authority' refers to the nine members appointed to the Authority under section 7 of the Irish Medicines Board Act. References to the Health Products Regulatory Authority should be understood to refer to the whole organisation.

4 CHAIRPERSON

4.1 The Chairperson is appointed by the Minister for Health from among the members of the committee. The Chairperson is a member of the Authority.

4.2 The Chairperson is responsible for the efficient conduct of the business of the committee, in particular by:

- planning the work of the committee together with the Secretary to the Committees,
- monitoring, together with the Secretary to the Committees, 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 committee,
- aiming to achieve consensus on issues discussed by the committee,
- ensuring, together with the committee and the Secretary to the Committees, the regulatory and scientific consistency of the committee's recommendations,
- co-ordinating, together with the Secretary to the Committees, the work of the committee with that of its subcommittees, and
- reporting on the activities of the committee as appropriate.

5 MEETINGS

5.1 Meetings are held with sufficient frequency to enable the committee to carry out its functions. If appropriate, the Chairperson will consult with the Authority or the staff of the Authority in determining the frequency of meetings.

5.2 Members of the committee may participate in meetings in person or via telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting. The Secretary to the Committees also attends the meetings.

5.3 Meetings are chaired by the Chairperson. In his/her absence, an acting Chairperson is appointed from among the members of the committee.

5.4 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 Committees in advance of the meeting.

5.5 The quorum for meetings is one half of the appointed committee membership plus one.

5.6 Members are expected to attend all meetings, if possible. Member attendance is recorded on the HPRA Annual Report and made public.

5.7 Where a member does not attend committee meetings for a period of twelve consecutive months, and following a failure to satisfactorily resolve the matter, the Chairperson will write to the Authority recommending that the Authority inform the Minister for Health about the member's non-attendance. Until the matter is resolved, the quorum will be reduced by one.

5.8 The agenda is established by the Chairperson and if appropriate, in consultation with the Authority or members of the staff of the Authority, and the Secretary to the Committees. It is circulated with related papers in advance of the meeting.

5.9 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.

5.10 Any employee of the Health Products Regulatory Authority (HPRA) or other person may be invited to attend for particular items 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 Committees.

6.2 The minutes indicate the names of the attendees, and in respect of each item on the agenda:
- a summary record of the proceedings,
- the decisions taken or the conclusions reached by the committee.

6.3 Draft minutes are sent to members as soon as possible after the meeting. Minutes can be approved by written procedure between meetings or at the next Committee meeting provided it is within a reasonable timeframe. A quorum is required for the minutes to be adopted. Once adopted the minutes are signed by the Chairperson. If adopted by written procedure, the minutes are added to the next meeting for information.

7 WRITTEN PROCEDURE

In the event that a meeting is required and for logistical reasons cannot be arranged, the Committee can carry out its business by written procedure (usually email) as follows:

7.1 The Chairperson or Secretary to the Committees may initiate a written procedure for decisions, recommendations or to provide an opinion.

7.2 The written proposal and, where required, accompanying documents 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, recommendation of opinion to be agreed by written procedure.

7.4 A full report on the outcome of the procedure is presented at the next meeting of the committee.

8 REPORTING

8.1 The outcome of meetings is reported to the Authority. The Chairperson will inform the Authority of significant issues discussed at the committee and, where necessary, present recommendations for the Authority's consideration and decision.

9 SUBCOMMITTEES

9.1 The committee may appoint subcommittees from time to time and as it sees fit to perform its function.

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

9.3 The committee may at any time dissolve a subcommittee.

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

9.5 The committee may regulate the procedure of subcommittees but, subject to any such regulation, subcommittees may regulate their own procedure.

9.6 The Chairperson will notify the Minister for Health of the establishment of a subcommittee, of the purpose of the subcommittee and of the names of its members.

9.7 The Minister for Health may, if he or she considers it appropriate, appoint additional persons to be members of any subcommittee.

9.8 The terms of reference and rules of procedure of subcommittees are determined and reviewed periodically by the committee and reports on the proceedings of the subcommittees are submitted to it.

10 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

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

10.2 Members of the committee will abide by the HPRA's Code of Conduct and Conflicts of Interest Policy (for Authority, Committee Members and External Experts).

10.3 Members of the committee will make an annual declaration of financial or other beneficiary interest in any industry or organisation regulated by the Authority. They should also declare any new interests as soon as they arise by submitting an updated declaration of interests.

10.4 Where a member has any financial or other beneficiary interest in relation to any agenda item he or she must inform the Secretary to the Committee in advance of the meeting in writing. At the beginning of each meeting, there will be a standing agenda item relating to declarations of interests during which members will declare any financial or other beneficiary interest in any agenda item. The member will withdraw from the meeting while the item is considered and will not vote or act as a member in relation to it.

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

11 LEGAL ISSUES

11.1 The committee may avail of legal advice from the HPRA'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 Authority and the committee, and are made public.

12.2 These terms of reference and rules of procedure are to be read as standing orders in accordance with Section 9(5) of the Act.