

Global Medical Technology Alliance Governance Framework

January 2013

Mission

Members of the Global Medical Technology Alliance (GMTA) support the objectives of providing safe, effective and innovative medical technology that saves and enhances lives, benefiting people and society. The GMTA is a forum in which members exchange information and jointly develop and advocate policies that encourage innovation to address patients' healthcare needs. 1

Objectives

The objects or purpose of GMTA include:

- Development and dissemination of information pertaining to medical technology policies and issues on a global basis
- Coordination of common policy positions for effective representation at a global level of the medical technology industry, generally and in forums such as World Health Organization (WHO), World Bank (WB), World Intellectual Property Organization (WIPO), and World Trade Organization (WTO)
- Encouragement of an international policy environment that supports the
 development of the medical technology industry, including harmonised
 regulatory systems, appropriate payment levels, efficient coverage
 determination systems, patient access to medical technologies, and a
 strong intellectual property system to support technology research and
 development and promote equitable access to medical devices
- Promotion of, and support for, principles of ethical conduct and practices in the marketing and distribution of medical technology products
- Liaison with other international bodies such as patient associations and professional societies, and

¹ "Medical technology" is used here to mean medical devices, medical equipment and diagnostic products. This term does not include pharmaceuticals or vaccines.



 Support for, and/or liaison with, international collaborative forums that can advance the GMTA Mission, such as the International Medical Device Regulators Forum (IMDRF), the Global Medical Device Nomenclature Agency (GMDN), Asian Harmonization Working Party (AHWP), Latin American Harmonization Working Party (LAHWP), Health Technology Assessment International (HTAi), and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Membership

(a) Full members

- National medical technology associations which are formally constituted organisations comprised of companies which manufacture or supply medical technology
- Regional medical technology associations which are formally constituted organisations comprised of national associations and/or companies which manufacture or supply medical technology
- Associations from the same national or regional area which are formally constituted organisations comprised of national associations and/or companies from a specialist industry sector (eg. devices, imaging, diagnostics)

(b) Associate members

 Formally constituted organisations which provide business representation at a national level and which provide support to the medical technology industry but which are not specialist medical technology associations (eg medical device committees of national chambers of commerce)

(c) Affiliate members

• Formally constituted organisations that are not full members but which support the operations of the industry (eg. GS1 Healthcare).



Membership criteria

(a) Full members

The criteria for full membership include:

- Each member association must have a code of business practices consistent with the GMTA objective of supporting principles of ethical conduct and practices in the marketing and distribution of medical technology products
- The member association must be representative of the medical technology industry in its territory by virtue of the number of members, diversity of members, and period for which it has been established
- Agreement to accept and abide by GMTA's governance framework.

(b) Associate members

The criteria for associate membership include:

Agreement to accept and abide by GMTA's governance framework.

(c) Affiliate members

The criteria for affiliate membership include:

Agreement to accept and abide by GMTA's governance framework.

A potential member must submit a formal application in writing to the co-chairs of GMTA (see footnote 2) who will determine the eligibility of the applicant. The members of GMTA will formally accept or reject the application at the next GMTA meeting following submission of the application.

Policy development

The following process applies for development and adherence to policy positions of GMTA.



Any GMTA member may present a draft policy paper for consideration by GMTA members. The paper should define the issue, provide background and present recommendations for GMTA consideration.

If the member wants the paper to be considered for discussion at the next GMTA meeting, the paper must be distributed at least 30 days in advance to allow members to consult their members. The paper should be sent to the current chair² of the GMTA for immediate distribution to the entire membership. The paper will be discussed at the meeting, with a timetable established for decision making. The sponsor must also indicate how the proposal would be used – e.g., for a specific upcoming meeting of an international organization, for general advocacy with third parties, or for internal GMTA use.

Decision Making

The members of GMTA have agreed to an opt-in process for decision-making, in which a GMTA member must indicate to the GMTA chair that it is prepared to accept a proposal on behalf of the member association.

After a proposal is debated and, if needed, revised, the chair or the proponent may solicit each member's support. A member may, at that time, indicate: (a) support; (b) non-support; (c) still considering. If five or more GMTA members³, with broad representation across GMTA geographies indicate their support – and no sustained opposition – then the GMTA logo may be affixed to the proposal, and the document then becomes an official GMTA document.

If the GMTA approves a particular policy proposal, any members that could not initially support a proposal could opt-in at a later date. That is, those GMTA members in the (b) or (c) categories could indicate support when their membership has given approval.

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²The chair currently alternates between AdvaMed and Eucomed, with each association chairing GMTA for six months with AdvaMed from March to October, and Eucomed from October to the following March.

³ One of the main purposes of the GMTA is to reflect the medical technology industry's views on a global basis. In that respect, associations in the GMTA should have members that operate internationally and not sell just in their respective home country markets.



Use of GMTA name and logo

Except as provided in this clause, no individual member of GMTA may use the GMTA logo or name or purport to represent GMTA. The logo and name may only be used on material reflecting the consensus position of GMTA members (as outlined in the previous paragraph), and to represent collective GMTA views and advocacy as agreed by GMTA members. A full member may use the logo and name on its website with a link to the GMTA website, to denote membership of GMTA. If the member ceases to be a member of GMTA it must immediately remove the logo, name and link to the GMTA website.