HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Terms of Reference and Rules of Procedure of the HPRA Leadership Team

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1 ESTABLISHMENT

1.1 The HPRA Leadership Team is established by the Health Products Regulatory Authority (the 'Authority').

2 MANDATE

(General)

2.1 The HPRA Leadership Team assists the Chief Executive in the management of the activities of the Authority.

(Functions devolved from the Authority)

2.2 The HPRA Leadership Team is responsible for carrying out the competent authority functions for the regulation of medicinal products for human use; clinical trials on medicinal products for human and veterinary use; clinical investigations; medicinal products for veterinary use; medical devices; blood and blood components; tissues and cells; human organs; cosmetics; controlled drugs; drug precursors and protection of animals used for scientific purposes as set out in the legislation listed at http://www.hpra.ie/homepage/about-us/legislation, other than functions reserved by the Authority.

2.3 Save for clinical trials on human medicines, clinical investigations on medical devices, and cases relating to scientific animal protection, the HPRA Leadership Team, on proposals to refuse, requests the advice of the Advisory Committee for Human Medicines, the Advisory Committee for Veterinary Medicines, or the Advisory Committee for Medical Devices, as appropriate.

2.4 In cases of an urgent public and/or animal health matter of a serious or significant nature as deemed by the Chief Executive, the HPRA Leadership Team takes decisions, including suspensions and urgent suspensions, on public and/or animal health matters where the urgency is such that the Authority cannot be convened. The Chairperson of the Authority is informed of the decisions at the earliest opportunity and the Authority as soon as practical.

2.5 The HPRA Leadership Team approves decisions to prosecute an offence through the courts or to refer it to the Director of Public Prosecutions.

2.6 The Leadership Team carries out any other function that the Authority may devolve to it.

3 COMPOSITION

3.1 The Leadership Team consists of the Chief Executive and the directors as defined.

4 MEETINGS

4.1 A licensing and regulatory meeting is held each week and a Leadership Team meeting every second week, or as appropriate. Additional meetings may be held at the discretion of the Chief Executive.

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

4.3 In relation to the licensing and regulatory meeting, the tables of applications and other regulatory decisions will be circulated in advance of the meeting. Members not attending the meeting can review the tables and indicate approval or otherwise by email. Emails received from members will be considered as part of the decision taken at the licensing meeting and will form part of the quorum.

4.4 Meetings are chaired by the Chief Executive or member of the Leadership Team. One of the directors is nominated by him/her to chair the meeting.

4.5 The Leadership Team 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.

4.6 The quorum for meetings is greater than half of the appointed Leadership Team membership.

4.7 The agenda is established and is circulated with related papers before the meeting. Separate agendas are prepared for the licensing and regulatory, and general management meetings.

4.8 Each member of the Leadership Team 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 Chief Executive has a casting vote.

4.9 Any employee of the HPRA or other person may be invited to attend for particular items at the discretion of the Chief Executive but they are not entitled to vote.

5 MINUTES OF MEETINGS

5.1 Minutes of each meeting are prepared by the Secretary to the Committees. Separate minutes are prepared for the licensing and regulatory, and general management meetings.

5.2 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 Leadership Team

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

6 URGENT DECISIONS

6.1 Between meetings, it may be necessary to take urgent decisions. Normally, urgent decisions will be taken by convening a quorate meeting or by written procedure (usually email).

6.2 A full report on the outcome of the urgent business and the decisions taken shall be presented at the next meeting of the Leadership Team.

7 WRITTEN PROCEDURE

7.1 The Chairperson or Secretary to the Committees 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 The quorum must be reached for any decision taken by written procedure.

7.4 A full report on the outcome of the procedure and the decision taken is presented at the next meeting of the Leadership Team.

8 REPORTING

8.1 The Chief Executive reports to the Authority at each Authority meeting, and includes in the report any request to the Authority for decisions to be taken on matters arising from the HPRA Leadership Team meetings.

9 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

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

9.2 Members of the Leadership Team may not have a financial or other beneficiary interest in any industry regulated by the Authority. Members will make an annual declaration of financial or other beneficiary interest and a declaration under the Ethics in Public Office Act.

9.3 Members of the Leadership Team will abide by the HPRA's Code of Conduct.

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

10 DEVOLVED FUNCTIONS

(General)

10.1 The members of the HPRA Leadership Team, while retaining responsibility for assisting the Chief Executive, will devolve many of the day-to-day activities to appropriately-qualified staff.

(Licensing)

10.2 The HPRA Leadership Team devolves certain licensing activities to staff as listed in Appendix 1.

11 LEGAL ISSUES

11.1 The Leadership Team 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 Leadership Team, and are made public.

12.2 These terms of reference and rules of procedure are to be read as standing orders in accordance with the IMB Act 1995, as amended.

APPENDIX 1 FUNCTIONS DEVOLVED BY THE HPRA LEADERSHIP TEAM TO STAFF

HUMAN MEDICINES
The modification of authorisations to conduct clinical trials on medicinal products for human use
The variation of authorisations for medicinal products for human use
The variation of certificates of registration for homeopathic medicinal products
The variation of certificates of registration for herbal medicinal products
The variation of authorisations to manufacture medicinal products for human use
The variation of authorisations to manufacture investigational medicinal products for human use
The variation of authorisations to wholesale medicinal products for human use
The issue of certificates of free sale; certificates of manufacture and free sale; certificates of pharmaceutical product; and certificates of GMP compliance of a manufacturer
The issue of statements of non-compliance with GMP
The issue of statements of licensing status of pharmaceutical product
Annual updates/communications and immediate notifications for active substance registrations
MEDICAL DEVICES
The issue of certificates of free sale for export purposes
The issue of national derogations or other measures to provide for continued placing on the market of specific medical devices where other relevant regulatory approvals already exist
The issue of production notices, compliance notices and quarantine notices for medical devices
The registration and, when relevant, validation of medical device economic operators and relevant medical devices
The issue of statements of non-compliance with requirements of MDR or IVDR relevant to medical device economic operators and notified bodies
BLOOD, TISSUES AND ORGANS
The variation of authorisations for blood establishments
The variation of authorisations for tissue establishments

The variation, removal and addition of conditions, and substantial change of authorisations for organ procurement organisations or transplantation centres
VETERINARY MEDICINES
The variation of licences to conduct veterinary clinical field trials
The variation of authorisations for medicinal products for veterinary use
The variation of certificates of registration for homeopathic veterinary medicinal products
The variation of certificates of registration for veterinary medicinal products granted under Article 5(6) of Regulation 2019/6
The variation of authorisations to manufacture medicinal products for veterinary use
The issue of certificates of free sale; certificates of manufacture and free sale; certificates of pharmaceutical product; and certificates of GMP compliance of a manufacturer
The issue of statements of non-compliance with GMP
The issue of statements of licensing status of pharmaceutical product
Annual updates/communications and immediate notifications for active substance registrations
SCIENTIFIC ANIMAL PROTECTION
Any amendments or renewals of any scientific animal protection authorisations
The issue of animal welfare or compliance notices
The approval of transfer of project authorisations
CONTROLLED SUBSTANCES
The grant of licences to import and export controlled drugs
The grant of licences for the import and export of scheduled substances (precursor chemicals)
COSMETICS
The issue of certificates of free sale for export purposes
The issue of compliance notices and prohibition orders for cosmetic products