# STAGO CODE OF BUSINESS ETHICS

Version: November 2022

# STAGO GROUP CODE OF BUSINESS ETHICS

## PRESIDENT'S MESSAGE

The successful business operation and reputation of STAGO are built upon the principles of fair dealing and the ethical conduct of our employees, managers, directors and officers (hereafter referred as "Employees").

Our reputation for integrity and excellence requires careful observance of the spirit and letter of all applicable laws and regulations, as well as a scrupulous regard for the highest standards of ethics.

The continued success of STAGO is dependent upon our customers' trust and we are dedicated to preserving that trust. Each of us owe a duty to STAGO and its customers to act in a way that will merit the continued trust and confidence of the public.

STAGO will comply with all applicable laws and regulations and expects all its directors, officers, and Employees to conduct business in accordance with the letter, spirit, and intent of all relevant laws and to refrain from any illegal, dishonest, or unethical conduct.

In addition to this Code of Business Ethics which sets at a global level the fundamental principles of integrity, fairness and honesty to be applied worldwide by all Employees of the STAGO group, local internal policies are implemented in every STAGO entity to maintain a safe and secure work environment for its Employees.

Compliance with this policy of business ethics is the responsibility of every STAGO Employee.

An Ethics Committee is created at STAGO INTERNATIONAL's headquarters in Asnières, France. Compliance Officers may also be designated, when relevant, at the level of the different STAGO entities.

We recognize the hard work and constant attention needed to maintain high ethical standards in the workplace.

**We believe that it is the commitment of each individual Employee to this Code of Business ethics which will demonstrate STAGO's dedication to integrity, professionalism, quality, respect and honesty.**

# TABLE OF CONTENTS

# INTRODUCTION

This Code of Business Ethics (hereinafter the “Code”) applies to all Employees, including all officers, directors and managers, of STAGO International, and of all its affiliates around the world (“STAGO”).

This Code is completed by country-specific supplements, among other to describe the Code compliance procedure applicable in each country.

In addition, this Code applies, where incorporated by way of express contractual agreement, to STAGO’s vendors, distributors, suppliers, customers and clients (collectively referred to as “Business Partners”).

This Code of Business Ethics is not intended to supplant nor supersede (i) country-specific internal applicable rules, nor (ii) any national laws or regulations that may impose particular requirements upon STAGO Employees or Business Partners who engage in certain activities in those countries.

All STAGO Employees should independently ascertain that their interactions with Business Partners comply with all current national and local laws and regulations.

This Code represents an act of self-discipline. STAGO Employees should also acknowledge that the Code is to be applied in the spirit, as well as in the letter.

STAGO Employees, directors and officers are expected to understand and comply with STAGO’s Code of Business Ethics. STAGO Employees, directors and officers should read this Code, be sure to understand its requirements, and to ask questions as necessary.

Ultimately, STAGO’s ability to enforce the Code is based in large part on the willingness of STAGO Employees to follow the Code’s requirements and on their willingness to report alleged violations of the Code.

**Each STAGO Employee, who learns of or suspects a Code violation is invited to report such alleged Code violation**. STAGO Employees who report a concern in good faith about an alleged Code violation are protected from any form of retaliation. All reports will be handled with seriousness and with discretion.

**This Code of Business Ethics is given to each Employee when he/she is hired by STAGO.**

STAGO has the right to amend, modify or revise this Code of Business Ethics in accordance with applicable laws**.**

# 1. MAINTAINING A SECURE WORK ENVIRONMENT

## Respect and Non-discrimination

STAGO cultivates respect for humans and their diversity. STAGO is committed to an environment of equality and advancement opportunity for all qualified individuals. The diversity of our Employees is a strength that we will continue to promote and support throughout the STAGO group.

STAGO will not tolerate any discrimination whether based on sex, age, social origin, religion, ethnic origin, marital status, nationality, sexual orientation, political opinion or disability.

## Respect of Human Rights and Prevention of Modern Slavery and Human Trafficking

STAGO is committed to respecting and promoting human rights in its activities and business relations as well as taking steps to ensure that modern slavery and human trafficking is not taking place in its business and supply chains. In doing so it takes account of the Universal Declaration of Human Rights, the United Nations Guiding Principles on Business, Human Rights and the fundamental conventions of the International Labor Organization and relevant local laws on modern slavery and human trafficking. STAGO has the responsibility to ensure that its employees work in conditions that are ethical and non-hazardous and that its business partners do not use or support any form of forced labor or child labor.

## Harassment and violence Free Workplace

STAGO is committed to providing a work environment that is free from violence and harassment in any form.

Accordingly, STAGO prohibits any member of management and any employee from making unwelcome and/or unsolicited sexual advances. STAGO also prohibits any conduct that creates an offensive working environment.

STAGO will not tolerate workplace violence in any form including threatening behaviours, assaults, harassment, intimidation, bullying, taunting, constant teasing, or any other conduct that leads to violence in the workplace.

## Safety and Security

STAGO strives to provide a safe and healthy work environment for all Employees. Employees must comply with all STAGO safety and health requirements, whether established by management or by local laws. Accordingly, Employees are expected: to conduct themselves in a safe manner; use good judgment and common sense in matters of safety; observe all posted safety rules; and follow all safety regulations. Please note STAGO is a smoke free environment. Smoking and vaping (using electronic cigarettes) is permitted in designated areas only.

# 2. CORPORATE INFORMATION

## Asset Protection

STAGO's assets include, among other things, customer and employee private information, network operations and facilities, computer systems and passwords, security procedures, company facilities and their locations, technical and marketing research data, product development information, business plans and strategies, other business confidential information, and STAGO property.

STAGO Employees handling these assets in the course of their employment must keep such information safe and secure from theft, destruction, and loss. Accordingly, STAGO Employees must take all appropriate precautions to protect these STAGO assets, systems and premises. Such precautions include the proper handling of assets, properly securing these assets, and ensuring that visitors are properly escorted.

## Intellectual Property

Intellectual property includes information protected by STAGO's trademarks, patents or copyrights, the use of which is restricted by applicable intellectual property laws. To safeguard STAGO's intellectual property from illegal copying or other misuse, STAGO Employees must ensure that intellectual property is properly labelled with or identified by trademark, service mark or copyright symbols.

If a STAGO Employee is unsure whether or what protection is necessary or appropriate for a particular item, or he/she believes disclosure or use by a third party is improper, such employee must contact the Legal Department.

## Proper Use of Others' Intellectual Property

STAGO Employees must respect the proprietary rights of others by complying with all applicable laws and agreements that protect the intellectual property rights of others, including all business providers, competitors or customers. Unless a STAGO Employee obtains the intellectual property owner's specific prior consent, such employee may not copy, distribute, display, perform, or modify third-party copyrighted materials, or conduct peer-to-peer or other file sharing of copyrighted materials. A work may be protected by a copyright even if there is no notice on the work.

## Protecting STAGO's Reputation

STAGO's reputation as a company is a key asset. STAGO Employees are responsible for protecting this valuable asset. Use of the company brand and logo must adhere to approved corporate identity specifications. Unless a STAGO Employee receives prior approval from its management, such Employee may never suggest that she/he is speaking on behalf of STAGO when presenting her/his personal views at community, professional or cultural functions, or on the Internet.

## Protecting STAGO's Confidential Information

STAGO expects undivided loyalty to the interests of the company, including protection of the company's trade secrets and its private and confidential Business Partner information. "Confidential information" refers to all non-public information, in any form, emanating at any time from Stago International, its affiliates, any Stago Business Partner, or any other person that relates in any way to the business or operations of STAGO.

Confidential information includes STAGO information that is labelled "confidential" as well as information that is not labelled as "confidential" but by its nature should be reasonably construed as being confidential to STAGO. Examples include STAGO business plans, operations plans, strategy plans, financial data, product and service information, Business Partner data, sales data, company reports and, insofar as permitted by national local laws, personnel information, contracts and related information.

Employees must preserve and protect trade secrets and Confidential Information including all physical and non-physical forms of that information. Employees may not share such privileged information with people outside of the company or discuss such matters with other STAGO Employees unless such Employees have a clear business need for the information. Any inquiries from outside sources that claim to have a "need to know" should be referred to a member of the STAGO Senior Management Team. Employees who terminate employment with STAGO are obligated to continue to maintain the confidentiality of proprietary information obtained or developed while employed by STAGO.

## Company Records

STAGO strives to maintain accurate business records and to protect company funds and assets. STAGO is committed to maintaining a system of internal controls that ensures compliance with applicable laws and regulations, and that promotes the full, accurate and timely disclosure of information in STAGO's reporting to: internal management, senior management of STAGO parent organizations, external auditors, and external parties including regulatory and governmental authorities.

It is the responsibility of all STAGO Employees to ensure that STAGO's records including documents, electronic information, voicemails, and any other form of media are properly managed, handled, stored and, where applicable, destroyed as appropriate in accordance with retention guidelines. In the normal course of performing the job, Employees will likely receive, create, and transact with company records. Employees are required to properly maintain these records, to ensure that they are properly filed, labelled, and that access is appropriately limited to those with a business need to access the records.

## Financial Reporting

STAGO must maintain accurate financial records of its business transactions and must ensure proper reporting to auditors of its financial results. Financial records could include company-wide financial records, specific business unit transactions, as well as individual travel and expense reimbursement invoices. These and many other forms of financial information must be managed properly and must be appropriately presented when requested. To the extent that Employees create, handle, or are otherwise involved in the handling of financial records they must ensure that the records are accurate, properly maintained, and appropriately represented in internal and/or external financial disclosures.

## Truth of Statements in Advertising

STAGO expects that all business communication of or by STAGO will be factual, in good taste, free from false or exaggerated claims or statements, and otherwise legal. STAGO Employees who, by virtue of their roles or function, communicate about STAGO products must comply fully with any and all applicable laws and regulations that relate to such communications. STAGO Employees have the responsibility to know, to become aware of, to inquire, and to regularly update themselves about the legal requirements that apply, if any, to the business communications made on behalf of STAGO. STAGO Employees are encouraged to speak with their manager about such matters so as to: (1) confirm whether any specific laws apply to the business communications by the STAGO employee in connection with his/her position; and (2) to the extent such laws do apply, to confirm the manner of compliance with such laws.

## Data Protection/Data privacy

STAGO and its affiliates, agents, Employees and/or other representatives are required to comply with all applicable data protection laws, legal privacy, medical or general confidentiality requirements which apply to any STAGO activity or its representatives relating to an identified or identifiable natural person. This may include patient information but also information relating to STAGO Employees, Business Partners, suppliers, agents, distributors and any other persons. All STAGO Employees must comply with the applicable data protection laws and STAGO data privacy policy or policies when dealing in any way with personal data. The breach of data protection laws may entail financial sanctions.

These obligations may vary depending on applicable local and national laws, particularly regarding confidentiality of such information. Specific guidance on data privacy should be submitted to the Legal Department if applicable.

# 3. COMPLIANCE AND INTEGRITY IN THE MARKETPLACE

STAGO's business operations are highly regulated. As a company working in the Health Industry, STAGO must respect all applicable laws but must also commit to the highest quality standards. Health Authorities worldwide monitor STAGO activities closely. Strict compliance with all Health Authority requirements, as well as with the requirements of other regulators at all levels of government, is obligatory.

STAGO strives to conduct business with Business Partners and competitors with complete honesty and integrity. STAGO expects Employees to serve Business Partners and contend with competitors in a professional and ethical manner.

## Relations with Suppliers/Business Partners

Buying decisions must always be based on competitive price, quality, value, and delivery or on specific selection criteria listed in invitations for bids. STAGO expects Employees to have friendly relations with suppliers, consultants, and other Business Partners;

STAGO Employees must be open, honest, business-like and completely ethical. Confidential information, such as bids submitted to STAGO in connection with the purchase of equipment, supplies and services must be maintained in strictest confidence in order to avoid giving or removing any competitive advantage with respect to any of several suppliers. Disclosure of such information is unethical even if STAGO appears to be benefiting from such disclosure.

## Gifts and Entertainment

To avoid the appearance of impropriety, it is important that STAGO Employees refrain from offering and decline any gifts from Suppliers or Business Partners which would raise even the slightest doubt of improper influence. STAGO Employees occasionally may provide modest gifts to Business Partners, but these should be modest in value and in accordance with the applicable country-specific requirements imposed by STAGO affiliates and the laws and regulations applicable where the Business Partner is licensed to practice. A “Gift” refers to the transfer of any item of value including goods and services without compensation.

Under no circumstances should cash or cash equivalents (e.g. tickets to sporting events) be accepted as a business courtesy or gratuity.

STAGO Employees entertaining Business Partners must always have a legitimate business purpose. STAGO prohibits entertainment activities that compromise the business judgment, impartiality or loyalty of Employees or Business Partners.

When Business Partners are Healthcare Professionals, entertainment or gifts may be prohibited or very regulated in certain jurisdictions ( *Please refer to the Section Relations with Healthcare Professionals below )*

STAGO Employees may accept a reasonable level of entertainment from Business Partners so long as the entertainment meets any additional requirements imposed by the STAGO affiliate for whom they work.

Additionally, STAGO Employees must refrain from offering and decline:

- Any entertainment offered as part of an agreement to do, or not to do, something in return for the activity;
- Any entertainment offered that might compromise STAGO’s reputation or ethical standards; and
- Participating in any activity the employee knows or should know will cause the party offering the entertainment to violate any law, rule, regulation or the ethical standards of their own employer.

## Confidentiality of Business Partner Information

From time to time, STAGO may enter and be bound to various Non-Disclosure Agreements (NDAs) with one or more Business Partners. Under the terms of such NDAs, Business Partners may share with STAGO Employees certain of their proprietary, privileged and/or business confidential information for the purposes of a business transaction, while requiring STAGO Employees who have access to such information to maintain confidentiality of the information. STAGO Employees are required to hold such Business Partner information diligently and in strict accordance with the terms of the corresponding NDAs. STAGO Employees are encouraged to speak to their manager to the extent that they have any questions about the proper use of, as well as any concerns associated with, Business Partner information.

## Respect for free competition

**STAGO is committed to respect free competition and to comply with antitrust legislation in all markets in which it operates.**

Violation of laws and regulations designed to promote competition and free enterprise has serious consequences for the Company and for individuals. Below are some examples of activities with important antitrust implications which are strictly forbidden:

- *Agreeing with competitors to fix prices or other terms of sale.*
- *Boycotting or otherwise refusing to deal with certain suppliers or customers.*
- *Dividing sales opportunities with competitors by territory or product line.*
- *Agreeing with distributors on resale pricing or imposing to distributors prices or discount for their resale.*
- *Price discrimination.*
- *Pricing to drive a competitor out of business.*
- *Disparaging, misrepresenting, or harassing a competitor.*

Antitrust issues may require legal analyses which are very complex. Any questions regarding the propriety of possible actions should be directed to the General Counsel or local in house Legal counsel if applicable.

The following points are given as examples:

**Basic Do's and Don'ts:**

Don't AGREE with STAGO's competitors or anyone else outside of STAGO:

- To fix prices or conditions of sales of STAGO products.
- To limit STAGO production, agree production quotas, or otherwise limit the supply, either geographically or by class of customer.
- To blacklist or boycott customers, competitors or suppliers.
- To limit or control STAGO investments or technical developments in the market.

DON'T DISCUSS OR EXCHANGE INFORMATION with STAGO competitors on any subject relating to the issues mentioned above.

In other words, DO NOT have formal or informal discussions with STAGO's competitors or anyone else outside of STAGO on the following:

- Individual company prices, price changes, terms of sales, etc.
- Industry pricing policies, price levels, changes, etc.
- Price differentials, price mark-ups, discounts, allowances, credit terms.
- Costs of production or distribution, cost accounting formulas, methods of computing costs.
- Individual company figures on sources of supply, costs, production, inventories, sales, etc.
- Information as to future plans concerning technology, investments, or the design, production, distribution or marketing of particular products or services including proposed territories or customers.
- Matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from market.

