HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Terms of Reference and Rules of Procedure
Clinical Expert Subcommittee (Panel I)

MGT-P0009-2
22 DECEMBER 2015

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1 ESTABLISHMENT

1.1 The Clinical Expert Subcommittee is established by the Advisory Committee on Human Medicines (ACHM).

2 MANDATE

2.1 The subcommittee advises the ACHM and the Health Products Regulatory Authority (the 'Authority') on clinical matters referred to it relating to medicinal products for human use. Where the subcommittee advises the Authority, such advice will not be subject to confirmation by the ACHM.

3 COMPOSITION

3.1 The subcommittee consists of a panel of experts appointed by the ACHM for a period not exceeding the duration of the term of office of the ACHM and any person appointed to it by the Minister for Health.

3.2 Subcommittee members are paid allowances for expenses as the Authority may, with the consent of the Minister for Health and Minister for Finance, determine.

4 CHAIRPERSON

4.1 The Chairperson is appointed by the ACHM from among the subcommittee members. The Chairperson is a member of the ACHM.

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

- planning the work of the subcommittee together with the secretary to the subcommittee,
- monitoring, together with the secretary to the subcommittee, 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 subcommittee,
- ensuring, together with the subcommittee and the secretary to the subcommittee, the regulatory and scientific consistency of the subcommittee's recommendations, and
- reporting on the activities of the subcommittee as appropriate.

5 MEETINGS

5.1 Meetings are held with sufficient frequency to enable the subcommittee to carry out its functions. If appropriate, the Chairperson will consult the officers of the HPRA in determining the frequency of meetings.

5.2 The selection of members to be invited to each meeting is determined by the particular clinical expertise required for the agenda items.

5.3 Members of the committee may participate in meetings by telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting. The Secretary to the Authority also attends the meetings.

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

5.5 If invited members cannot attend all or part of a meeting, they should notify the secretary to the subcommittee in advance of the meeting.

5.6 The agenda is established by the Chairperson and if appropriate, in consultation with the ACHM or members of staff of the Authority, and the secretary to the subcommittee. It is circulated with related papers in advance of the meeting.

5.7 Each member 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.

5.8 Any employee 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 subcommittee.

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

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

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

8 REPORTING

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

9 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

9.1 The names of the subcommittee members and their professional qualifications are made public.

9.2 Members of the subcommittee will make an annual declaration of financial or other beneficiary interest in any industry regulated by the Authority.

9.3 At each meeting, the members present 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 subcommittee in advance of the meeting in writing. He or she will withdraw from the meeting while the item is considered and will not vote or act as a member in relation to it.

9.4 Members of the subcommittee will abide by the Code of Conduct approved by the Authority.

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

10 LEGAL ISSUES

10.1 The subcommittee may avail of legal advice from the Authority's solicitor on any issues which may arise.

11 GENERAL PROVISIONS

11.1 These terms of reference and rules of procedure are approved by the ACHM and the subcommittee, and are made public.