



## Committee General Terms of Reference

### 1.0 Role 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.

### 2.0 Membership

2.1 The number of members 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 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 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, 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 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.

### 3.0 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or company that nominated him/her as a member of the Committee of the company's nomination of the member is otherwise withdrawn;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 until the next annual nominations

#### **4.0 Operation of the Committee**

- 4.1 If the committee reports directly to the Board, the Committee Chair will be appointed by the Board from among its number, except for those committees requiring independent Chairs (e.g. Code Authority). If the Committee reports to another committee, the Chair of the Committee will be appointed by the Board from among the members of the Committee.
- 4.2 The chairs responsibilities include
- a) Scheduling meetings and determining agendas;
  - b) Guiding the meeting according to the agenda and time available;
  - c) Ensuring all discussion items end with a decision, action or definite outcome;
  - d) Reviewing and approving the draft minutes before distribution; and
  - e) Reporting to the Board as required
- 4.3 The chair of the Board is an ex officio member of the Committee
- 4.4 The Chief Executive Officer will appoint a staff member to act as the 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 Board at least quarterly, outlining its performance against its Terms of Reference and Objectives.
- 4.7 Board Directors may attend Committee meetings with the approval of the Chair.

4.8 With the approval of the Committee Chair, the Secretary of the Committee may invite other staff members to attend or part meeting to provide information or seek input from Committee members.

4.9 Members of Committees may be paid an honorarium, as negotiated with the Chief Executive Officer.

## **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 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.

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.

## **7.0 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 meeting minutes will be taken by the Secretary, circulated to the members within 5 working days 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 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.

## 9.0 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 MTAA 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 staff of MTAA may engage in discussion and/or negotiation with relevant government representatives and may invite representatives to attend Committee meetings.

## 11.0 Authority

11.1 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.

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

Document Authorised By:	Document Maintained by:	Next Review Date:
MTAA Board: 08/12/2020	Business Operations & Company Secretary	1 July 2023

## Schedule 1

<b>Committee Name:</b>	Regulatory Affairs Committee
<b>Purpose:</b>	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 the new EU Medical Device Regulations of April 2017 and international regulatory harmonisation forums (IMDF).
<b>Objectives:</b>	<ol style="list-style-type: none"> <li>1. Advise other MTAA strategic committees on regulatory matters and coordinate in areas of overlap (e.g. HTA review and regulatory review).</li> <li>2. Define the MTAA regulatory strategic plan and direction.</li> <li>3. Appoint the Chair and, if required, the Core Team of the Regulatory Forum.</li> <li>4. Consider and approve industry positions prepared and recommend by the Regulatory Forum.</li> <li>5. Manage the interaction with TGA via the RegTech forum.</li> </ol>
<b>Governance:</b>	The Committee supports, takes direction from and reports to the Public Affairs Committee.
<b>Board Representative(s):</b>	N/A
<b>Chair:</b>	As appointed by the Board.
<b>Secretary:</b>	As determined by the CEO.
<b>Membership:</b>	<p>The Chair and a maximum of eighteen industry (18) 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 life cycle 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> <p><i>Adapted from the RAPS Regulatory Affairs Professional Development Framework – Level IV Regulatory professionals</i></p>
<b>Meetings:</b>	Eight per annum.
<b>Meeting dates:</b>	2023 dates to be confirmed