Failure to respect these basic rules may lead to very heavy fines for STAGO, (for example, in the European Union, such fines can reach up to 10 % of total STAGO turnover) and may also

lead to criminal sanctions, including jail sentences, for the individuals who did not respect such rules.

## Conflicts of Interest

STAGO strives to encourage and promote objectivity in business decision-making. STAGO Employees have a duty of loyalty to the organization and are expected to make business decisions with STAGO's best interests in mind and to exercise business judgment independent of external influences such as personal financial interests, external business relationships, outside employment, and familial relationships. Avoiding conflicts of interest is critical to maintaining integrity and honesty in the way STAGO conducts its business.

Potential conflicts of interest can arise in any of the following circumstances - when a STAGO employee:

- Accepts gifts from a potential Business Partner;
- Accepts additional employment by another company;
- Has a financial interest in a Business Partner or competitor;
- Places business with any firm in which the employee or an immediate family member of an employee has a financial interest; or
- Inappropriately communicates with a competitor.

STAGO prohibits Employees from using company property, information, resources or position for personal gain or to compete with STAGO in any way. STAGO also prohibits Employees from taking or diverting to any third party any business opportunity that is discovered through the use of any of STAGO's property, information or resources.

## Relations with Healthcare Professionals

STAGO's relationships with Healthcare Professionals are heavily regulated in most jurisdictions and strictly enforced by STAGO as well as by various regulatory or governmental agencies.

Generally speaking, a Healthcare Professional is any individual or entity, directly or indirectly involved in the delivery of healthcare that can purchase, prescribe, lease, recommend, or use STAGO products. The rules that govern the payment of anything of value such as gifts, meals, entertainment, honoraria, sponsored trips or grants, are complex and differ across countries.

STAGO Employees must read and comply with the applicable rules for each country which are indicated in the local supplement of the STAGO Code of Business Ethics.

The consequence for failing to comply with these rules can result in significant monetary and sometimes criminal penalties. If, by virtue of their role at STAGO, STAGO Employees are in contact with Healthcare Professionals, it is their duty to know the applicable laws and STAGO policies that pertain to dealing with Healthcare professionals and to strictly adhere to such rules. More information on these regulations can be found under the local STAGO current policies for Health Care Professionals.

## Customs and international trade controls

STAGO Employees, commit to comply with and to ensure that their Intermediaries and Business Partners comply with all enforceable local and international regulations applicable in terms of customs as well as to respect potential economic and financial restrictions applicable in terms of war zones and/or embargos.

States and international organizations draw up and update lists mentioning persons and states which are subject to economic and financial sanctions:

- Office of Foreign Assets Control ("OFAC"), the American Treasury department draws up the "Specially Designated Nationals List" ("SDN List"), which can be accessed on: https://www.treasury.gov/ofac/downloads/sdnlist.pdf;
- Bureau of Industry and Security ("BIS"), the American Trade Department draws up the "Denied Person List" ("DPL"), the "Unverified List" and the "Entity List", which can be accessed on https://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern ;
- France draws up a synthetic table of the existing restrictive measures per country which can be accessed on: https://www.tresor.economie.gouv.fr/services-aux-entreprises/sanctions-economiques;
- The European Union publishes on its website a consolidated list of persons, entities and organizations which are subject to sanctions. This list can be accessed on: https://data.europa.eu/data/datasets/consolidated-list-of-persons-groups-and-entities-subject-to-eu-financial-sanctions?locale=en

STAGO Employees may not enter into an agreement with any person, State, entity, or state entity which is subject to international restrictions or sanctions.

Such rules are complex and are different for each country. When in doubt as regards to the beneficiary of a transaction, STAGO Employees, must consult the Legal department before entering or executing an agreement.

In case of breach of the abovementioned rules, STAGO and/or its Employees, expose themselves to heavy economic or financial sanctions as well as severe criminal sanctions (fines and imprisonment sentences).

STAGO Employees must also comply with laws and regulations which have an impact on technology, software, financial transactions, import and export of goods and services, as well as cross-border information exchanges including exchanges by electronic means.

# 4. INTEGRITY IN GOVERNMENT RELATIONSHIPS AND ANTI - BRIBERY

STAGO is committed to doing business with the government in every country in a manner that is fully compliant with any and all applicable laws and regulations. STAGO Employees must be aware of and adhere to the laws and regulations that pertain to doing business with the government. These laws and regulations generally have three purposes: to obtain the best possible products and services at the best value; to promote full and open competition based on specifications and evaluations criteria that allow interested suppliers to respond appropriately; and to eliminate waste, fraud, and abuse.

STAGO Employees must comply with all rules established by government officials for procuring products and services. This includes, but is not limited to, dealing with government officials in an environment of openness and under circumstances that avoid any perception of concealment, the appearance of impropriety, or any actual or potential conflict of interest.

## Contacts with Government Officials

STAGO strives to develop and maintain good relationships and effective communication with all levels of the government. Contacts with government officials must never be conducted in a way that would be in violation of applicable laws and regulations or could cast doubt on STAGO's integrity. All contacts on STAGO's behalf with government officials to influence legislation, regulatory policy or rulemaking must be performed under the direction of the STAGO Senior Management Team. This includes the hiring of outside law firms or public affairs firms to make such contacts on behalf of STAGO. Activities of certain STAGO Employees with government entities may be subject to lobbying and gift laws and accordingly should be done in consultation with the STAGO Senior Management Team before there is any contact with public officials in connection with such activities.

## Entertainment or Gifts for Government Officials

STAGO Employees are prohibited from offering any gifts, gratuities or non-business related entertainment for the personal use of Employees or officials of any government agency or elected officials to whom STAGO is seeking to sell, is selling goods or services, or is lobbying. The only exceptions to this rule are company sanctioned gifts of a token nature with STAGO's company logo. These gifts typically include coffee mugs, pens, awards, plaques, certificates and bags.

For more details see the local country applicable procedure and relevant laws.

## Anti-bribery

STAGO is committed to conducting its activities free from the influence of bribery and corruption. STAGO Employees must observe the highest ethical standards when conducting business.

In France, as well as in most countries in the world ( FCPA in the US and UK Bribery Act for the UK) , anti-bribery legislations exist which prohibit STAGO either offering or providing anything of value to persons who are employed by either government or private sector employers or who act for them, e.g. as their agents, for the purpose of inducing them to show favour to STAGO or to show disfavour to anyone else in relation to the employer's affairs or business, or to act improperly by failing to act in good faith or impartially when carrying out their activities for the employer or principal, or by failing to act consistently with any position of trust they may hold. STAGO is also prohibited from providing anything of value as a reward for any such behaviour.

STAGO is also responsible for (and prohibited from) anything of value being passed on to an official, or to an employee or agent of a customer, or of a prospective customer, via an intermediary (i.e. some other person or entity which could be a company or even a hospital or laboratory) in the circumstances set out in the preceding paragraph.
This prohibition also applies to situations where the item of value is not provided direct to the official, or to the employee or agent of the customer, but is instead provided to or for the benefit of another person or entity, which might include a medical institution or laboratory.

In the case of STAGO, relevant officials, Employees or agents in this context are likely to include (but not be limited to) Healthcare Professionals and hospital personnel (e.g. hospital laboratory personnel or procurement specialists) who are working in government hospitals as well as in the private, non-state operated healthcare sector, e.g. hospitals working for private medical insurers, and consultants in private practice. Anything of value or any advantage that is provided to relevant officials or to Employees or agents must be in full compliance with the applicable laws and this Code.

These anti - bribery legislations are actively enforced and individuals are very often the target for prosecution by the relevant authorities in each country.

Some of these anti - bribery laws - in particular the FCPA for the US and the UK Bribery Act in the UK- and the French law SAPIN II may also have extraterritorial effect if all conditions are met.

## 5. COMPLIANCE AND EXPRESSING CONCERNS

Failure to comply with this Code of Ethics may result in disciplinary action.

The STAGO Group Ethics Committee, in liaison with the local compliance officers, coordinate the programs on ethics and compliance. Their role is to help STAGO Employees in resolving any question or interpretation of STAGO's Code of Ethics and other related matters. They also help the managers in managing any compliance issues they might face.

STAGO Employees are incited to speak to their local compliance officer, or to STAGO's Group Ethics Committee, about any unethical behaviour that they might know about, or when such Employees have doubts about the best course of action to follow in a given situation, in order to allow STAGO to resolve the problem.

With respect to the whistleblowing of a known or suspected infringement of this Code of Ethics, no sanction or retaliatory action will be taken against the whistleblower or against any facilitator or any other natural or legal person having a connection with the whistleblower who based his/her whistleblowing on the genuine belief that a STAGO Employee behaved in a way that constitutes an infringement of this Code of Ethics. In addition, retaliation is prohibited against anyone who cooperates in an enquiry into an alleged infringement of this Code.

Any person who takes (or attempts to take) retaliatory actions against a STAGO Employee, any facilitator or any other natural or legal person having a connection with this Employee, who based her/ his whistleblowing on a genuine belief, exposed himself/herself to any appropriate disciplinary action. Furthermore, these retaliatory actions would be considered null and void.

If a STAGO Employee uses the whistleblowing mechanism while she/he knows she/he is using it for a false alert or for an alert that is solely meant to be detrimental to someone else, the STAGO Employee involved will expose herself/ himself to disciplinary actions.

**We invite you to carefully read the procedure about the whistleblowing mechanism included in your local supplement to this Code of Ethics in order: to identify the members of the STAGO's Group Ethics Committee and your local compliance officer; to have a detailed description of the procedure to follow when you are willing to use the whistleblowing mechanism.**

# TCOAG IRELAND CODE OF BUSINESS ETHICS

Local supplement for Ireland

Version: July 2023

This addendum complements the STAGO Group's Code of Ethics (hereinafter referred to as the "**Group Code of Ethics**") and provides details about the implementation of the Group Code of Ethics in Ireland (hereinafter referred to as the "**Irish Code of Ethics**").

The Group Code of Ethics and the Irish Code of Ethics combine to form a single code of ethics (hereinafter referred to as the "**Code of Ethics**") that applies to:

- all employees of Tcoag Ireland Limited (hereinafter referred to as the "**Employee(s)**");

- business Partners (resellers, distributors, suppliers, customers, providers and, generally speaking, all STAGO Group including Tcoag co-contractors, whether these players operate in the public or private sector, hereinafter referred to as the "**Business Partner**" or the "**Business Partners**");

- intermediaries (sales agents, consultants, brokers, representatives and, generally speaking, all third parties acting as intermediaries in a business transaction on behalf of the STAGO Group including Tcoag, hereinafter referred to as the "**Intermediary**" or the "**business Intermediaries**");

- Tcoag Ireland.

In the event of difficulties interpreting the provisions of the Group Code of Ethics and those of the Irish Code of Ethics, Employees should consult STAGO's Legal Department.

All Tcoag Employees are required at all times to comply with Irish regulatory requirements and relevant codes applicable to their behaviour. In this regard the following requirements should be noted in particular:

## 1. LEGISLATION ON ANTI-CORRUPTION

The Criminal Justice (Corruption Offences) Act 2018 (the "Corruption Offences Act") is the principal legislation in Ireland which prohibits bribery and corruption in Ireland. The Corruption Offences Act establishes a number of offences which apply in both the private sector and public sector. All Tcoag Employees are subject to the Corruption Offences Act.

***Offences***

A number of offences under the Corruption Offences Act reference acting 'corruptly'. The Corruption Offences Act defines acting 'corruptly' as "*acting with an improper purpose personally or by influencing another person, whether by means of making a false or misleading statement, by means of withholding, concealing, altering or destroying a document or other information, or by any other means*". The phrase 'improper purpose' is not defined. Nevertheless, it can include, but is not limited to, behaviour which is illegal, dishonest or constitutes a breach of duty.

- *Active and passive corruption*

  It is an offence for a person (whether directly or indirectly) to corruptly (a), give, agree to give or offer, or (b) request, accept or obtain or agree to accept a gift, consideration or advantage, from / to any person, as an inducement to, or reward for, or otherwise on account of, any person doing any act, or making any omission, in relation to his or her office, employment, position or business.

- *Active and passive trading in influence*

  It is an offence to corruptly (whether directly or indirectly) offer, give or agree to give a gift, consideration or advantage in order to induce another person to exert an improper influence over an act of an official in relation to the office, employment, position or business (active trading in influence). It is also an offence to corruptly (whether directly or indirectly) request, accept, obtain or agree to accept or corruptly request, accept or obtain a gift consideration or advantage, for oneself or for any other person on account of promising or asserting the ability to improperly influence an official to do an act in relation to the office, employment, position or business of that official (passive trading in influence). It is immaterial whether or not the ability to exert any improper influence actually existed or whether it was exerted or if it led to the intended result.

- *Corruption in relation to office, employment, position or business*

  It is an offence for an Irish official, acting directly or indirectly, by himself or herself or with another person, to perform an act in relation to his or her office, employment, position or business for the purpose of corruptly obtaining a gift, consideration or advantage for himself or herself or for any other person. Further, an Irish official who uses confidential information obtained in the course of his or her office, employment, position or business for the purpose of corruptly obtaining a gift, consideration or advantage for himself or herself or for any other person shall be guilty of an offence.

- *Giving a gift, consideration or advantage that may be used to facilitate an offence*

  It is an offence for a person to give a gift, consideration or advantage to another person where the first-named person knows, or ought reasonably to know, that the gift, consideration or advantage, or a part of it, will be used to facilitate the commission of an offence under the Corruption Offences Act.

- *Creating or using a false document*

  It is an offence for a person, acting directly or indirectly, by himself or herself or with another person, to corruptly create or use a document that they know or believe to contain a statement that is false or misleading in a material way, with the intention of inducing another person to do an act in relation to the recipient's office, employment or business, in such a way that it prejudices the recipient. A document, for the purposes of this offence, broadly covers any record or written material (including in any electronic device) and includes copies of any such documents.

- *Intimidation*

  It is an offence for a person, acting directly or indirectly, by himself or herself or with another person, to threaten harm to another person with the intention of corruptly influencing that person or another person to do an act in relation to the person's office, employment, position or business.

- *Foreign Offences*

  The Corruption Offences Act also provides that if a corruption or bribery offence takes place outside Ireland, it may be prosecuted in Ireland if it is also an offence in that foreign jurisdiction and if the person committing the act is an Irish citizen, an Irish resident, an Irish official or an Irish company or body corporate.

- *Corporate Offences*

  Tcoag may also be guilty of a corruption or bribery offence under the Corruption Offences Act if the offence is committed by an officer or employee of Tcoag with the intention of obtaining or retaining business or an advantage for Tcoag. Tcoag Employees therefore expose Tcoag to criminal liability, as well as themselves, if the requirements of the Corruption Offences Act are not adhered to. In such cases, it is a defence for Tcoag to show that it took all reasonable steps and exercised all due diligence to avoid the relevant offence being committed.

- *Gifts & Advantages*

  Importantly, the Corruption Offences Act does not take the value or type of gift, consideration or advantage into account when determining if an offence has been committed. There is no minimum threshold under which a gift or advantage will be deemed not to constitute a bribe. Even small payments or benefits are prohibited if they are intended as bribes. Such gifts will fall within the scope of prohibited acts if provided "corruptly".

  A bribe can potentially be cash or its equivalent but it can also be anything which is of value to a person or someone connected to them (eg, a relative or friend) or an advantage. 'Anything of value' can include, but is not limited to, things such as cash and any payment or reimbursement in the form of, among others, promotion fees, sponsorship fees, consulting fees and commission fees. It also includes non-monetary benefits such as gifts, entertainment, favours, loans and loan guarantees, investment or business opportunities, the use of property or equipment, transportation, and the payment or reimbursement of debts.

  An 'advantage' does not have to be financial in nature and may include, for example, any form of gift, donation, job offer or preferential treatment. An advantage may also consist of facilitation payments.

  It is important to remember that an advantage does not have to actually be given or received to fall foul of the Corruption Offences Act. Regardless of whether a payment or anything of value is given, and regardless of whether the recipient of a payment or a thing of value takes any action in response to a promise or payment, the intention to give or receive an advantage is sufficient to fall foul of the law.

