

COMMITTEE GENERAL TERMS OF REFERENCE

1. Roles and Objectives of the Committee

- 1.1. The overarching role of the Committee is 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. The specific purpose and objectives of the Committee are defined in Schedule 1.

2. Membership

- 2.1. The number of members of the Committee will be as determined by the Board and listed in Schedule 1.
- 2.2. The term of office for a committee member will be two years, with members eligible for reappointment.
- 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 from among the employees of MTAA Members 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).
- 2.5. The Board shall appoint members to the Committee. Where possible, company representative members should be drawn from a cross section of companies, device sectors and states.
- 2.6. Excluding Board representatives, ex officio members of the Committee and Chairs of committees that report to the Committee, no Member company may have more than one representative on the Committee, unless the Board determines that an additional representative from a member company is warranted due to the subject expertise of the representative.
- 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 matter.
- 2.8. Company Representative Members of the Committee deliberate as representatives of industry and do not participate as representatives of their 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. Casual Vacancies

- 3.1. A casual vacancy in the office of a member of the Committee occurs if:
 - a) the entity or company represented by the member ceases to be a Member of MTAA

- b) the member ceases to be employed by the entity or company that nominated him/her as a member of the Committee or the company's nomination of the member is otherwise withdrawn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
 - d) the member is absent from three consecutive meetings of the Committee without the Committee approving leave of absence; or
 - e) the member 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.

4. Operation of the Committee

- 4.1. All Committees report directly to the Board, with the exception of sub-committees of the Code Authority.
- 4.2. The Board will appoint committee chairs on the following basis:
 - a) for the Public Affairs Committee, MedTech Conference Committee, Women in MedTech Committee and Finance Committee, the Committee Chair will be appointed by the Board from among its number.
 - b) for the Code Authority and the Code Monitoring Committee, the Board will appoint an independent Chair.
 - c) for the remaining Committees, the Chair of the Committee will be appointed by the Board from among the members of the Committee.
- 4.3. The Chair's responsibilities include:
 - d) scheduling meetings and determining agendas (in consultation with the Committee Secretary)
 - e) guiding the meeting according to the agenda and time available
 - f) ensuring all discussion items end with a decision, action, or definite outcome
 - g) reviewing and approving the draft minutes before distribution; and
 - h) reporting to the Board as required.
- 4.4. The Chair of the Board is an ex officio member of the Committee.
- 4.5. The Chief Executive Officer will appoint a staff member to act as the Secretary of the Committee.
- 4.6. The Committee will meet not less than 4 times per year.
- 4.7. The Committee will report to the Board at least quarterly. At least annually, the Committee will outline its performance against its Terms of Reference and Objectives.
- 4.8. Board Directors may attend Committee meetings with the approval of the Chair.
- 4.9. With the approval of the Committee Chair, the Secretary of the Committee may invite other staff members to attend a meeting or part meeting to provide information or seek input from Committee members.
- 4.10. Members may attend meetings in person or by electronic means.
- 4.11. Independent members of Committees may be paid an honorarium, as negotiated with the Chief Executive Officer.

- 4.12. The Chief Executive Officer may appoint one of the independent members of the Committee as Deputy Chair who shall act as Chair in the absence of or when directed by the Chair.

5. Quorum

- 5.1. With the exception of the Code Authority and its sub-committees the following applies:
- A quorum consists of at least 50% of the total number of members of the Committee.
 - If the Chair is not present the Deputy Chair will assume the role of chair of the meeting.
 - If there is not a Deputy Chair of the Committee or the Deputy Chair is not present, a Board Representative will assume the role of chair of the meeting.
 - If a Board Representative is not present or willing to chair, the Committee will appoint a member of the Committee to chair the meeting.
- 5.2. For the Code Authority and its sub-committees a quorum consists of the Chair (or in the absence of the Chair, the Deputy Chair) plus 50% of the total number of other members of the Committee.

