

Terms of Reference and Rules of Procedure Committee for Scientific Animal Protection Appeals



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1 **AUTHORITY**

1.1 The Authority Committee for Scientific Animal Protection Appeals was established by the Authority on 23 April 2014.

2 MANDATE

2.1 The committee advises the Authority on appeals to an order or notice issued under Directive 2010/63/EU and S.I. No. 543 of 2012, as amended.

3 COMPOSITION

- 3.1 The committee consists of six members drawn from the Advisory Committee for Veterinary Medicines, Advisory Committee for Human Medicines, Advisory Committee for Medical Devices or external experts. The members appointed will have expertise or scientific knowledge of the subject area and or in the regulation of scientific matters.
- 3.2 The committee will be constituted each time that it is tasked with conducting an appeal. It follows that different members might be appointed each time an appeal is made in respect of a different project.
- 3.3 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 Finance, determine.

4 CHAIRPERSON

- 4.1 The Chairperson is appointed by, and is a member of, the Authority. The Chairperson will ordinarily be the Chairperson of the Advisory Committee for Veterinary Medicines.
- 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 subcommittee,
 - monitoring, together with the secretary to the committee, 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,

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

5 MEETINGS

- 5.1 Meetings are held as and when appeals are received.
- 5.2 Members of the committee may participate in meetings by telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting. In so participating, they should ensure that they are alone and their conversations with the committee cannot be overheard.
- 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 committee in advance of the meeting.
- 5.5 The quorum for meetings is one half of the appointed committee membership plus one.
- 5.6 Where a member does not attend committee meetings, and following a failure to satisfactorily resolve the matter, the Chairperson will write to the Authority recommending that the Authority remove the member from the committee. Until the matter is resolved, the quorum will be reduced by one.
- 5.7 The agenda is established by the Chairperson and if appropriate, in consultation with the committee or members of the staff of the Authority, and the secretary to the committee. The agenda is circulated with related papers in advance of the meeting.
- 5.8 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.
- 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.
- 5.10 The committee may request advice from an appropriate external expert.

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6 MINUTES OF MEETINGS

- 6.1 Minutes of each meeting are prepared by the secretary to the committee.
- 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.
- 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 ADVICE TO THE AUTHORITY

- 7.1 The advice of the committee in relation to appeals is presented to the Authority. The Chairperson will inform the Authority of any significant issues discussed at the committee and present recommendations for the Authority's consideration and decision.
- 7.2 The Chairperson may not take part in any vote on an appeal by the Authority.

8 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

- 8.1 Members of the committee will make an annual declaration of financial or other beneficiary interest in any industry regulated by the HPRA.
- 8.2 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 committee 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.
- 8.3 Members of the committee will abide by the HPRA Code of Conduct.
- 8.4 Members of the committee are required not to disclose information received by them while performing their duties, even after their duties have ceased.

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9 LEGAL ISSUES

9.1 The committee may avail of legal advice from the HPRA's solicitor on any issues which may arise.

10 GENERAL PROVISIONS

10.1 These terms of reference and rules of procedure are approved by the Authority and the committee.

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