## 2. ENTERTAINMENT AND GIFTS

EU Regulation 2017/746 on in vitro diagnostic medical devices was transposed in Ireland by S.I. No. 256/2022 (In Vitro Diagnostic Medical Devices) Regulations 2022. These regulations revoke the previous Irish regulations implementing the IVDR's predecessor, Directive 98/79/EEC on in-vitro diagnostic medical devices (IVDD), and alongside S.I. No. 257/2022 - European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022, regulate the placing on the market and the putting into service of in vitro diagnostic medical devices in Ireland.

These laws do not contain any provisions regulating 'entertainment and gifts'. Accordingly, the provision of entertainment and gifts is covered by industry codes published by industry bodies of which Tcoag is a member.

## IMA Guidelines on Interactions with Healthcare Professionals

Tcoag is a member of the Irish Medtech Association (IMA) (formerly the Irish Medical Devices Associate (IMDA)). The IMA is a member association of MedTech Europe. The IMA adopted the Eucomed Guidelines on Interactions with Healthcare Professionals ("the **Eucomed Code**") and published the IMA Guidelines on Interactions with Healthcare Professionals – Guidance Document (the "**IMA Guidance Document**", appended hereto at Appendix 2). MedTech Europe published a new Code of Ethical Business Practice (the "**MedTech Europe Code**", appended hereto at Appendix 3) in March 2022[1] which replaces the Eucomed Code. While the MedTech Europe Code has not yet been implemented in Ireland, the IMA, as a member of MedTech Europe, obliges its members to abide by the new code.

Tcoag Employees should review the IMA Guidance Document as well as the MedTech Europe Code applicable at the time the proposed entertainment / gift is being considered.

Members occasionally may provide inexpensive, branded or non-branded items as gifts to healthcare professionals, if they are modest in value with a maximum value of thirty (30) Euros and in accordance with national and local laws, regulations and industry and professional codes where the healthcare professional is licensed to practise. Gifts must relate to the healthcare professional's practice, benefit patients or serve a genuine educational function. They must not be given in the form of cash or cash equivalents. Occasionally, educational items of greater value may be provided to a healthcare organisation, provided it serves a genuine educational function, is of benefit to patients and is not provided to a healthcare professional for personal use. Provision of educational items or gifts must not improperly promote Tcoag's products.

Where member-sponsored product training and education is being made available to healthcare practitioners, reasonably priced meals may be provided and any additional hospitality as may be appropriate for overnight stay. Any hospitality should be reasonable in value and subordinate in time and focus to the educational purpose of the training. Member companies may not pay or reimburse lodging expenses at top category or luxury hotels and accommodation or other services should not cover a period of stay beyond the duration of the event. Air travel may only be reimbursed at economy or standard class unless the flight time is longer than five (5) hours. It is not permitted for members to pay for meals, travel, accommodation or other expenses for spouses or guests of healthcare professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the meeting. Entertainment, which includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events and other leisure arrangements is not permitted and shall in any case respect the "Expense Report" policy. The event location should not become the main attraction of the event.

From 1 January, 2018, direct financial or in kind support may no longer be provided to healthcare professionals to cover costs of their attendance at third party organised educational events, with the exception of third party organised procedure training.

Educational Grants may be provided to support a third party organized educational event, namely with funds to support (i) the general running of a conference, (ii) Health Professionals attendance to the conference, and (iii) Faculty. It is important to have in mind that this support cannot be provided directly to Health Professionals.

---

[1] https://www.medtecheurope.org/wp-content/uploads/2017/06/medtech-europe-code-of-ethical-business-practice-2022.pdf

Sales and promotional meetings should as a general rule occur at or close to the healthcare professional's place of business. Members may pay for reasonably priced meals. Where plant tours or demonstrations of non-portable equipment are necessary, members may also pay for reasonable travel and accommodation costs of healthcare professionals. It is not permitted for members to pay for meals, travel, accommodation or other expenses for spouses or guests of healthcare professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

Tcoag Employees shall undertake to strictly adhere to the "Expense Report" policy on STAGO's Intranet site with regard to hospitality they may offer to Tcoag Business Partners and Intermediaries.

### Civil Service Code

The Irish Civil Service Code of Standards and Behaviour (the "Civil Service Code") sets out guidelines in relation to dealings with Government and public offices. In particular the Civil Service code states that:

*"Civil servants should not receive benefits of any kind from a third party which might reasonably be seen to compromise their personal judgement or integrity. The overriding concern is that the actions of civil servants be above suspicion and not give rise to any actual or potential conflict of interest, and that their dealings with commercial and other interests should bear the closest possible scrutiny."*

The Civil Service Code also states that cash, gift cheques or any vouchers that may be exchanged for cash may not be accepted by public servants regardless of the amount.

In relation to the entertainment of Government or public officials the Civil Service Code states that:

*"in their contacts with outside organisations or persons, every care must be taken by civil servants to ensure that their acceptance of hospitality does not influence them, and could not reasonably be seen to influence them, in discharging their official duties."*

### Ethics in Public Office Acts

The Ethics in Public Office Acts 1995 and 2001, prohibits the receipt of any gifts by office holders which are over €650 in value. **However, Tcoag prohibits all gifts to employees of public offices.**

This restriction extends to gifts to the spouse of an office holder, or the child of an office holder or his/her spouse.

## 3. DEALING WITH BUSINESS PARTNERS & INTERMEDIARIES AND ACCOUNTING

### Dealings with Business Partners

Tcoag shall select its Business Partners carefully and objectively, taking into account their reputation, the quality of their services and their commitment to act in compliance with current regulations and the highest ethical standards, including the Code of Ethics.

In this regard, Tcoag Employees shall undertake not to initiate business dealings or enter into a contract with a Business Partner, with the exception of contracts subject to the Irish Public Procurement framework (see below), without:

- first verifying their reputation, skills and activities using the Procedure available on Tcoag's Intranet site "Third Party Assessment Procedure";

- formalising through a written contract the terms and conditions of the business relationship and verifying that this contract includes the clauses listed in the "Third Party Assessment Procedure" referred to above.

The "Third Party Assessment Procedure" applies exclusively to all of Tcoag distributors, customers and first-tier suppliers.

Tcoag Employees shall undertake not to proceed with or accept payments made in breach of the "Third Party Assessment Procedure".

The provisions of this article as well as the "Third Party Assessment Procedure" do not apply to all contracts regulated by the Irish Public Procurement framework.

### Dealings with Intermediaries

Tcoag Employees shall undertake not to initiate business dealings with an Intermediary without first:

- verifying their reputation, skills and activities in accordance with the "Third Party Assessment Procedure"; available on Tcoag's Intranet site*;*

- formalising through a written contract the terms and conditions of the business relationship and verifying that this contract includes the clauses listed in the "Third Party Assessment Procedure".

Furthermore, Tcoag Employees shall undertake not to proceed with or accept payments made in breach of the "Third Party Assessment Procedure".

### Reliability and transparency of accounting entries

Tcoag prohibits the falsification of accounting entries or any other accounting or financial document.

Tcoag prohibits all of its management and Employees from making false or incomplete statements or statements likely to mislead any accountant or person in charge of operational auditing or internal control. This involves, for example, accurately identifying all gifts, benefits or hospitality.

## 4. PUBLIC PROCUREMENT

Public Procurement is the acquisition, whether under formal contract or not, of works, supplies and services by public bodies. Guidelines and 'circulars' addressed to public bodies in relation to Public Procurement Policies have been published by the Office of Government Procurement which are in line with EU Treaty principles and EU Directives on Public Procurement. Tcoag Employees should be aware of these guidelines at all times when dealing with public bodies.

It should be remembered that public bodies must adhere to these guidelines and no steps should be taken to attempt to avoid the necessary procedures.

On 28 March 2023, the Department of Public Expenditure, NDP Delivery and Reform published Circular 05/23 (the "**2023 Circular**"), which provides for a substantial increase in the revised threshold at which goods, services and works must be advertised on eTenders.

Particular regard should be had to the monetary thresholds in relation to public contracts. For contracts under €5,000 written and oral offers from one or more competitive supplier may be accepted. If a tender falls between €5,000 and the relevant threshold specified in the table below (**Table 1**), contracting authorities are only required to request **three** quotes (for services, supplies and goods) or **five** quotes (for works and works-related services) which can be done via an email / fax. If a contract is over the relevant threshold specified below, a formal tender document must be drawn up and advertised to prospective suppliers on the public website www.etenders.gov.ie. Contracting authorities are required to publish contract award notices for any contract award above €25,000 on completion of the award. This appears to include works and works-related services in addition to goods and services. Importantly, the 2023 Circular reiterates the requirement that a contract award notice must be published for "*any contract awarded under a Framework Agreement*" – regardless of the value of that call-off contract.

**Table 1**

| Type | Revised Thresholds (ex VAT) |
|---|---|
| Services/Goods | €50,000 |
| Works-related services | €50,000 |
| Works | €200,000 |
| Circular 40/02 notifications to Comptroller and Attorney General's Office | €25,000 |

Above these thresholds there are EU rules on Public Procurement which must be adhered for works, supplies and services by public bodies. Details in relation to same can be found here: https://www.gov.ie/en/news/fc9e9-revision-of-eu-thresholds/ .

## 5. COMPETITION LAW

Tcoag Employees must at all times act in a manner which does not contravene Irish Competition Law. The Competition Acts 2002 - 2022 (the "Competition Act") prohibit and render void "*all agreements between undertakings, decisions by associations of undertakings and concerted practices which have as their object or effect the prevention, restriction or distortion of competition in trade in any goods or services in the State or in any part of the State*". The Competition Act lists some specific types of behaviour which are expressly prohibited. These include agreements which:

- fix prices;
- limit or control production or markets;
- share markets or sources of supply;
- apply dissimilar conditions to equivalent transactions with other trading parties; or

- attach supplementary obligations to a commercial contract which have nothing to do with the subject of the contract (e.g. tying).

Furthermore, the Competition Act prohibits the abuse of a dominant position. It is important to recognise that it does not prohibit a dominant position - only its abuse. Examples of an abuse of a dominant position within the market could include:

- predatory pricing which involves deliberately setting prices below cost to drive competitors out of the market;
- exclusive dealing which involves imposing contractual obligations that restrict competitors' access to customers or suppliers;
- refusal to supply which relates to denying access to essential goods or services to competitors without valid justification;
- margin squeeze, which involves setting prices at such a level that competitors cannot viably compete in downstream markets; and
- abusive contractual terms, whereby a dominant undertaking imposes unfair or excessively restrictive terms on customers or suppliers.

The Competition Act also prohibits any breach of the competition rules of the European Union as contained in Articles 101 and 102 of the Treaty on the Functioning of the European Union.

A breach of the Competition Act may expose both Tcoag and its executives to criminal sanctions and civil actions for damages by 'victims' of anti-competitive behaviour in breach of the Competition Act.

The sanctions for breach of the Competition Act include the imposition of civil fines ranging from €10,000,000 to 10% of Tcoag's annual turnover.

The Competition Act (as a result of the enactment of the Competition (Amendment) Act 2022) also enforces significant fines that may be imposed by the courts in criminal proceedings for infringements of competition law (up to €50 million or 20% of an undertaking's turnover in the preceding financial year). Directors and managers are also liable to both fines and / or imprisonment of up to ten (10) years as well as personal civil liability.

## 6. WHISTLE-BLOWING MECHANISM

Pursuant to the Protected Disclosure Act 2014, as amended by the Protected Disclosures (Amendment) Act 2022 (together, and as may be amended from time to time, the "Act"), as well as the Code of Ethics, Tcoag Workers (as defined below in Appendix 4) are entitled to raise concerns within their workplace in relation to matters that are serious and of obvious concern to their workplace, amounting to relevant wrongdoings.

The whistleblowing mechanism is detailed in Appendix 4 of the local supplement of the Group Code of Ethics and is part of the Code of Ethics.

## 7. CERTIFICATION AT THE TIME OF RECRUITMENT

Each Tcoag Employee must certify, when starting work under their contract that they understand their obligations and the responsibilities that come with them.

All Employees shall receive a copy of the Group Code of Ethics and the Irish Code of Ethics and must acknowledge receipt of it and sign the certification included in Appendix 1.

## 8. SANCTIONS AND DISCIPLINARY SCHEME

Any breach of the Group Code of Ethics or the Irish Code of Ethics by Tcoag Employees may result in disciplinary proceedings being initiated, notwithstanding any actions that might be brought against the Tcoag Employees in question before a civil or criminal court.

The Group Code of Ethics and the Irish Code of Ethics combined form an inseparable set referred to as the Code of Ethics. This document came into effect on 1 December 2017, and has undergone reviews and updates in July 2022 and July 2023.

# Appendix 1. Code of Ethics Certification

All Tcoag Employees must sign this certificate when beginning employment and when the Code of Ethics undergoes substantial changes.

Tcoag shall undertake to adhere to the highest standards of integrity. This means that Tcoag shall undertake to conduct business ethically and by adhering to all applicable legislation.

All Employees must understand that all illicit or inappropriate activity can be damaging to STAGO Group and Tcoag's reputation and can have adverse implications for both Tcoag, the STAGO Group, and the people involved.

Tcoag encourages conduct that is ethical and in keeping with all applicable legislation and regulations and, in addition, expects its Employees to adhere to the highest ethical standards.

**I hereby certify and acknowledge that:**

1) **I have received and read the Group Code of Ethics and the Irish Code of Ethics.**

2) **I fully understand my obligation to adhere to the Code of Ethics.**

3) **I noted that all Employees are encouraged to report all breaches of the Code of Ethics or applicable legislation and regulations, either to the Compliance Officer or the Group Ethics Committee.**

4) **I am aware that any breach of the Code of Ethics may result in disciplinary sanctions, including dismissal of the person in question, as well as criminal or civil sanctions for the person involved.**

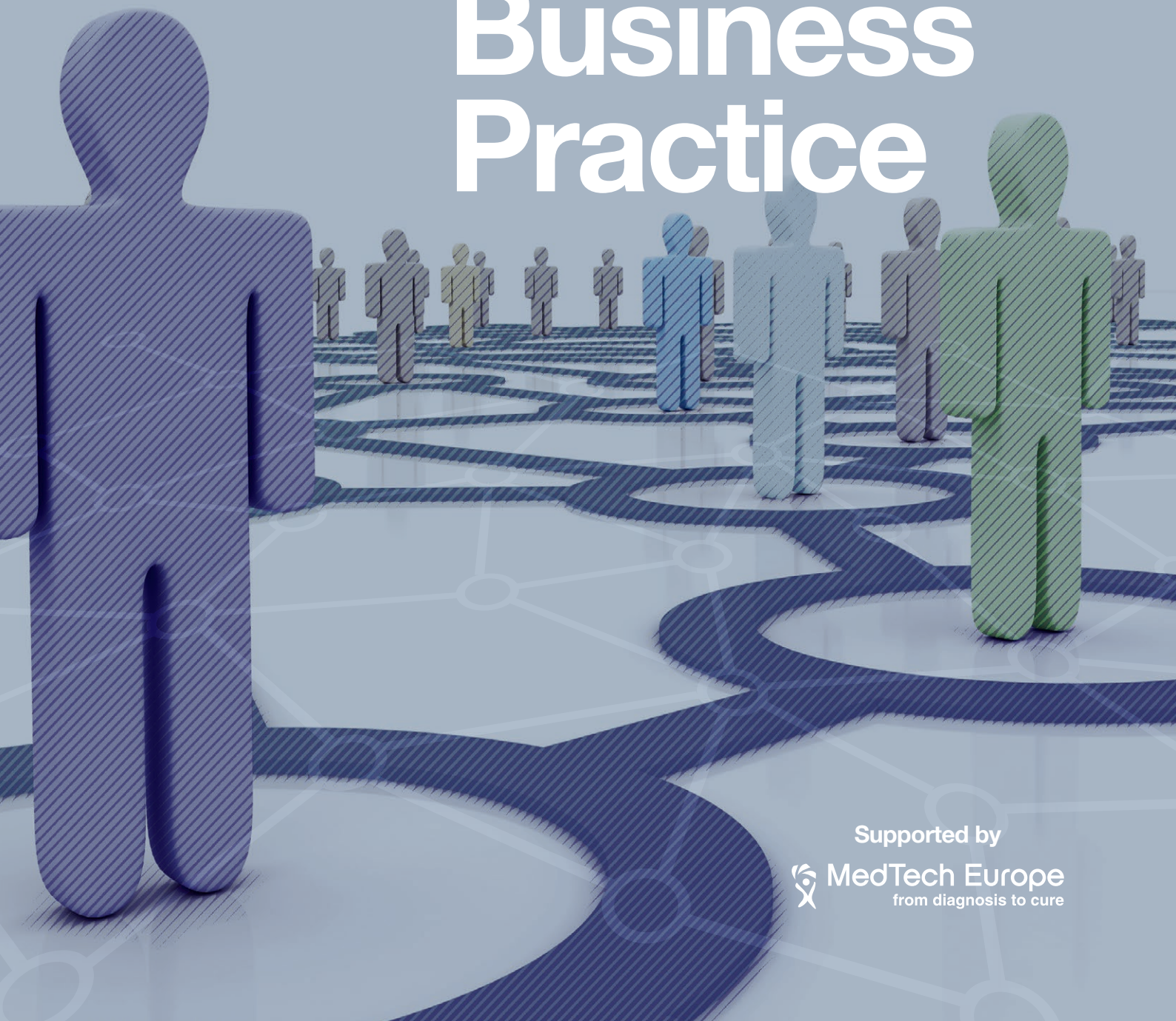
| _____ | _____ | _____ |
|---|---|---|
| **NAME** | **Signature** | **Date** |

# Appendix 2. IMA Guidance Document

Irish Medtech Association
Ibec

Guidelines on Interactions with Healthcare Professionals

# Code of Ethical Business Practice



Supported by
MedTech Europe
from diagnosis to cure

# Contents

# Introduction

## Promoting an Ethical Industry

### The Irish Medtech Association is the business association within Ibec representing the medical technology sector in Ireland. Irish Medtech Association's broad focus is to promote and support an environment that encourages the sustainable development and profitable growth of our multinational and small to medium size medical technology companies in Ireland companies.

