HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Terms of Reference and Rules of Procedure
Audit and Risk Committee

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1 AUTHORITY

1.1 The Health Products Regulatory Authority (the Authority) has established an Audit and Risk Committee (ARC) as a Committee of the Authority to support the Authority for issues of risk, control and governance by reviewing the comprehensiveness of meeting the Authority and the Chief Executive's assurance needs and reviewing the reliability and integrity of these assurances.

2 RESPONSIBILITIES

2.1 The ARC will advise the Authority on:

- the strategic processes for risk, internal control and governance~~;~~, including giving an independent view in relation to risks and risk management systems;
- the accounting policies, the financial statements, and the annual report of the organisation, including the process for review of the financial statements, levels of error identified, and the management letter of the external auditor;
- the monthly management accounts
- the planned activity of both internal and external audit;
- Approval of the Audit Charter;
- adequacy of management's responses to issues identified by audit activity, including external audit's management letter of representation;
- assurances relating to the management of risk and corporate governance requirements for the HPRA;
- where appropriate, proposals for tendering for either internal or external audit services;
- anti-fraud policies, protected disclosures processes, and arrangements for special investigations; and
- The ARC will also periodically review its own effectiveness and report the results of that review to the Authority.

3 MEMBERSHIP

3.1 The ARC shall have a minimum of three members comprising of at least two members of the Authority, neither of whom may be the Chairperson of the Authority, who will be appointed for a period of three years or the term of office of the Authority member.

3.2 ~~The third member~~Other members shall be either a member of the Authority or an expert external to the HPRA~~.~~ who has previously been co-opted in accordance with clause 3.3.

3.3 The ARC may;
- co-opt additional members to provide specialist skills, knowledge and experience, and
- procure specialist ad-hoc advice at the reasonable expense of the HPRA, subject to budgets agreed by the Authority.

3.4 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 the Authority from among the members of the ARC.

4.2 The Chairperson is responsible for ensuring:
- the ARC is appropriately resourced,
- the ARC reviews internal audit reports and management responses and ensures that actions are followed up,
- reports to the ARC contain relevant information and are provided at the right time in an appropriate format,
- absent ARC members are briefed on meetings and attendance records are maintained and reviewed annually,
- the ARC report to the Authority and submit regular written reports or the minutes to the Authority containing relevant information,
- matters arising are reported at each subsequent meeting, and
- they have involvement in the appointment of new ARC members.

5 MEETINGS

5.1 Meetings are held four times a year. Additional meetings may be held if considered necessary.

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 The quorum is two.

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

5.5 Each member of the ARC present has one vote. Decisions are made by consensus or by a majority of the votes of the members present.

5.6 The Chief Executive, Deputy Chief Executive and the Secretary to the ARC attend some or all of the meetings as required by the ARC but they are not entitled to vote. The ARC can request the external auditors or internal auditors to attend as necessary. The ARC may also ask all attendees to leave the meeting to allow for a frank and open discussion.

5.7 A closed session of the ARC members can take place at the end of each ARC meeting.

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.

5.9 The Authority can ask the ARC to convene further meetings to discuss particular issues on which they seek the ARC's advice.

6 INFORMATION REQUIREMENTS

6.1 For each meeting, as appropriate, the ARC will be provided with:
- a report summarising any significant changes to the HPRA's strategic risks and a copy of the strategic/ corporate risk register,
- a progress report from the internal auditors,
- a progress report from the external auditors,
- management assurance reports, and
- reports on the management of major incidents, near misses and lessons learned.

6.2 As and when appropriate, the ARC will also be provided with:
- proposals for the terms of reference for internal audit/internal audit charter,
- the internal audit strategy,
- reports from internal audit,
- quality assurance reports from internal audit,
- draft financial statements of the organisation,
- a report on any changes to the accounting policies,
- external auditor's management letter,
- a report on any proposals to tender for audit functions where appropriate,
- a report on co-operation between internal and external audit, and
- the organisation's risk management strategy.

7 MINUTES OF MEETINGS

7.1 Minutes of each meeting are prepared by the secretary to the ARC.

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

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

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 ARC.

9 REPORTING

9.1 The secretary to the ARC circulates the minutes of ARC meetings to the secretary to the Authority.

9.2 The ARC formally reports to the Authority as required, subject to a minimum requirement to report annually.

10 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

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

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

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 ARC 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 ARC will abide by the Code of Conduct approved by the HPRA.

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

11 ACCESS / LEGAL ISSUES

11.1 The representative of the internal auditors and the representative of the external auditors will have free and confidential access to the Chairperson of the ARC.

11.2 The ARC may avail of legal advice from the Authority'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 ARC, and are made public.