

MTAA REGULATORY SUBCOMMITTEE

Terms of Reference

1.0 Role and Objectives of the Subcommittee

- 1.1 The Regulatory Subcommittee (Subcommittee) is a subcommittee of the Access Committee.
- 1.2 The Subcommittee will support the Access Committee in the strategic development and delivery of Association policies in matters pertinent to its expertise as determined by the Access Committee from time to time.
- 1.3 The Subcommittee will develop regulatory focused strategic initiatives for the Association, including:
 - a) reviewing the effectiveness of the regulatory system for medical technology in Australia
 - b) contributing to the Association's involvement with international regulatory organisations
 - c) liaising with Australian government departments and industry associations in Australia and overseas, and
 - d) providing advice on the professional development of regulatory staff in the medical technology sector.
- 1.4 The Subcommittee will provide specialised regulatory expertise to assist with the work of the MTAA Access Committee

2.0 Membership

- 2.1 The number of members of the Subcommittee will not exceed 11, plus the Chair and the Chair of the Regulatory Affairs Committee.
- 2.2 The term of office for a Subcommittee 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 Subcommittee member with subject expertise to ensure adequate industry coverage.
- 2.4 Nominations will be invited annually by the MTAA Secretariat from among the senior regulatory staff of voting Members of the Association (or those regulatory staff with approximately 10 years' experience) 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 Subcommittee, except as otherwise agreed by the Board.
- 2.5 Where more nominations are received for a Subcommittee than there are positions available, the Board shall select the members in consultation with the Chair of the

Subcommittee. Where possible, members should be drawn from a cross section of companies, device sectors and states.

- 2.6 Excepting the Chair of the Regulatory Affairs Committee, an individual member of the Subcommittee cannot be a member of the Regulatory Affairs Committee, although a company may be represented on both committees.
- 2.7 Member company representatives who are not members of the Subcommittee 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 Subcommittee 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 Subcommittee 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 Subcommittee or the company's nomination of the member is otherwise withdrawn;
 - c) the member resigns from the Subcommittee; or
 - d) the member is absent from three consecutive meetings of the Subcommittee 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 Subcommittee

- 4.1 The Subcommittee 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 Access Committee.
- 4.3 The Chairman of the Board and the Chief Executive Officer are ex officio members of each Subcommittee.
- 4.4 The Chief Executive Officer will appoint a member of the Secretariat to act as the ex officio Secretary of the Subcommittee.
- 4.5 The Subcommittee will meet not less than 4 times per year.
- 4.6 The Access Committee will monitor the activities of the Subcommittee.

- 4.7 The Subcommittee will report to the Access Committee at least quarterly, outlining its performance against its Terms of Reference.
- 4.8 Directors may attend Subcommittee meetings with the approval of the Chair.
- 4.9 The Secretary of the Subcommittee may invite other members of the Secretariat to attend a meeting or part meeting to provide information or seek input from Subcommittee members.
- 4.10 Members may attend meetings in person or by electronic means.

5.0 Quorum

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

6.0 Governance

- 6.1 A member of the Subcommittee 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 Subcommittee regarding the matter nor any vote relating to it.
- 6.2 All Subcommittee members shall be required to undertake the MTAA training programs on the Code of Practice and anti-competitive behaviour.
- 6.3 All Subcommittee 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 Subcommittee members no later than one week prior to the assigned meeting date.
- 7.2 Subcommittee meetings will be minuted by the Secretary and confirmed at the Subcommittee's next meeting.

8.0 Voting

- 8.1 Decisions of the Subcommittee must be made by a simple majority vote of the attending Subcommittee 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 Subcommittee 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 Subcommittee 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 Subcommittee meetings.

11.0 Authority

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

TERMS OF REFERENCE, MTAA REGULATORY SUBCOMMITTEE		
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