We are fortunate to work in an industry whose main aim is to bring hope to patients and it's important that we do so in an ethical manner to ensure quality of care but also good business practice. We as an industry have responsibility both to patients and to the healthcare providers and system. The long collaborative tradition between the medical technology industry and the healthcare profession has produced groundbreaking treatments which have transformed healthcare and patient quality of life. However, it is widely recognised that medical technology companies and the healthcare profession are entering a new era in terms of how they deal with each other. MedTech Europe (the European organisation representing the medical technology industry) published the new MedTech Europe Code of Ethical Business Practice on 1st January 2017. The MedTech Europe Code allowed for an additional year to phase out direct sponsorship, by the entire medtech industry. We are now at this juncture. The Irish Medtech Association as a member association of MedTech Europe has adopted this code and over the past number of years we have been busy providing guidance and information to Members about the Code. The Code is mandatory for all Members of the Irish Medtech Association. It is not meant to restrict or in any way hamper how companies do business with healthcare systems, but instead sets expectations and norms concerning the conduct of business and our interaction with healthcare professionals.

The Code of Ethical Business Practice for the Irish medical technology industry is comprehensive in its commitment to high ethical standards. It governs all interactions between medical technology companies and healthcare professionals and it is supplemented by detailed guidelines which clarify and distinguish between appropriate and inappropriate activity in areas such as:

- Appropriate support of scientific and educational conferences
- Legitimate consulting agreements with HCP's
- Provision of educational grants and charitable donations
- Provision of modest hospitality and gifts

The Irish Medtech Association is committed to this code and we look forward to working with our Members and other

stakeholder to oversee its continued implementation. The Irish Medtech Association recognises that compliance with applicable laws and regulations as well as adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the medical technology industry.

The Code sets out the minimum standards appropriate to the various types of activities carried out by the Members. The Code is not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon Members and all Members should independently ascertain that their activities comply with all current national and local laws, regulations and professional codes.

Furthermore, Members must be mindful of the fact that they may be liable for the activities of third party intermediaries who interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activity involving Member companies' products. Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation impose obligations upon the third party (for example, third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives) to comply with provisions set out in the Code or equivalent guidelines[2].

# Key Legislation

The medical technology industry in Ireland, in common with other industries, is subject to national and supranational laws which govern many aspects of their business operations. The Irish Medtech Association underlines compliance with the following laws and regulations as having particular relevance to the medical technology industry:

- Safety, Quality and Performance Laws;
- Advertising and Promotion Laws;
- Data Protection Laws;
- Anti-corruption Laws;
- Environmental Health and Safety Laws;
- Competition Laws.

National and European Union (EU) competition legislation applies not only to Members in their business operations, but also to the Irish Medtech Association, each of the association's working groups and any sub-group within the associations, irrespective of size and name. Liability under competition laws may be strict and a Member may become liable for the infringement of such laws by other Members of an association group in which it participates. Accordingly, Members must make every effort to observe EU and national competition laws in all their interactions.

# Aims and Principles of the Code

The interaction between Members and Healthcare Professionals and Healthcare Organisations is an important feature in achieving the Irish Medtech Association's mission to make safe, innovative and reliable technology and related services available to more people. For example:

## Advancement of Medical Technologies

The development of innovative medical devices, technologies and in vitro diagnostics and the improvement of existing products require collaboration between Member Companies and Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services.

## Safe and Effective Use of Medical Technology

The safe and effective use of medical technology and related services requires Member Companies to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support.

## Research and Education

Member Companies' support of bona fide medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

2. For further details, please refer to the Eucomed/AdvaMed Third Party SMIs guidance

**Q1: Does the definition of Healthcare Professional include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a super-market chain?**

**A1:** No, the definition of Healthcare Professional does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Member Companies' medical devices for or on behalf of medical or clinical personnel. For example, if a Member Company's medical devices are sold as part of the common merchandise of the retail outlet, interactions between the Member Company and the purchasing professional do not fall under the Code. However, where the Member Company's medical devices are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall under the Code.

**Q2: Must a Member Company require Employer Notification to be given whenever Company personnel meet HCPs at an HCO? (added in September 2016)**

**A2:** No. Unless the Member Company's interaction with an HCP entails a transfer of value or raises a potential conflict of interest there is no requirement for Employer Notification. However, Member Companies must comply with any access requirements imposed by HCOs to visiting Member Company personnel.

**Q3: What is the Conference Vetting System (CVS) and, is CVS approval required for all Third Party Organised Educational Events before a Member Company can provide support to these events? (added in November 2016)**

**A3:** The Conference Vetting System (see the Glossary) has been established as the online, binding and centralised decision-making process to help Member Companies review the compliance of relevant Third Party Organised Educational Events with the Code. It is managed independently of the MedTech Europe Secretariat and Members and is under the supervision of the MedTech Europe Compliance Panel. CVS approval is only required for Third Party Organised Educational Events which fall within its scope, as provided here. Where there is a CVS decision in relation to a specific Third Party Organised Educational Event, this decision is binding upon all Member Companies.

In each such interaction Member Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry. To achieve this aim, the Code provides guidance on the interactions of Member Companies with both Healthcare Professionals and Healthcare Organisations, based upon the following underlying principles:

## The Principle of Image and Perception

Member 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 Organisations.

## The Principle of Separation

Interaction between industry and Healthcare Profes- sionals / Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies' products.

## The Principle of Transparency

Interaction between industry and Healthcare Professionals / Healthcare Organisations must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, Member Companies shall nevertheless maintain appropriate transparency by requiring prior written notification to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction.

## The Principle of Equivalence

Where Healthcare Professionals are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must be commensurate with, and represent a fair market value for, the services performed by the Healthcare Professional.

### The Principle of Documentation

For interactions between a Member Company and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a Member Company, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Member Company. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the Member Company for a reasonable period of time to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

## Interpreting the Code

The use of capital letters indicates that a word or expression is a defined term, the meaning of which is set out in the Glossary. Any phrase introduced by the terms: including, include, in particular, or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.

## Administering the Code

Compliance with the Code and with this Complaints Procedure and Panel Constitution is mandatory for members of the Irish Medtech Association. The Code is administered by a Panel Administrator and by a panel of independent representatives. The independent panel is chaired by an independent solicitor/barrister. The panel may comprise of up to five, but not less than four independent experts. In the event that there are five, the areas of expertise should be categorised as follows: Legal, Company/Commercial, Clinical, Patient/Research, Public/Patient interest.

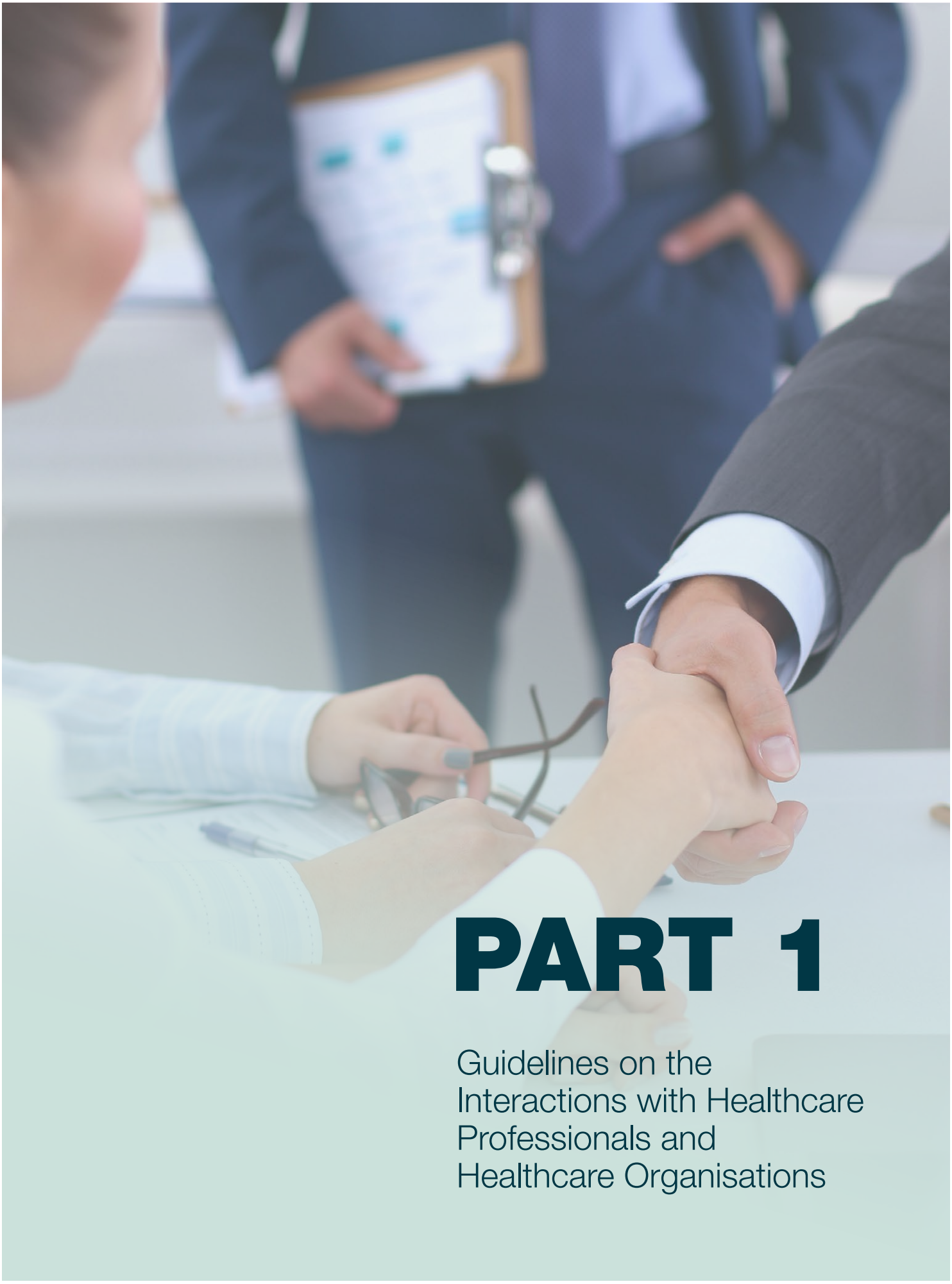
A full overview of complaints procedure and sanctions are available on http://www.irishmedtechassco.ie/ethics

The introduction of more stringent rules on Educational Grants means that member companies are obliged to disclose financial contributions to HCPs. Ethical Medtech (https://www.ethicalmedtech.eu) is a platform, supported by MedTech Europe, dedicated to ethics and compliance projects in the Medtech industry. MedTech Europe have provided Irish Medtech Association members (whether MedTech Europe members or not) access to this portal for disclosure of financial contributions.

If an Irish Medtech Association member company is funding third party educational events, i.e., Educational Grants, promotional activity (e.g. booths) and satellite symposia), - they must ensure that the conference has been vetted under the Conference Vetting System.

## Implementation

This edition of the Code is effective from 1st January 2018.



# PART 1

## Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations

Chapter 1

# General Criteria for Events

## Member Companies may invite Healthcare Professionals to Company Events and Third Party Organised Educational Events.

### 01. Event Programme

The Event programme should directly relate to the specialty and/or medical practice of the Healthcare Professionals who will attend the Event or be sufficiently relevant to justify the attendance of the Healthcare Professionals. For Third Party Organised Educational Events, the agenda should be under the sole control and responsibility of the third party organiser.

A Member Company shall not organise Events which include social, sporting and/or leisure activities or other forms of Entertainment, nor support such elements where part of Third Party Organised Educational Events. For Third Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the Third Party Organised Educational Event.

### 02. Event Location and Venue

The Event location and venue should not become the main attraction of the Event. For the location and the venue, Member Companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday- oriented, or that of an Entertainment venue.
- The Event location and venue should be centrally located when regard is given to the place of residence of the majority of invited participants.
- The need for ease of access for attendees.
- The Event location and venue should be in or near a city or town which is a recognised scientific or business centre, suitable for hosting an Event which is conducive to the exchange of ideas and the transmission of know- ledge.
- Member Companies must take into account the season during which the Event is held. The selected time of year must not be associated with a touristic season for the selected geographic location.

**Q4: What is meant by "legitimate" or "genuine" as used in the definitions of 'Company Event' and 'Third Party Organised Educational Conferences'?**

**A4:** Any Event should be relevant to the Healthcare Professional attendees; the detailed programme should be available sufficient time prior to the Event; present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). If it is a Third Party Organised Educational Event the Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.

**Q5: Can a Member Company organise or support an Event at a hotel that offers leisure facilities such as golf, casinos or water sports?**

**A5:** No, it would not be appropriate for Member Companies to organise or support Events at hotels centred around leisure facilities such as golf, casinos or ski/water sports. An important factor in evaluating a hotel is its suitability for business meetings, including the availability of conference facilities. For hotels which include minor leisure and sporting facilities, such as a spa, while it would not be reasonable to exclude these venues if otherwise appropriate, Member Companies must exercise caution. The Event agenda should be arranged in such a way that Healthcare Professionals attending the Event would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to enable guests to use the leisure and sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals.

**Q6: Under the Code, what is meant by "ease of access" in relation to Event location and venue?**

**A6:** When originating location of the majority of attendees is considered, Event location and venue need to be in close proximity to an airport and / or train station with appropriate international connections, with associated reliable ground transportation infrastructure to the venue.

**Q7: Under the Code, how does the "season" impact evaluation of Event location and venue?**

**A7:** For European and international Events, ski resorts in the ski season, island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question. Member Companies must not support or organise Events at these locations during those seasons.

## 03. Guests

Member Companies are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for Guests of Healthcare Professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the Event.

## 04. Reasonable Hospitality

Member Companies may provide reasonable hospitality to Healthcare Professionals in the context of Company Events and Third Party Organised Educational Events but any hospitality offered must be subordinate in time and focus to the Event purpose. Member Companies must in any event meet the requirements governing hospitality in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the Event is being hosted.

