

MTAA REGULATORY AFFAIRS COMMITTEE
Terms of Reference

1.0 Role and Objectives of the Committee

- 1.1 To support the Board in the strategic development and delivery of Association policies in matters pertinent to its expertise as determined by the Board from time to time.
- 1.2 To discuss operational issues facing the Association's members in their interactions with the Therapeutic Goods Administration (TGA) in meeting the regulatory requirements for supplying medical technology in Australia.
- 1.3 To develop and submit papers, proposals and feedback to the TGA on regulatory issues through the TGA/Industry Regulatory and Technical Consultative Forum.

2.0 Membership

- 2.1 The number of members of the Regulatory Affairs Committee (**Committee**) will be not exceed 20 plus the Chair.
- 2.2 The term of office for a Committee member will be two years, with members eligible for reappointment for a further two years.
- 2.3 The Board reserves the right to retain or recruit a Committee member with subject expertise to ensure adequate industry coverage.
- 2.4 Nominations will be invited annually by the MTAA Secretariat from among the appropriately qualified and experienced regulatory affairs staff of voting Members of the Association to fill such vacancies as have occurred during the previous year, either by the expiration of a member's term of office or by the creation of a casual vacancy (para 3.0). Representatives of Associate member companies or Honorary members will not be eligible to nominate for membership of the Committee, except as otherwise approved by the Board.
- 2.5 Where more nominations are received for a Committee than there are positions available, the Board shall select the members in consultation with the Chair of the Committee. Where possible, members should be drawn from a cross section of companies, device sectors and states.
- 2.6 Excepting the Chair of the Committee (4.2), an individual member of the Committee cannot be a member of the Regulatory Subcommittee although a company may be represented on both committees.
- 2.7 Member company representatives who are not members of the Committee may be invited by the Chair to attend a meeting (or part of a meeting) to assist in discussion of a particular matter at issue.

- 2.8 Members of the Committee deliberate as representatives of industry and do not participate as representatives of their parent companies. In the event of absence from a meeting, it is not appropriate for the committee member to delegate attendance to another member of the same company.

3.0 Casual Vacancies

- 3.1 A casual vacancy in the office of a member of a Committee occurs if:
- a) the firm or company represented by the member ceases to be a Member of the Association;
 - b) the member ceases to be employed by the firm or company that nominated him/her as a member of the Committee or the company's nomination of the member is otherwise withdrawn;
 - c) the member resigns from the Committee; or
 - d) the member is absent from three consecutive meetings of the Committee or fails to attend 75% of meetings held in a calendar year, without leave of absence.
- 3.2 The Board may appoint a person with suitable expertise to fill a casual vacancy until the next annual nominations are sought.

4.0 Operation of the Committee

- 4.1 The Committee Chair will be appointed by the Board on the recommendation of the Director, Regulatory Affairs.
- 4.2 The Chair is required to be a member of the Regulatory Subcommittee.
- 4.3 The Chairman of the Board and the Chief Executive Officer are ex officio members of the Committee.
- 4.4 The Chief Executive Officer will appoint a member of the Secretariat to act as the ex officio Secretary of the Committee.
- 4.5 The Committee will meet not less than 4 times per year.
- 4.6 The Committee will report to the MTAA Board at least quarterly, outlining its performance against its Terms of Reference.
- 4.7 Directors may attend Committee meetings with the approval of the Chair.
- 4.8 The Secretary of the Committee may invite other members of the Secretariat to attend a meeting or part meeting to provide information or seek input from Committee members.
- 4.9 Members may attend meetings in person or by electronic means. A member who is unable to attend a meeting may, with the prior approval of the Chair, arrange for an appropriately informed and well briefed delegate to attend on their behalf.

- 4.11 Members of the Committee are expected to actively participate in consultation and working groups.

5.0 Quorum

- 5.1 A quorum consists of the chair plus 50% of the total number of other members of the Committee.

6.0 Governance

- 6.1 A member of the Committee must disclose any conflict of interest or likelihood of a conflict of interest, in any matter under consideration. If a conflict is disclosed the member may not participate in the deliberations of the Committee regarding the matter nor any vote relating to it.
- 6.2 All Committee members shall be required to undertake the MTAA training programs on the Code of Practice and anti-competitive behaviour.
- 6.3 All Committee members shall be required to abide by the Confidentiality, Trade Practices legislation, and other requirements of the Association as may be determined by the Board from time to time.

7.0 Agenda and Minutes

- 7.1 The agenda and any accompanying documentation will be distributed to Committee members no later than one week prior to the assigned meeting date.
- 7.2 Committee meetings will be minuted by the Secretary and confirmed at the Committee's next meeting.

8.0 Voting

- 8.1 Decisions of the Committee must be made by a simple majority vote of the attending Committee members, that is, more than 50% of the members in attendance at the meeting (in person or via electronic means).
- 8.2 Experts and observers do not have voting rights at meetings.

9.0 Liaison with Members

- 9.1 The Committee will ensure that non-confidential information relating to its areas of operation is disseminated by the Secretary to the Members of the Association on a regular basis either in person or electronically, and that Member input is sought on matters at issue.

10.0 Liaison with Government representatives

- 10.1 With the approval of the Chief Executive Officer, the Committee and relevant senior members of the Secretariat may engage in discussion and/or negotiation with relevant government representatives and may invite such representatives to attend Committee meetings.

11.0 Authority

- 11.1 Recommendations of the Committee regarding policy matters will be placed on the Agenda for the next meeting of the MTAA Board for approval.

TERMS OF REFERENCE, MTAA REGULATORY AFFAIRS COMMITTEE		
Document authorised by : MTAA Board	Version: 16.2	Next Review Date: 1 July 2017