

JOINT STATEMENT ON GLOBAL HARMONIZATION OF ETHICAL BUSINESS PRINCIPLES IN MEDICAL TECHNOLOGY

3rd May 2018

Background

The Global Medical Technology Alliance (GMTA) member associations represent companies that develop, produce, manufacture and market the medical devices, diagnostic products and digital health technologies that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our represented companies produce nearly 85 percent of the health care technology purchased and utilized annually around the world. Our companies range from the largest to the smallest innovators and bring medical technology to patients around the world in every setting.

GMTA member associations consider it their mission to advance compliance and ethical business practices, and associations are committed to facilitating ethical interactions between companies, third party distributors, and healthcare professionals (HCPs) and healthcare organizations (HCOs) globally in order to promote innovation and increase patient access to advanced medical technology.

As healthcare and medical technology innovation extends beyond national and cultural boundaries, there is a growing need to promote internationally a harmonized environment of ethical business conduct among manufacturers, distributors, HCPs and HCOs. As stated in the 2011 Global Statement on Ethical Interactions Between Medical Technology Companies and Healthcare Professionals, signed by many MedTech industry associations around the world, these associations share common goals to encourage adherence to an agreed set of ethical business principles. In this statement, we pledge to work together to achieve those goals on a global basis. This joint statement is a foundational document that renews our joint commitment and expresses further commitments to advance together.

Joint Statement

1. We will continue to jointly assist our member companies to implement ethical business practices and to collaborate around the world to promote high ethical standards in the global medical technology community.
2. We embrace a shared understanding of the importance of striving toward global and harmonized ethical business practices. We acknowledge and express our commitment to making ethical business practices a priority and upholding the following principles, which we agree are essential elements of an effective medical technology code of ethics:
 - Industry Codes aim at guiding the necessary interactions between MedTech industry and Healthcare Professionals. These Codes are key to supporting the development and research of innovative technologies as well as ensuring safe and effective use of these technologies, ultimately for the benefit of the patient.
 - Industry Codes do not take the place of legal requirements; companies must adhere to applicable international, national and local laws and regulations.
 - Companies should, at all times, consider the image and perception of the medical technology industry that will be projected to the public when interacting with Healthcare Professionals and Healthcare Organizations.

- High level principles act to underpin the ethics of any industry code. These principles may include:
 - Integrity – dealing honestly, truthfully and fairly with all parties.
 - Independence – medical decisions should be in the best interest of the patient, and MedTech companies should not influence these decisions through undue or improper advantages.
 - Appropriateness – arrangements conform to proper commercial standards and are free from corrupt practices.
 - Transparency & Documentation – Companies shall document and be open and transparent regarding relationships between the parties.
 - Advancement – ensuring that relationships are intended to advance medical technology, innovation and patient care

- Key interactions of the Companies with HCPs and HCOs should be addressed in Codes of Ethics. For the MedTech industry the following interactions are:
 - Consulting Arrangements: Under specific conditions, Companies may engage HCPs to provide genuine services that support research and development but may not engage HCPs as a means of inappropriate inducement. Payment for these services should be at fair market value and appropriately documented.
 - Third Party Educational Events: Under specific conditions, Companies may support bona fide independent, educational, scientific or policy-making conferences promoting scientific knowledge, medical advancement and assist in the delivery of effective healthcare as long as they are not used as a means of inappropriate inducement.
 - Company-Organized Training and Educational Events: Under specific conditions, Companies may provide education and training to HCPs on product (and services) specific technology deployment, use and application to facilitate the safe and effective use of medical technologies, and these programs should be conducted in venues that are conducive to learning and convenient for attendees. When necessary, reasonable travel and lodging costs may be provided, as well as reasonably priced meals as a part of these programs.
 - Sales and Promotional Meetings: Under specific conditions, Companies may organize legitimate sales and promotional meetings with HCPs.
 - Educational and Promotional Items: Under specific conditions, Educational and Promotional Items may be provided as long as they benefit patients or serve a genuine educational function for HCPs.
 - Entertainment: Entertainment such as recreational activities, sporting events and cultural or artistic activities should never be provided directly or indirectly to HCPs by Companies.
 - Charitable Donations, Research Grants, and Educational Grants: Under specific conditions, Companies may provide support to organizations for bona fide, legitimate research, education, and charitable missions.
 - Demonstration and Evaluation Products: Under specific conditions, Companies may provide reasonable quantities of medical technology products and equipment to HCPs at no charge for evaluation and demonstration purposes, provided that such products are not given or intended as an inappropriate inducement.
 - Ensuring Effective Implementation: For codes to be meaningful, they must be effective, not solely paper commitments. Companies should formulate appropriate policies and procedures to foster compliance with the Code of Ethics by employees and third-party intermediaries. Associations should give consideration as to how to support their members in this regard.

- Third Party Sales and Marketing Intermediaries (SMIs): Third Party SMIs must abide by all local laws and Codes of Practice and comply with all applicable and ethical principles and standards contained in the GMTA members' individual Codes of Ethics.

3.To advance global ethical standards embodying these principles, we will explore the formation of a Global Network of Compliance Professionals drawn from our member companies and representatives from GMTA member associations in other countries. To ensure that codes of ethics address the latest trends in the medical technology industry, we will explore ways to address new areas of compliance risk, such as relations with third-party intermediaries, new business models and the evolution beyond HCPs as the primary purchasers of medical technology (e.g. global buyers, government purchasers and insurance companies).

Agreed by the Global Medical Technology Alliance
www.globalmedicaltechnologyalliance.org