The Code seeks to find a balance between the courteous and professional treatment of Healthcare Professionals by Member Companies, with the desire to avoid even the appearance that hospitality may be used by Member Companies as a means to induce Healthcare Professionals to purchase, prescribe or recommend Member Companies' products.

Accordingly, Member Companies must assess what is "reasonable" in any given situation and regional variations will apply. As a general guideline, "reasonable" should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations and professional codes of conduct. The term "hospitality" includes meals and accommodation and it is important that Member Companies differentiate between "hospitality" which is permitted and Entertainment which is not. Please refer to the Glossary for the definition of Entertainment.

Member Companies may not pay for or reimburse Healthcare Professionals' lodging expenses at top category or luxury hotels. For the avoidance of doubt, if the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Member Companies to offer participants meals and accommodation at the same hotel. However, accommodation and/or other services provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

## 05. Travel

Member Companies may only pay or reimburse for reasonable and actual travel. Travel provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

For air travel, in principle, this means that Member Companies can only pay or reimburse economy or standard class unless the flight time is of a duration of greater than 5 hours including connection flights, in which case business class can be considered. First class is never appropriate.

## 06. Transparency

Member Companies must ensure full compliance with national laws with regard to the disclosure or approval requirements associated with such financial support and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, as a minimum, by requiring Employer Notification (as defined in the Glossary) is made prior to the Event.

Member Companies may provide financial and/or in kind support (e.g. Member Company products) to Third Party Organised Educational Events in accordance with the rules of this Code. Such Events include:

- Third Party Organised Educational Conferences;
- and Third Party Organised Procedure Training meetings.

**Q8: What does the term "facilitate" mean where used in connection with the Guest expenses?**

**A8:** The term "facilitate" refers to the prior arrangement, organisation or booking of meals, travel or accommodation by or on behalf of a Member Company on behalf of the Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in his/her own right, irrespective of who pays. Such actions are open to misinterpretation. If Healthcare Professionals attending the Event wish to be accompanied by a Guest who does not have a professional interest in the information being shared, the Healthcare Professional must take sole responsibility for the payment and organisation of the Guest's expenses.

**Q9: In the event that a Healthcare Professional is accompanied by a Guest at the Event, may this Guest be admitted to any Company Event, or Third Party Organised Educational Events?**

**A9:** It is not appropriate for a Guest of a Healthcare Professional to attend either Company Events (including Satellite Symposia) or Third Party Organised Educational Events (unless the individual qualifies as a participant in their own right), nor is it appropriate, in the interest of maintaining the scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches and coffee breaks) even when the Healthcare Professional pays for the Guest's expenses.

Member Companies, however, may financially support Third Party Organised Educational Events which offer extra-curricular programmes/activities beyond the scientific, educational or training sessions for Guests of Healthcare Professionals (such as touristic activities and hospitality), always provided that such an extra -curricular programme/activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, facilitated or reimbursed by, a Member Company.

**Q10: Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a Healthcare Professional for a specific amount to cover all or part of the Health- care Professionals' travel or accommodation expenses for attendance at the Event?**

**A10:** It is not acceptable to make an advance payment to a Healthcare Professional to cover prospective expenses. Payments should generally be made to the supplier/vendor or intermediary agency. Alternatively Member Companies may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts.

**Q11: May Member Companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the Event programme attended?**

**A11:** Generally, travel and accommodation support offered by Member Companies to Healthcare Professionals should be tailored to the duration of the Event. Member Companies must always keep in mind the impression which may be created by the arrangements for any meeting.

**Q12: Under the Code, is Employer Notification required for each interaction with a Member Company? For example, is such notification required each time a Member Company pays for a reasonably priced meal or gives a Healthcare Professio- nal a gift, which is otherwise in line with the requirements of the Code?**

**A12:** Employer Notification is required whenever a Member Company engages a Healthcare Professional or whenever a member makes a financial contribution to the Healthcare Professional's medical education. Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest gifts related to the Healthcare Professional's practice, do not require Employer Notification.

**Q13: Are Member Companies required to provide additional written notification under the Code to the hospital administration, Healthcare Professional's superior (or other locally-designated body) for Member Company/ Healthcare Professional interactions in countries where there are compulsory notification systems already in place?**

**A13:** No. Only the compulsory notification is required. Additional notification under the Code is not required in countries where specific notification requirements of law or regulation govern the transparency of interactions between industry and Healthcare Professionals. The transparency provisions of the Code apply only in countries where there is an absence of national transparency laws and regulations.

**Q14: When making Employer Notification, are Member Companies required to provide details of the proposed financial contribution Member Companies will make to the Healthcare Professional in exchange for the services rendered?**

**A14:** The written notification must comply with national laws, regulations and professional codes of conduct. In countries where specific provision is not made, there is no requirement to notify employers of the amounts involved. Under the Code, Member Companies must ensure that the level of remuneration is commensurate with the services provided and not greater than a fair market value. However, the purpose of the Employer Notification is to provide transparency on the nature of the interaction between the Member Company and the Healthcare Professional and to enable the employer to raise objections if they perceive a potential conflict or have other issues concerning the interaction.

Chapter 2

# Third Party Organised Educational Events

## 01. Third Party Organised Educational Conferences

Member Companies may support in cash and/or in kind Third Party Organised Educational Conferences (see the Glossary) which comply with:

- Chapter 1: General Criteria for Events;
- and where applicable, has approval via the Conference Vetting System (see the Glossary)[2].

Where permitted under national law, regulations and professional codes of conduct, Member Companies may provide financial and/or in kind support to Third Party Organised Educational Conferences (always provided that the Third Party Organised Educational Conference has been approved via the Conference Vetting System, where appropriate) through grants and other types of funding, such as:

### A. Educational Grants

Please refer to Chapter 4: Grants and Charitable Donations for guidance on Educational Grants.

### B. Promotional Activity

Member Companies may purchase packages that may include promotional and advertising services, for example, advertisement space and booth space for company displays. Member Companies should ensure that the overall image projected by the promotional activity at Third Party Organised Educational Conferences is perceived as professional at all times. It should never bring discredit upon or reduce confidence in the medical technology industry.

### C. Satellite Symposia

Member Companies may purchase satellite symposia packages at Third Party Organised Educational Conferences and provide presentations on subjects that are consistent with the overall content of the Third Party Organised Educational Conference. Member Companies may determine the content of these satellite symposia and be responsible for speaker selection.

2. For scope of application of CVS please refer to: www.ethicalmedtech.eu

**Q15: What is meant by "in kind support" as used in Chapter 2, Section 1 of the Code in connection with "Third Party Organised Educational Conferences"? (added in September 2016)**

**A15:** "In kind support" must be provided to the Healthcare Orga- nisation (HCO) and Member Companies should ensure that any such in kind support does not, nor is perceived to, circumvent the prohibition of Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third Party Organised Educational Conferences. Examples of "in kind support" which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements. For example, it would not be appropriate for Member Companies to handle the conference registration, travel, or accommodation arrangements for individual (and identifiable) Healthcare Professionals delegates at a Third Party Organised Educational Conference.

**Q16: Please provide examples of appropriate booth activties which will be perceived as professional?**

**A16:** Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies' products and services and related literature. Therefore, other activities should be limited and reasonable and in principle, only soft drinks and snacks should be served.

**Q17: Can a Member Company for example be present via a satellite symposium, rent booth space at a Third Party Organised Educational Conference which organise a satellite symposium and/or rent booth space at a Third Party Organised Educational Conference taking place outside of the Med- Tech Europe Geographic Area and which was assessed as non-compliant by the Conference Vetting System (CVS)? (modified in October 2016)**

**A17:** Yes, Member Company can organise a satellite symposium and/or rent booth space at a Third Party Organised Educational Conference taking place outside of the MedTech Europe Geographic Area and which was assessed as non-compliant by the Conference Vetting System provided that there are no Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area supported by an Educational Grant. Please refer to Annex I for a detailed visualisation of the scope CVS and its impact on commercial activities.

## 02. Third Party Organised Procedure Training

Member Companies may support Third Party Organised Procedure Training either via Educational Grants (in accordance with Chapter 4: Grants and Charitable Donations) or by providing financial support directly to individual Health-care Professionals to cover the cost of attendance at Third Party Organised Procedure Training sessions in accordance with the following rules:

- Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events. Member Companies may therefore pay travel, hospitality and the registration fee.
- Where applicable, the Third Party Organised Procedure Training has approval via the Conference Vetting System (see the Glossary)[3].
- For financial support to Third Party Organised Procedure Training meetings Member Companies must apply the requirements governing conduct and attendance at such meetings in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the meeting is being hosted.

3. For scope of application of CVS please refer to: www.ethicalmedtech.eu

**Q18: Can Member Companies directly support attendance by Healthcare Professionals engaged to speak only at satellite symposia at Third Party Organised Educational Conferences, e.g. registration fee, travel and/or accommodation?**

**A18:** Member Companies must ensure compliance with the Code and enter into a consulting agreement with the Healthcare Professional engaged to speak at the satellite symposium. The consulting agreement may include payments in respect of registration fee, travel and/or accommodation where appropriate.

**Q19: What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings? (added in September 2016)**

**A19:** Both Third-Party Organised Educational Conferences (see the Glossary) and Third-Party Procedure Trainings (see the Glossary) are a type of Third Party Organised Educational Events. Therefore, they must comply with Chapter 1. General Criteria for Events; and, where applicable, are subject to the Conference Vetting System (see the Glossary). However, unlike Third Party Organised Educational Conferences, Third Party Organised Procedure Trainings are not subject to the phase out of direct support for the attendance of Healthcare Professionals. Nonetheless, for Third Party Organised Procedure Trainings the following three criteria shall apply:

- Programme: Unlike Third Party Organised Educational Conferences which are theoretical in nature, Third Party Organised Procedure Trainings consist of practical, hands-on trainings, generally involving more than one provider/ manufacturer/ sponsor. This must be evident by the programme of the Event.

*“...unlike Third Party Organised Educational Conferences, Third Party Organised Procedure Trainings are not subject to the phase out of direct support for the attendance of Healthcare Professionals”*

**A19: Contd.**

The programme, which is often referred to as a “course”, rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or medical technologies). Examples may include courses aimed at acquiring or improving the Healthcare Professional’s skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices; etc. The programme must also include practical demonstrations (and/or actual live surgeries, where allowed). Examples of practical demonstrations may include surgery simulations where technologies are used on cadavers; skin models; synthetic bones; cath labs; etc.

- Venue: Third Party Organised Procedure Trainings are typically organised in a clinical environment, as opposed to, e.g., a classroom setting.

  For the avoidance of doubts, the adjective “clinical” includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.

  Examples of clinical environment include hospitals or clinics, where medical treatment on real patients may be given; as well as conference rooms which are appropriately set up to simulate medical procedures, for example with the presence of medical technologies to be used on cadavers; skin models; synthetic bones; etc.

- Stand-alone event: Third Party Organised Procedure Trainings must stand-alone. Where the majority of the Training is not given in a clinical environment, for example, where the Training is orga-nised in connection, adjacent to or at the same time as a larger Third Party Organised Educational Conferences, that Training will not qualify as a Third Party Organised Procedure Training, as defined in the Code.

Chapter 3

# Company Events

## 01. General Principles

Member Companies may invite Healthcare Professionals to Company Events. Such events include, as defined in the Glossary:

- Product and Procedure Training and Education Events
- Sales, Promotional and Other Business Meetings

Company Events should comply with the principles mentioned in Chapter 1: General Criteria for Events.

Where there is a legitimate business purpose, Company Events may include or take place in Member Company's manufacturing plant or Healthcare Organisations, used by the Member Company as reference centres.

## 02. Product and Procedure Training and Education Events

Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, Member Companies should make product and procedure training and education available to relevant Healthcare Professionals.

Member Companies shall ensure that personnel conducting the Product and Procedure Training and Education Events have the appropriate expertise to conduct such training.

## 3. Sales, Promotional and Other Business Meetings

Where it is appropriate, Member Companies may organise Sales, Promotional and Other Business Meetings where the objective is to discuss product and related services features and benefits, conduct contract negotiations, or discuss sales terms.

In addition to the principles laid down in the Chapter 3, Section 1, Sales, Promotional and Other Business Meetings should also comply with the following more stringent requirements:

- Such meetings should, as a general rule, occur at or close to the Healthcare Professional's place of business;
- It is not appropriate for travel or accommodation support to be provided to Healthcare Professionals by Member Companies, except where demonstrations of non-portable equipment are necessary.

**Q21: Is it appropriate for Member Companies to invite Healthcare Professionals on company plant or factory tours where the Healthcare Professionals reside outside the country of location of the plant or factory?**

**A21:** Yes, it is appropriate for Member Companies to invite Healthcare Professionals to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose and the tour complies with the Code in all respects.

**Q22: Under the Code, Chapter 3, Point 2, what is meant by "Company Organised Education Events"? (added in September 2016)**

**A22:** "Company Organised Education Events" is a Company Event as defined in the Glossary, whose objective is genuine and bona fide medical education, and the enhancement of professional skills. "Educational" or "education" means communicating information directly concerning or associated with the use of Member Companies' medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations. In all cases the information and/ or training must directly concern a Member Company's medical technologies, therapies and/or related services.

This means that a Member Company must meet the following tests when organizing such an Event in order to be compliant with the Code:

a) The entire Event must comply with the criteria of Chapters 1 and 3;

b) The programme must be rigorous from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals who are attendees at the Event.

c) The programme must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective. This means that the education part must fill most of the Program.

**A22: Contd.**

d) Information on the programme, clearly indicating the name of the Company organising the Event, should be made available sufficiently in advance in order for invited Healthcare Professionals to be able to make a reasoned judgment as to the rigor and quality of the programme, provided however that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality or nature of the programme.

e) The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day event, commences or ends on a mid-day or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non- educational events or activities organised for the other part of the day. Furthermore, there should be no significant gaps in the programme which would permit Healthcare Professionals to engage in non-scientific or non-educational activities. For example, early morning sessions should not be followed by late afternoon or evening sessions with large blocks of free time in between.

**Q23: Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Education Events?**

**A23:** No. Cruise ships, golf clubs or health spas and venues renowned for their entertainment facilities are not appropriate venues and should not be used. Appropriate examples include hospital, clinic or surgical centre laboratory, educational, conference, or other appropriate settings, including Member Companies' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required "hands on" training.

**Q24: What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Education Events?**

**A24:** If the participants are primarily of one country, the venue should be in the specific country involved. If the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen. It is expected that the country selected is the residence of at least some of the participants of the Product and Procedure Training and Education Event.

**Q25: Can a Member Company use a meeting venue outside Europe?**

**A25:** Yes, provided the participants are from multiple countries outside Europe. If the participants are primarily from within Europe, the venue should be in Europe. It is expected that the country selected (and the state, if the location is in the United States) is the residence of at least some of the participants of the Product and Procedure Training and Education Event.

*"The programme must be rigorous from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals who are attendees at the Event."*

Chapter 4

# Grants and Charitable Donations

## 01. General Principles

**a**. Grants and Charitable Donations (see the Glossary) shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by Member Companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services.

**b.** A Member Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying organisation or entity, as the case may be. Grants and Charitable Donations shall not be provided in response to requests made by Health- care Professionals unless the Healthcare Professional is an employee or officer of the qualifying organisation or entity and submits the request in writing on behalf of the qualifying organisation or entity.

**c.** The payment (or provision of other support) by way of any Grant or Charitable Donation shall always be made out in the name of the recipient organisation and shall be paid directly to the organisation. A Member Company shall not provide Grants or Charitable Donations in the name of any Healthcare Professional. In addition, all Grants and Charitable Donations shall identify the Member Company as the provider of the Grant or Charitable Donation.

**d.** It must in all cases be lawful under applicable national laws and regulations for the Grant or Charitable Donation recipient to receive and benefit from the particular type of Grant/Charitable Donation.

**e.** Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a specific prospective recipient. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.

**f.** All Grants and Charitable Donations must be appropriately documented by the Member Company. Moreover, Grants and Charitable Donations shall only be provided in response to a written request submitted by the requesting organisation or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties.