6. 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 member of the Committee has a conflict of interest in relation to a specific matter, the member must abstain from voting on that matter. The member may participate in the discussion on that matter, subject to the approval of the Committee.
- 6.2. All Committee members shall be required to undertake the MTAA training programs on the Code of Practice and anti-competitive behaviour. This training must be completed prior to the first meeting of the Committee.
- 6.3. All Committee members shall be required to abide by the Confidentiality, Trade Practices legislation, and other requirements of MTAA as may be determined by the Board from time to time.

7. 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 meeting minutes will be taken by the Secretary, circulated to the members within 10 working days and confirmed at the Committee's next meeting.

8. 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. If there is an equality of votes, the Chair of the meeting shall have a second or casting vote.

- 8.3. Experts and observers do not have voting rights at meetings.

9. 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 MTAA on a regular basis either in person or electronically, and that Member input is sought on matters at issue.

10. Liaison with Government and External Representatives

- 10.1. With the approval of the Chief Executive Officer, the committee, and relevant senior staff of MTAA may engage in discussion with relevant government and/or external representatives and may invite representatives to attend Committee meetings.

11. Authority

- 11.1. The committee may not make any financial or contractual commitment on behalf of MTAA.
- 11.2. The Committee may not seek proposals from external service providers without the approval of the Chief Executive Officer.
- 11.3. The Committee may not make any determination of MTAA policy but may provide advice to the Board on any area falling within its jurisdiction to assist the Board in formulating policy.
- 11.4. Recommendations of the Committee regarding policy matters will be placed on the agenda for the next meeting of the Board for approval.

Document History

Version	List of changes per section	Author	Date
V.1	Transfer onto new template. Implement version control. Update Operations. quorum, governance and authority requirements.	Director Finance and Administration, Company Secretary	25 November 2024

Document Approval

Authorised by:	Date:	Next Review Date
MTAA Board	10 December 2024	31 December 2025

Regulatory Affairs Committee

Purpose:	To develop industry positions and decide on the strategic direction of MTAA on regulatory matters within the scope of the Therapeutic Goods Act, the Medical Devices Regulations and the Advertising Code, alignment with EU Medical Device Regulations and international regulatory harmonisation forums (IMDF).
Objectives:	<ol style="list-style-type: none"> 1. Advise other MTAA strategic committees on regulatory matters and coordinate in areas of overlap (e.g. HTA review and regulatory review). 2. Define the MTAA regulatory strategic plan and direction. 3. Appoint the Chair and, if required, the Core Team of the Regulatory Forum. 4. Consider and approve industry positions prepared and recommend by the Regulatory Forum. 5. Manage the interaction with TGA via the RegTech forum.
Governance:	<p>The Committee reports to the Board.</p> <p>To ensure alignment of MTAA's advocacy strategy, the Committee provides regular reports to the Public Affairs Committee</p>
Board Representatives:	Not Applicable
Chair:	As appointed by the Board.
Secretary:	As determined by the Chief Executive Officer.
Membership:	<ul style="list-style-type: none"> • The Chair and a maximum of nineteen (19) industry representatives, unless the Board determines that another maximum is appropriate. • Skills and experience: Members assume a strategic lead role representing the industry regulatory perspective while proactively developing new and often innovative approaches for pursuing industry objectives within the regulatory framework. Based upon a strong and extensive understanding of the role of the profession in the product lifecycle and the dynamics of regulatory processes, these professionals are also engaged in policy development within their organisations and with external groups. (Example job titles: may include directors in some organisations, vice president, executive director, chief regulatory officer) <p><i>Adapted from the RAPS Regulatory Affairs Professional Development Framework – Level IV Regulatory professionals</i></p>

Meetings:	At least Eight (8) per annum
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Document History

Version	List of changes per section	Author	Date
V.1	Transfer onto new template. Implement version control. Update governance requirements	Director Finance and Administration, Company Secretary	24 November 2024

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