**Q26: Under the General Principles in Chapter 4. Grants and Charitable Donations, what is meant by an "independent decision-making/ review process"?**

**A26:** In accordance with the Principle of Separation, an "independent decision-making/review process", is a process where the decision-making criteria are not primarily sales-driven and where the Member Company's sales function does not decide upon and/or approve a decision to provide a Grant or Charitable Donation. For example, such a process could be led by a Member Company's legal, finance or compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria for review and decision-making.

**Q27: Under the Code, what is meant by "prior evaluation of any associated risks and of the relevant information" relating to a Grant or a Charitable Donation??**

**A27:** Prior to deciding to provide a Grant or a Charitable Donation, the Member Company must evaluate the appropriateness of the award of the proposed Grant or Charitable Donation to the pro-posed recipient. Such an evaluation shall consider all the circumstances including, but not limited to, consideration of the legal status and structure of the requesting (i.e. prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation shall be documented and shall be based on information available to the Member Company, such as information or documentation available from public sources.

For Educational Grants provided in relation to Third Party Organised Educational Events, this may also include information of how the funds have been applied by the recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of any previous Grant.

**Q28: What does "sufficient information" mean where used in connection with documentation of Grants and Charitable Donations?**

**A28:** The written request by a requesting organisation should include as a minimum a detailed description of the scope and purpose of the programme, activity or other project, which is the object of the Grant or Charitable Donation. It shall also contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget.

**g.** This section of the Code (Chapter 4: Grants and Charitable Donations) is not intended to address the legitimate practice by Member Companies of providing appropriate rebates, additional product and/or service offerings, including free of charge, or other comparable pricing incentive mechanisms ("value adds") which are included in competitive and transparent centralised purchasing arrangements, such as, for example, tenders.

## 02. Charitable Donations

Member Companies may make unrestricted Charitable Donations for genuinely charitable or other philanthropic purposes. "Unrestricted" in this context means that Member Companies shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

Charitable Donations may be made only to charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes and which are objectively engaged in genuine charitable or philanthropic activities. Charitable Donations shall always be made in accordance with the general principles set out in Chapter 4: Grants and Charitable Donations.

Restricted Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship (see Glossary), when Charitable Donations serve exclusively the benefit of the patient, are limited in value, or explicitly permitted by applicable national laws.

This section of the Code (Chapter 4: Grants and Charitable Donations– Charitable Donations) is not intended to address legitimate commercial transactions by Member Companies in the form of leasing of stands or booth space at Third Party Organised Educational Events and/or at any conference or event organised by a charity or other philanthropic organisation. Such activity is considered to be part of Member Companies' normal marketing activity.

Member Companies should, however, always consider the appropriateness of the location, venue and the general arrangements for any such events and the impression that may be created by the arrangements in order not to bring the industry into disrepute.

## 03. Educational Grants

Member Companies may provide restricted Educational Grants (see the Glossary) for the advancement of genuine medical education. "Restricted" in this context means that Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement. A Member Company shall also ensure that the Educational Grant agreement with the recipient organisation includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.

Member Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines, and publication shall commence no later than 31 December 2017.

Member Companies may provide Educational Grants for the following (non-exhaustive) purposes:

### a. Support for Third Party Organised Educational Events:

As a general principle, any Third Party Organised Educational Event supported by way of an Educational Grant from a Member Company to a Healthcare Organisation must:

- Comply with Chapter 1 – General Criteria for Events; and
- Where applicable, have approval via the Conference Vetting System (see the Glossary)[4]

#### a.1. Support for HCP Participation at Third Party Organised Educational Events:

Where the Educational Grant is provided for the purpose of supporting Healthcare Professionals' attendance at Third Party Organised Educational Events, the Healthcare Organisation receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement.

**Q29: Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?**

**A29:** No, a Member Company cannot make available a Charitable Donation to support the general running of a hospital or other Healthcare Organisation. A Charitable Donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main purposes. For the purpose of the Code and irrespective of their legal status, hospitals and Healthcare Organisations are considered to generally have health functions as their main purposes and accordingly are not generally considered to have charitable and/or philanthropic functions as their main purposes. It is not therefore appropriate to provide Charitable Donations to support their general running.

**Q30: Is it permissible for a Member Company to specify restrictions in relation to the final use of a Charitable Donation where a Member Company wishes its Charitable Donation to be applied as part of a specific aid programme or as part of the relief effort following a specific natural disaster, such as a major earthquake in a particular country? (added in September 2016)**

**A30:** Under the Code it is not appropriate for a Member Company to apply conditions or restrictions to the final use of a Charitable Donation which go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Member Companies may therefore impose general restrictions concerning the final use, such as the relief of a specific disaster in a particular country (e.g. for use to aid reconstruction and/or re-equipping of healthcare facilities following the earthquake in that country). However, Member Companies must take care that such general restrictions are not so specific that the Charitable Donation is no longer unrestricted. The Charitable Donation must not be misused or be perceived to influence through undue or improper advantages, purchasing decisions, nor should such Donation be contingent upon sales transactions or use or recommendation of Member Companies' products.

4. For scope of application of CVS please refer to: www.ethicalmedtech.eu

**Q31: Is it permissible for a Member Company to make a Charitable Donation to a Healthcare Professional's designated charity in instances where the Healthcare Professional has requested the Member Company to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the Member Company?**

**A31:** No. Under the Code it is not appropriate for a Member Company to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional irrespective of the underlying reasons. No exception can be made for sport events, such as payment of the registration charge to participate in a charity run.

**Q32: Under the Code, may a Member Company make a Charitable Donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in, or attend at, a fundraising sports or other event?**

**A32:** Yes, Charitable Donations made by Member Companies may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organisation. The Member Company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the Member Company should not invite Healthcare Professionals to attend such an event at the Member Company's expense. Furthermore, the Member Company is not permitted to suggest to the sponsoring organisation, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the Member Company's table.

**Q33: Can a small sized Healthcare Organisation receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events? (added in September 2016)**

**A33:** Yes, in principle. There are no size limits for Healthcare Organisations to receive Educational Grants; however, Member Companies must ensure that the final beneficiaries of the Educational Grant cannot be identified beforehand. For example, Healthcare Organisations composed of a single Healthcare Professional will in practice not be allowed to receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events, as the final beneficiary is known upfront.

**a.2. Support for Third Party Organised Educational Events:**

Where the prospective beneficiary of an Educational Grant is the organiser of the Third Party Organised Educational Event and is also a Healthcare Organisation, the recipient Health- care Organisation shall be solely responsible for:

- O The programme content;
- O The selection of Faculty; and
- O The payment of Faculty honoraria, if any.

Member Companies shall not have any detailed involvement in determining the content of the educational programme for selection of Faculty (see Glossary) and this shall be reflected in the written Grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme.

## b. Scholarships and Fellowships

Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the Glossary). Only Healthcare Organisations where Healthcare Professionals are in training shall be eligible to request and/ or receive such Educational Grants. A Member Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this shall be reflected in the written Grant agreement between the Member Company and the recipient HCO.

## c. Grants for Public Awareness Campaigns

Member Companies may also provide Educational Grants on a restricted basis to Healthcare Organisations for the legitimate purpose of providing information, promoting awareness and/ or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member Company is interested and/or involved.

## 4. Research Grants

Where permitted by national law, regulations, national guidelines and professional codes of conduct, Member Companies may provide restricted Research Grants (see the Glossary) to support clearly defined third party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the Member Company is interested and/or involved. Research Grants may include in kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the limited duration of the research.

Member Companies providing Research Grants shall ensure that they do not influence the research. However, in order to ensure that Research Grants are provided on a "restricted" basis, Member Companies shall clarify the intended research scope and purposes for which the Grant is requested and shall ensure that the written Grant agreement with the recipient organisation includes rights for the Member Company to verify that the Grant is applied solely for the agreed intended research use. Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research.

All requests for Research Grants from prospective Grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorisations or approvals. A Member Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project but shall not take any final decision regarding the Grant request unless and until the research receives formal ethics committee approval.

Research Grant agreements shall include provisions relating to adverse event reporting where appropriate, and shall require full disclosure of the Member Company and of the Grant by the Grant recipient organisation and the lead investigator in all oral or written presentations of the results.

For guidance on how Member Companies may undertake Member Company-initiated research please refer to Chapter 6: Research: Member Company-Initiated Research.

**Q34: How can Member Companies in practice ensure that Educational Grants made available for Third Party Organised Educational Events which are subject to the Conference Vetting System, are positively reviewed by CVS?**

**A34:** It is the responsibility of Member Companies to individually ensure compliance with this Code obligation. For example, Member Companies may themselves consider submitting relevant Third Party Organised Educational Events for CVS review or they may decide to include appropriate contractual obligations making it a pre-condition for an Educational Grant that the Third Party Organised Educational Event be submitted and positively assessed via the CVS, for example by the prospective Grant recipient or by a third party.

**Q35: Does Chapter 4: Donations and Grants – Educational Grants of the Code apply to requests received by Member Companies in the context of public procurement processes for educational support for Third Party Organised Educational Events from Healthcare Organisations and purchasing bodies?**

**A35:** No. Such requests and any subsequent financial or other support provided by a Member Company are not considered to be Educational Grants for the purpose of the Code. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice.

**Q36: In the event that a commercial organisation, such as a Professional Conference Organiser, organises a Third Party Organised Educational Event independently of any Healthcare Organisation, is it appropriate for Member Companies to sponsor such events and what rules shall apply? (modified in September 2016)**

**A36:** Member Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser organising a Third Party Organised Educational Event independently of any Healthcare Organisation. However, such arrangements do not fall within the definition of Educational Grant as Professional Conference Organiser are for-profit organisations. Sponsorship arrangements are therefore commercial in nature and Member Companies should consequently document these in a written commercial agreement in accordance with normal business practice and the requirements of the Code (Chapter 2: Third Party Organised Educational Events). In addition, where a Member Company provides funds earmarked for

**A36: Contd.**

the advancement of genuine educational purposes to a Professional Conference Organiser, acting independently of any Healthcare Organisation, all the Code provisions governing Educational Grants shall also apply. For example, if a Member Company provides funding to a Professional Conference Organiser to fund Healthcare Professional delegate places and expenses at a Third Party Organised Educational Conference, such Event, where applicable, must have CVS approval and the Member Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines.

**Q37: Can a Member Company pay for or reimburse travel costs to a Third Party Organised Educational Event for a Scholar or Fellow?**

**A37:** No, a Member Company cannot additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow attending a Third Party Organised Educational Event. Such costs shall be included in the Educational Grant supporting the Scholarship or Fellowship if it is intended that the Grant should extend to such attendance.

**Q38: What are examples of relevant disease awareness and health education for patients, carers and the general public for which a Member Company may legitimately provide an Educational Grant?**

**A38:** A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need or such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved. Such disease awareness campaigns must not, however, promote the use of particular therapies, services or promote specific Healthcare Organisations, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organisations

*"Research Grants may include in kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the limited duration of the research."*

*"A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need or such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved."*

Chapter 5

# Arrangements with Consultants

## 01. General Principles

Member Companies may engage Healthcare Professionals as consultants and advisors to provide bona fide consulting and other services, including but not limited to research, participation on advisory boards, presentations at Company Events and product development. Member Companies may pay Healthcare Professionals reasonable remuneration for performing these services. In all cases, consulting arrangements must be permitted under the laws and regulations of the country where the Healthcare Professional is licensed to practise and be consistent with applicable professional codes of conduct in that country.

The principles in this chapter are applicable to all consulting arrangements between Healthcare Professionals and Member Companies including where a consultant Healthcare Professional declines a fee for provision of their services.

Consulting arrangements shall not be contingent in any way on the prospective consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services.

When selecting consultants, Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with use of consultants. This process shall include a documented, prior evaluation of any such associated risks and of the relevant background information concerning each prospective consultant.

## 02. Criteria for Genuine

Consulting Arrangements In addition to the general principles above, the arrangements which cover genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

**a.** Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance.

**b.** The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.

**c.** Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified need. The volume or value of business generated by a prospective consultant or the Healthcare Organisation where s/he performs her/his professional activity is not a relevant criterion.

**d.** Consulting arrangements with Healthcare Professionals must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the nature of the services to be provided and the basis for payment for those services.

**e.** The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.

**f.** The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided.

**g.** Member Companies must maintain records of the services, and associated work products, provided by the consultant Healthcare Professionals and of the use made of those services by the Member Company.

## 03. Remuneration and Fair Market Value

The remuneration paid to Healthcare Professionals engaged as consultants by Member Companies shall reflect fair-market-value for the services provided. It shall not be in any way contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure in the course of their own professional practice or that may be purchased, leased, recommended, prescribed, used, supplied or procured by HCOs where they carry on their professional activities.

All payments made for services must comply with all applicable tax and other legal requirements. Member Companies may pay for expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation expenses incurred by consultants if attending meetings with, or on behalf of Member Companies. The written consulting agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the Member Company.

## 04. Disclosure and Transparency

Member Companies shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with the use by Member Companies of Healthcare Professionals as consultants. All required consents and approvals shall be obtained, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable. Where no such national requirements apply, Member Companies shall nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement.

Member Companies shall also include appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the Member Company and his/her involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation

**Q39: What is meant by Fair-Market-Value (FMV) in the context of consulting arrangements?**

**A39:** Fair-market-value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

**Q40: How should Member Companies determine Fair-Market- Value (FMV) for a service?**

**A40:** A Member Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company.

Chapter 6

# Research

## 01. Member Company-Initiated Research

Where there is a legitimate business need to do so, Member Companies may initiate, conduct, manage and finance scientifically valid research to generate data, whether pre or post-market. In this context, legitimate business needs for data include medical needs, including patient safety; research and development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post- market surveillance (PMS) and post-market clinical follow up (PMCF), vigilance, safety, or reimbursement and health economic, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making.

Where a Member Company uses a Healthcare Professional as a consultant, for example to lead a study on the Member Company's behalf (i.e. act as Principal Investigator), the Member Company shall ensure that such consulting arrangements comply fully with Chapter 5: Arrangements with Consultants.

In accordance with the Documentation Principle, any arrangements made by a Member Company to procure research-related services shall be set out in a written agreement which shall reference a written research protocol; written schedule of work and provide for all required consents, approvals and authorisations to be obtained prior to the commencement of the study.

Member Companies must ensure that their research activities comply with all applicable national laws, regulations and researchers' own professional codes of conduct, as well as with applicable Good Clinical Practice guidelines, if relevant.

In accordance with the Principles set out in the Introduction: Aims and Principles of the Code, Member Companies shall also ensure appropriate clinical trial transparency in relation to their research activities and results. This shall include appropriate disclosure of information about Member Companies' clinical trials, for example in external public registries and peer-reviewed journals.

Where Member Companies engage third party intermediaries for research (e.g. contract research organisations (CROs)), they shall ensure that the research conducted by these third parties on behalf of the Member Company is carried out in accordance with all applicable legal and ethical requirements, including the applicable requirements of the Code.

## 02. Member Company Post-Market Product Evaluation

Where there is a legitimate business need to do so, Member Companies may initiate, post-market third party evaluation of their products, therapies and/or related services and may therefore provide Evaluation Products under a written contract for services in order to obtain defined user evaluation by Healthcare Organisations in relation to the Evaluation Products.

Evaluation Products may be provided on a no charge basis in return for the requested user feedback from Healthcare Professionals at the Healthcare Organisation, which shall be formally described in a written protocol or questionnaire forming part of the contract.

Where the Evaluation Products are multiple-use Evaluation Products the defined period of time necessary for the evaluation and feedback to occur will depend on the frequency of anticipated use; the nature of the user evaluation feedback requested; the duration of any required training and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple-use Evaluation Products and that they have a process in place for promptly removing such multiple use Evaluation Products and/or any unused single-use Evaluation Products from the Healthcare Organisation's location at the conclusion of the evaluation period unless these are purchased by the Healthcare Organisation.

Provision of Evaluation Products and/or related services must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of Evaluation Products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of con- duct.

*"In accordance with the Documentation Principle, any arrangements made by a Member Company to procure research-related services shall be set out in a written agreement which shall reference a written research protocol"*

## 03. Third Party-Initiated Research

Please refer to Chapter 4: Grants and Charitable Donations: Research Grants.

**Q41: What is an example of an external public registry for clinical trial transparency?**

**A41:** Examples of an external public register for clinical trial transparency are www.clinicaltrials.gov or www.who.org

Chapter 7

# Royalties

## Healthcare Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or medical technologies.

They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

A royalty arrangement between a Member Company and a Healthcare Professional should be entered into only where the Healthcare Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method, such that the Healthcare Professional would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations. The foregoing is without prejudice to Member Companies' obligations to comply with any applicable obligations to pay royalties which may arise under applicable laws and regulations in some countries.

Arrangements involving the payment of royalties by or on behalf of Member Companies to a Healthcare Professional must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations. For example, royal- ties paid in exchange for intellectual property should not be conditional on:

- A requirement that the Healthcare Professional purchase, order or recommend any product, services or medical technology of the Member Company or any product or technology produced as a result of the development project; or
- A requirement to market the product or medical technology upon commercialisation.

Subject to national regulations and requirements, Member Companies should exclude from the calculation of royal- ties the number of units purchased, prescribed, used, or ordered by the Healthcare Professional and/or members of the Healthcare Professional's practice or Healthcare Organisation.

Chapter 8

# Educational Items and Gifts

**Member Companies exceptionally may provide inexpensive educational items and/or gifts, in accordance with national law, regulations and industry and professional codes of conduct of the country where the Healthcare Professional is licensed to practise.**

Member Companies may only provide such educational items and/or gifts in accordance of the following principles:

**a.** Educational items and/or gifts may be provided but these must relate to the Healthcare Professional's practice, or benefit patients, or serve a genuine educational function.

**b.** No educational items and/or gifts should be provided in response to requests made by Healthcare Professionals.

**c.** Educational items and/or gifts must not be given in the form of cash or cash equivalents.

**d.** Educational items and/or gifts must be modest in value, and can be branded or non-branded items.

**e.** A Member Company may occasionally provide educational items of greater value to a Healthcare Organisation always provided that the item serves a genuine educational function for the Healthcare Professionals at that Healthcare Organisation and is of benefit to patients. Such items shall not be provided to Healthcare Professionals for their personal use. The item shall also be related to the therapeutic areas in which the Member Company is interested and/or involved. For higher value educational items, Member Companies must maintain appropriate records of their provision of such educational items to Healthcare Organisations. Such items should not be part of the Healthcare Organisation's normal overheads or routine costs of operation.

**f.** Provision of educational items and/or gifts must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.

Member Associations shall provide guidelines on appropriate limits for gifts, in accordance with the principles above.

Prize draws and other competitions at Events are permissible if the prize awarded complies with Chapter 8: Educational Items and Gifts. In addition, it must comply with national laws, regulations and industry and professional codes of conduct.

This Chapter is not intended to address the legitimate practice of providing appropriate Evaluation Products, Demonstration products or Samples. For guidance on how Member Companies may provide Evaluation Products, Demonstration products or Samples, please refer to Chapter 6: Research and Chapter 9: Demonstration Products and Samples, as applicable.

**Q42: Under Chapter 8, what are examples of items of modest value that are "related to the Healthcare Professional's practice or for the benefit of patients".**

**A42:** Stationery items, calendars, diaries, computer accessories for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets are examples of modest value items that could be appropriately provided as gifts to Healthcare Professionals provided their value falls within the maximum value prescribed under national laws, regulations and industry and professional codes of conduct. Food, alcohol and items which are primarily for use in the home or car are not appropriate as they are not related to the Healthcare Professional's practice nor are they for the benefit of patients.

**Q43: May a Member Company provide a small gift to a Healthcare Professional to mark significant life events such as a marriage, birth, birthday or death?**

**A43:** The Code restricts the types of gift that may be given to a Healthcare Professional and it would not be appropriate to give gifts to mark significant life events such as a marriage, birth or birthday. However, in the case of death, it is for each Member Company to determine the appropriateness of making a tasteful gift as a mark of respect.

**Q44: Where Healthcare Professionals engaged by Mem- ber Companies as consultants or speakers decline a professional fee for their services, would it be appropriate for the Member Company to show its appreciation by giving the Healthcare Professional a small gift such as a bottle of wine or a bouquet of flowers?**

**A44:** No, it would not be acceptable for the Member Company to make such a gift because to do so could be open to misinter- pretation and would be likely to breach the Principle of Image and Perception. Moreover such gifts would not comply with Chapter 8. Educational Items and Gifts as they neither relate to a Healthcare Professional's practice nor serve an educational function.

**Q45: Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?**

**A45:** Examples of educational items of greater value that can be provided may include medical textbooks or anatomical models, but only if those relate to the therapeutic areas in which the Member Company is interested and/or involved.

Chapter 9

# Demonstration Products and Samples

## 01. General Principles

Member Companies may provide their own products as Demonstration Products and/or Samples (see the Glossary) at no charge in order to enable Healthcare Professionals and/or Healthcare Organisations (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/ or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Demonstration Products and/or Samples may be either single- or multiple-use products. Member Companies may also provide products from another company in conjunction with the Member Company's own Demonstration Products and/or Samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company.

Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Member Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Professionals and/or Healthcare Organisations, for example recording proof of delivery for any Demonstration Products and/or Samples provided and receipt of return for multiple-use Demonstration Products and/or Samples. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products and/or Samples no later than the time of the supply. The disclosure to Healthcare Professionals and Healthcare Organisations shall be in writing.

This Chapter is limited to the provision of Demonstration Products and/or Samples and related services at no charge and is not intended to apply to provision of pro- ducts or related services under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of rebates or pricing incentives in a public procurement context.

## 02. Demonstration Products (Demos)

Member Companies may provide examples of their products to Healthcare Professionals and/or Healthcare Organisations in the form of mock-ups (such as unsterilised single use products) that are used for Healthcare Professionals and patient awareness, education and training. For example, a

> *Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products no later than the time of the supply.*

Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product.

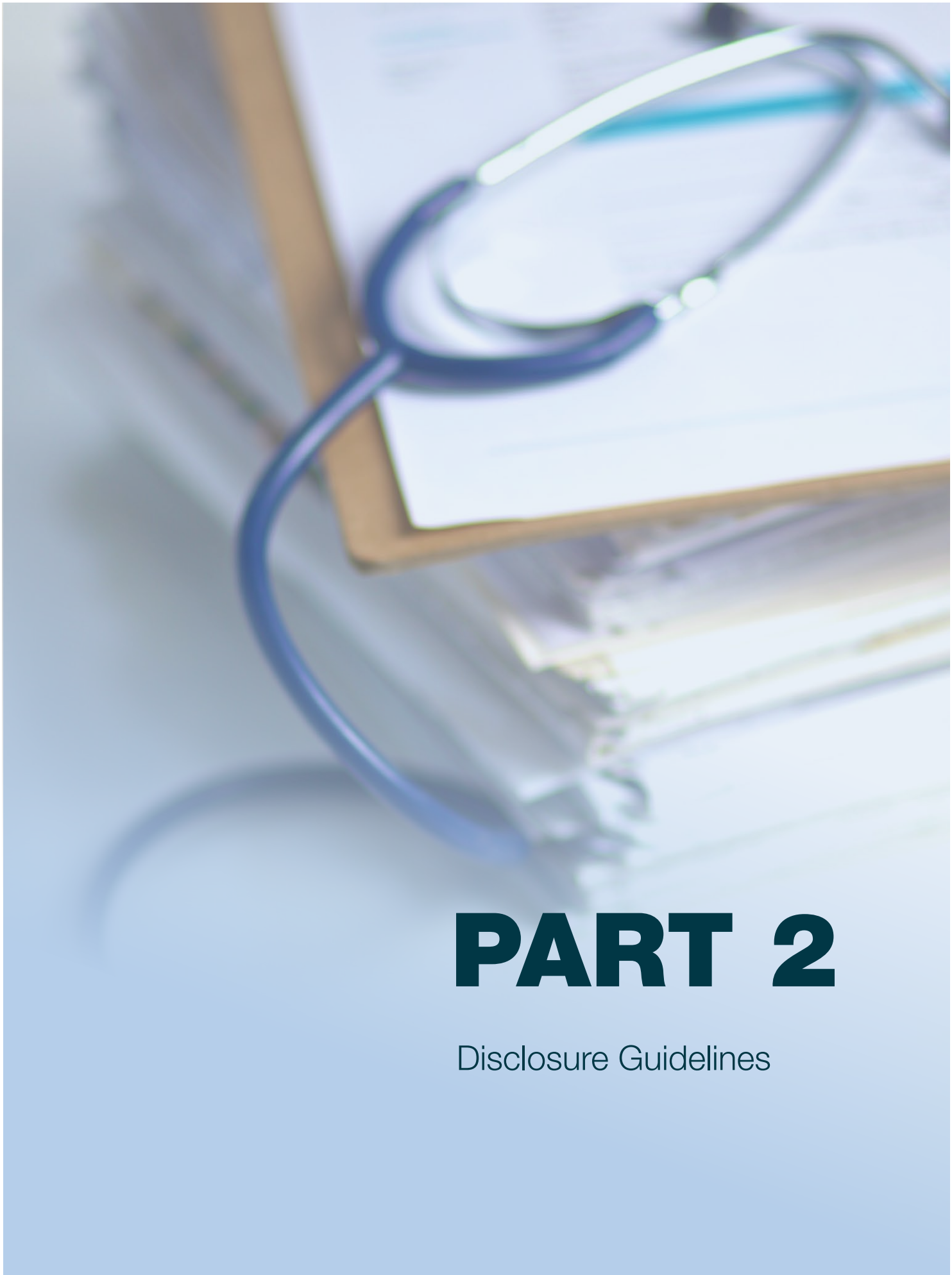
Demonstration Products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products no later than the time of the supply. It is recommended that the disclosure to Healthcare Professionals and Healthcare Organisations be in writing.

## 03. Samples

Member Companies may provide a reasonable number of Samples at no charge to allow Healthcare Professionals and/or Healthcare Organisations to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

For Samples, which are single-use products, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the Healthcare Professionals/ Healthcare Organisation to acquire adequate experience in dealing with the products.

For Samples, which are multiple-use products, the specific length of time necessary for a Healthcare Professional to familiarise him/herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of Healthcare Professionals who will need to acquire experience in dealing with the product and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple-use Samples and that they have a process in place for promptly removing such multiple use Samples from the Healthcare Professional's location at the conclusion of the familiarisation period.



# PART 2

## Disclosure Guidelines

# Preamble

Under the Irish Medtech Association Code of Ethical Business Practice (the "Code"), Member Companies are not permitted to pay registration fees, travel or hospitality expenses directly to individual Healthcare Professionals for their participation in educational conferences organised by third-parties as of 1st January, 2018.

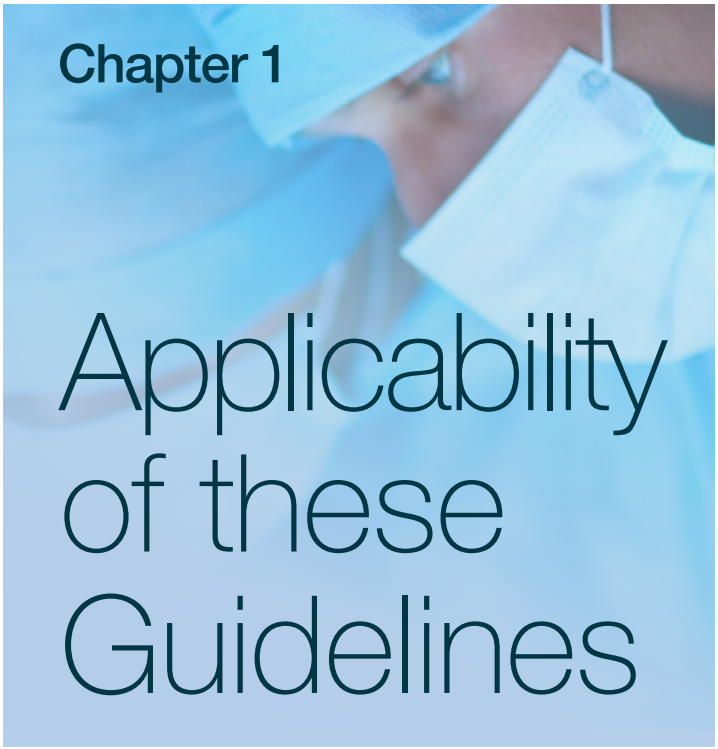
Medical Education may be supported through the provision of Educational Grants to Healthcare Organisations in compliance with the rules set out in the Code. To prevent abuses, specific safeguards when providing Educational Grants have been developed, including the obligation to disclose these Educational Grants.

Section 3 of Chapter 4 of the Code states that Member Companies shall document and publicly disclose all Educational Grants in accordance with these Disclosure Guidelines. These Disclosure Guidelines are therefore an integral part of the Code, and need to be interpreted as such.

For the avoidance of doubt, all funds provided by a Member Company for the advancement of genuine educational purposes to a Professional Conference Organiser ("PCO"), acting independently of any Healthcare Organisation, fall under the scope of these Disclosure Guidelines and are subject to the same conditions as Educational Grants. Whenever these Disclosure Guidelines refer to Healthcare Organisations, these shall also include Professional Conference Organisers.

All capitalised concepts used in the Guidelines are concepts defined in the Code.

Chapter 1



# Applicability of these Guidelines

## 01. Scope

These Disclosure Guidelines apply to Member Companies in their interactions with Healthcare Organisations based or registered in the MedTech Europe Geographic area.

Separate entities belonging to the same multinational company ("Affiliates") – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – shall be deemed to constitute a single company, and are as such committed to compliance with these Disclosure Guidelines.

Transfers of value that are not included in the definition of Educational Grants (as described in Chapter 4, Section 3 of the Code) and that consequently cannot be allocated to any of the categories set forth in Section 2.2 Aggregate Disclosure are not within the scope of these Disclosure Guidelines.

## 02. Applicability of these Disclosure Guidelines

Member Companies need not report the same information twice due to being bound by national laws, regulations or professional codes imposing disclosure obligations regarding Educational Grants (as described in Chapter 4, section

3 of the Code) equivalent to the ones imposed by these Disclosure Guidelines.

## 3. Applicability to Non-Member Companies

Non-member companies may implement these Disclosure Guidelines provided they are committed to ethical standards equivalent to those enshrined in the Code. Non-member companies may prove this commitment by obtaining the MedTech Europe Ethical Business Logo[2].

**Q1: Does the Disclosure Guideline's definition of "Affiliate" include legal entities belonging to the same parent Member Company but registered outside Europe?**

**A1:** Yes. Educational Grants made by Affiliates (parent companies are included in the definition of Affiliates to the effect of the Disclosure Guidelines) incorporated outside of MedTech Europe Geographical Area to Healthcare Organisations registered in Europe are within the scope of these Disclosure Guidelines. Any of the Affiliates registered in Europe can disclose these Educational Grants. Each Member Company can choose which Affiliate will report these Educational Grants made by Affiliates from outside the MedTech Europe Geographical Area.

2. The MedTech Europe Ethical Business logo is a symbol displayed by medical technology companies, distributors and other healthcare organisations to visibly demonstrate their commitment embracing and transcending the principles enshrined in the MedTech Europe Code for Ethical Business Practice.

**Q2: Are these Disclosure Guidelines applicable to third party intermediaries who interact with Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products?**

**A2:** No, these Disclosure Guidelines are not applicable to third parties such as third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives (list not exhaustive). Nevertheless, it is recommended to document arrangements concluded between Member Companies and third parties intermediaries in order to comply with the provisions set out in the Code.

**Q3: Where a national code already imposes disclosure obligations in a given country, where may Corporate Members disclose the Educational Grants?**

**A3:** Where a national code imposes disclosure obligations regarding Educational Grants (as regulated in Chapter 4, Section 3 of the Code) to the same extent as regulated by these Guidelines, Corporate Members, who are not a member of the National Association responsible for that national code, may choose either:
– To disclose only on the MedTech Europe platform; or
– To disclose on the national platform, if that possibility is provided for.

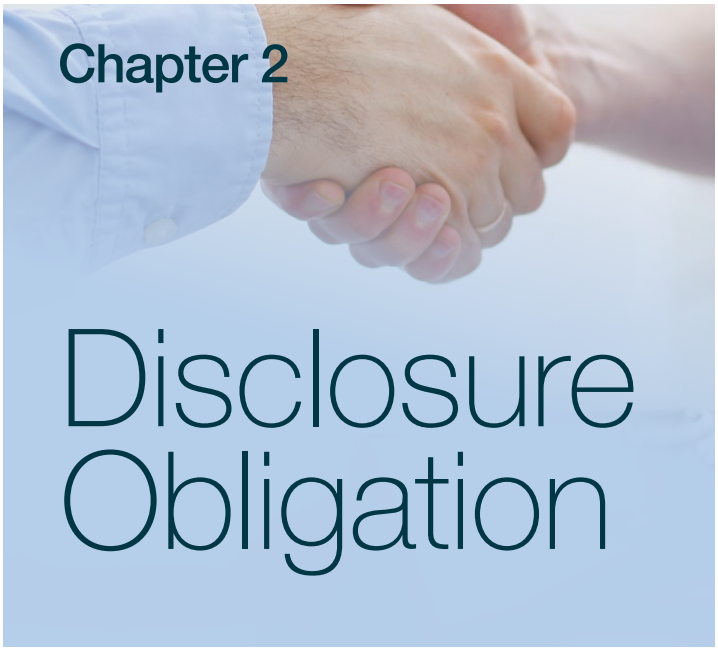
Corporate Members who are bound by this national code may choose either:
– To disclose only on the national platform or
– To disclose both on the MedTech Europe platform and the national platform.
This selected option shall be included in the Methodology Note.

**Q4: Who will decide if a national law, regulation or code imposes disclosure obligations regarding Educational Grants equivalent to the ones imposed by the Disclosure Guidelines?**

**A4:** The MedTech Europe Secretariat shall conduct a yearly assessment of the equivalence of national laws, regulations and/or professional codes imposing disclosure obligations with the MedTech Europe Transparency Obligations (as regulated in Chapter 4, Section 3 of the Code).

Members can at any time submit any information or documentation they possess that could be relevant for this assessment to the Secretariat.

The MedTech Europe Secretariat shall submit its assessment to the MedTech Europe Transparency Task Force, who will analyse the proposal. If the MedTech Europe Transparency Task Force agrees with the proposal, it will be submitted for approval to the MedTech Europe Compliance Network. If the disclosure obligations imposed by a national law, regulation or professional code are deemed equivalent to the ones imposed by the Disclosure Guidelines, the assessment will be made public on the MedTech Europe Transparency website. This selected option shall be included in the Methodology



Chapter 2

# Disclosure Obligation

## 01. General Obligation

Subject to the terms of these Disclosure Guidelines, each Member Company shall document and disclose all payments related to Educational Grants (as described in Chapter 4, section 3 of the Code) that it makes to a Healthcare Organisation based or registered in Europe, without limitation of value.

The disclosure of Educational Grants provided by Affiliates of the Member Company described above, but which are not registered in the MedTech Europe Geographic Area shall be made by any of the Affiliates comprising said Member Company that are registered in MedTech Europe Geographic Area.

## 02. Aggregate Disclosure

Educational Grants shall be disclosed on an aggregate basis. Each Affiliate of a Member Company shall disclose, for each clearly identifiable and separate recipient, the amounts paid as Educational Grants to such recipient in each Reporting Period3 which can be reasonably allocated to one of the categories set out below. Such amounts will be aggregated on a category-by-category basis, but itemised disclosure shall be made available upon request by the Member Company, as deemed necessary, to (i) the relevant recipient, and/or (ii) the relevant authorities.

Member Companies shall disclose an aggregate amount related to any of the categories set forth below:

**A.** Educational Grants to support Third Party Organised Events (including Support for HCP Participation at Third Party Organised Educational Events) and,

**B.** Other Educational Grants to Healthcare Organisations (including Scholarship, Fellowships and/or Grants for Public Awareness Campaigns).

## 03. Optional Object Specification

If desired, Member Companies may indicate the object of the Educational Grants disclosed for one or both categories set forth in Section 2.2 Aggregate Disclosure.

## 04. Methodology

Each Member Company shall create a note summarising the methodologies used by it in preparing the disclosures

and identifying Educational Grants for each category described in Section 2.2 Aggregate Disclosure. The note, including a general summary and/or country specific considerations shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants for purposes of these Disclosure Guidelines, as applicable. This Methodology Note shall be made available upon request by an interested party.

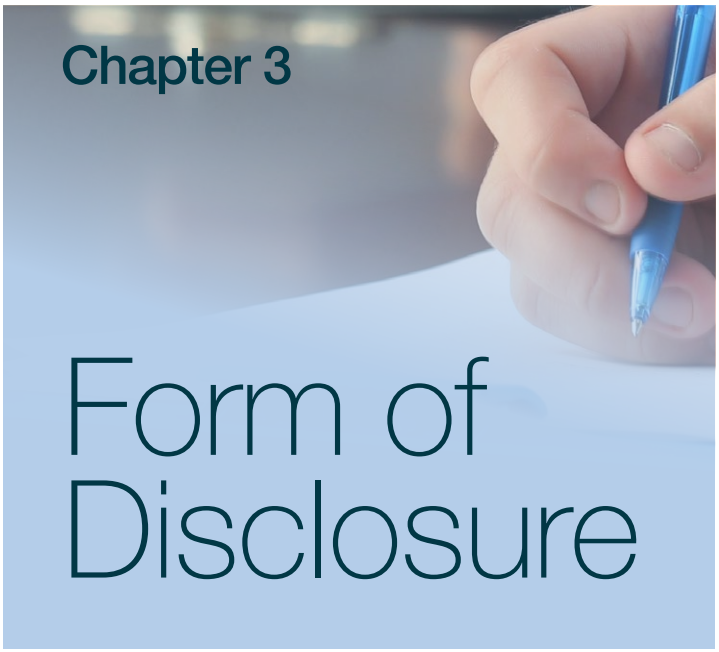
**Q5: Which Affiliate should disclose a particular Educational Grant?**

**A5:** To facilitate the tracking of Educational Grants made to individual Healthcare Organisations, it is recommended that the Affiliate making the payment in relation to a particular Educational Grant is the one disclosing the Educational Grant, but this is an internal decision of each Member Company.

A Member Company may choose to use internal arrangements of its choice to report the aggregated sum in relation to Educational Grants made by each legal entity composing the company (Affiliates) to a particular Healthcare Organisation during a disclosure period.

**Q6: When should a Methodology Note be made available?**

**A6:** Member Companies should create a comprehensive Methodology Note that would allow any Healthcare Organisation directly affected by a disclosure to understand how the amount disclosed was aggregated. The Methodology Note should therefore be made available upon specific request to Healthcare Organisations concerned about a particular disclosure that directly affects them. See Annex III



Chapter 3

# Form of Disclosure

## 01. Reporting Period

Disclosures shall be made on an annual basis and each Reporting Period shall cover a full calendar year.

## 02. Time of Disclosure

Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period.

## 03. Time of Publication

The disclosures shall be made public at the time of publication. The time of publication is the 31st August of the year of the relevant time disclosure.

## 04. Template and Language of Disclosure

For consistency purposes, disclosures made pursuant to these Disclosure Guidelines shall be made in English using the template set forth in the Annex.

## 05. Disclosure Platform

Disclosures shall be made on the EthicalMedTech website[4] unless the Member Company is already bound by national laws, regulations or professional codes as regulated in Section 1.2 Applicability of these Disclosure Guidelines.
Member Companies will remain liable for the accuracy of the disclosed data. For the avoidance of doubt, neither the Irish Medtech Association nor MedTech Europe shall not be held liable for (i) maintaining, correcting, deleting the published data nor (ii) for the storage of data after the three years period of disclosure in the public domain.

4. www.ethicalmedtech.org

## 06. Disclosures Retention and Modification

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication. The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

## 07. Enquiries Regarding Reported Disclosures

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication.

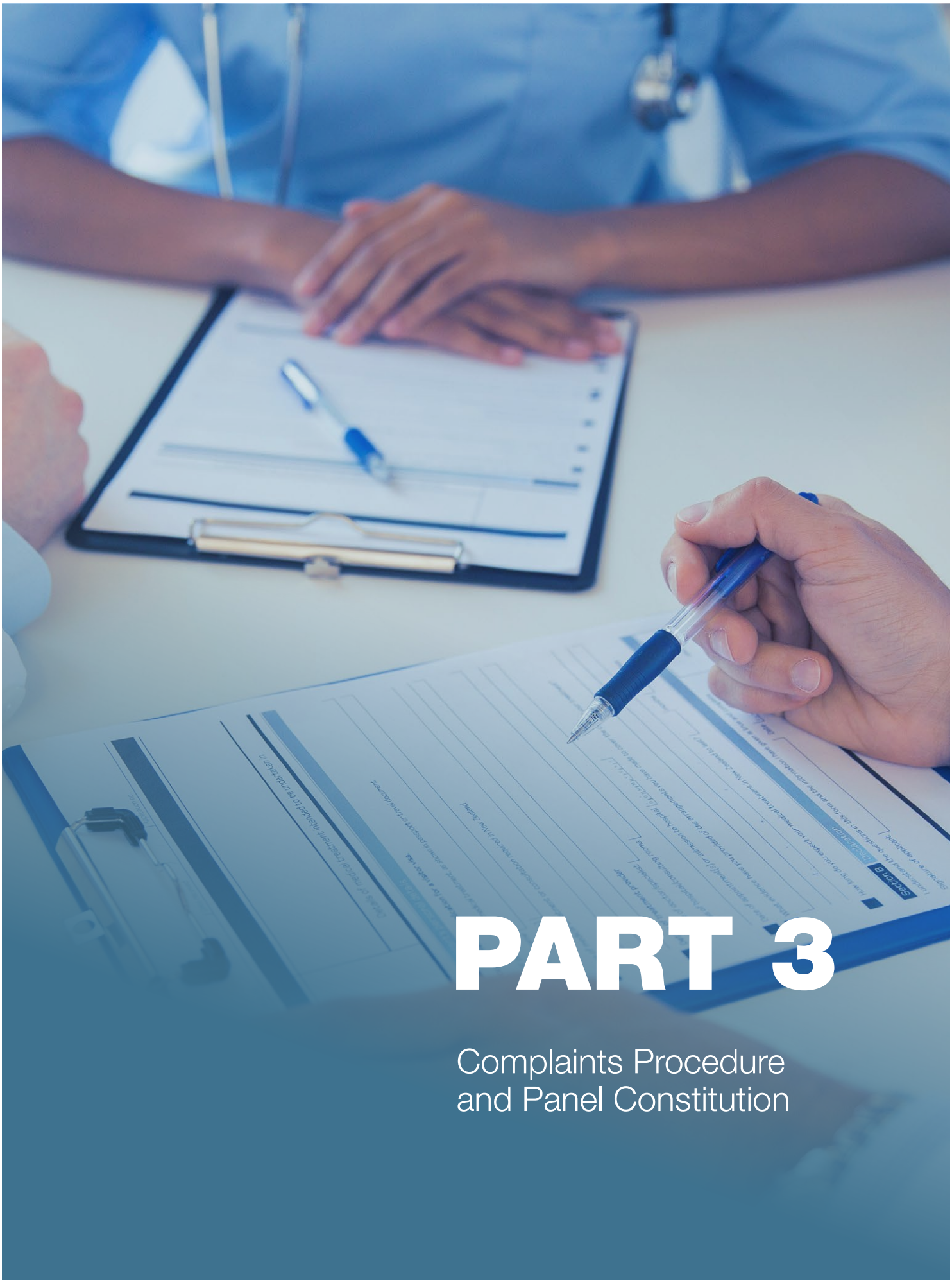
Member Companies shall make available to Healthcare Organisations upon request any data concerning their common contractual relations published in accordance with these Disclosure Guidelines at any time while the dis-closed information remains in the public domain as stated in Section 3.3 Time of Publication.

**Q7: When will the first Reporting Period start?**

**A7:** The first Reporting Period is the calendar year 2018, starting on the 1st January 2018, and ending on 31st December 2018.

**Q8: In what currency should the amounts payed be disclosed?**

**A8:** Disclosed amounts should be in the currency used in the payment. In the event the aggregate amount includes Educational Grants made in different currencies, the reporting company may choose in which currency they wish to disclose the aggregate amount, and keep appropriate record of the exchange rate used to convert the different currencies. This information will then be included in their Methodology Note.



# PART 3

## Complaints Procedure and Panel Constitution

Revised: [December 2017[1]

To be read in conjunction with the Irish Medtech Association Code of Ethical Business Practice
(Guidelines on Interactions with Health Care Professionals)

CONTENTS



# 1. Introduction

A Code of Ethical Business Practice ("the Code") has been adopted by the Irish Medtech Association. Compliance with the Code and with this Complaints Procedure and Panel Constitution ("the Procedure") is mandatory for members of the Irish Medtech Association. Anyone (individuals and non-member companies) can submit a complaint against a member company of the Irish Medtech Association, however, complaints made in relation to non-member companies do not fall within the scope of this Procedure and as such, will not be investigated.

The Code is administered by a Panel Administrator and by a panel of independent individuals ("the Panel") and the Panel is chaired by an independent solicitor/ barrister ("the Chairman"). The Panel or the Panel Administrator may ask the member company whose activities are the subject of a complaint ("the Respondent") for a complete response and may ask the parties to a case for further information in order to clarify the issues.

The company or individual making the complaint ("the Complainant") has the burden of proving their complaint on the balance of probabilities. Any Complainant wishing to use the Procedure must initially attempt to resolve any dispute with the Respondent through the dispute mechanism set out in Section 3 hereunder. Where the Complainant is an individual, they must initially attempt to contact the Respondent to resolve the complaint. They can do so by utilising the Respondent's internal or external whistleblowing and/or dispute resolution procedures, if available.

If such resolution does not prove possible then complaints are initially considered by the Chairman who will determine, if appropriate in consultation with the Complainant and/or Respondent, whether there is a case to answer.

Anonymous complaints (where the Complainant does not wish to disclose their identity to the Panel or Chairman) may be accepted at the discretion of the Chairman, however, the weight to be attached to any evidence may be adversely affected if the source is anonymous, and thus in many instances it will not be possible for such a complaint to proceed. Further detail regarding anonymous complaints is set out in Section 5 hereunder.

Confidential complaints (where the Complainant does disclose their identity to the Panel or Chairman but requests, whether at the outset or during the course of the complaint that their identity remains confidential) will be accepted from non-members. Where confidential complaints are received, the Panel and Chairman will endeavour not to disclose the Complainant's identity, save to the extent disclosure is required by Irish law, governmental or regulatory authority or by a court or other authority of this jurisdiction. However, Complainants wishing to make a confidential complaint should note that the ability of the Respondent to properly respond to information or matters put to them and therefore the Panel's ability to properly adjudicate on any particular complaint, may be adversely affected if the identity of the Complainant is kept confidential. In such circumstances the identity of the Complainant may be required to be disclosed to the Respondent but only with the Complainant's prior permission. If, in these circumstances, the Complainant does not grant permission to disclose their identity, it may not be possible for such a complaint to proceed. Confidential complaints will not be accepted from member companies.

# 2. Structure and Responsibilities

## Role of the Panel

2.1 The Panel will adjudicate in situations where a complaint is made that an Irish Medtech Association member (or an employee of that member) is in breach of one or more of the practices laid out in the Code.

2.2 The Panel and Chairman report to the Irish Medtech Association Board in respect of their activities and the operation and administration of this Procedure.

1. To be finalised

2.3 The Panel and Chairman will not be liable to the Complainant(s) and/or the Respondent(s) in contract, tort (including negligence and/or breach of statutory duty) or otherwise. The Panel and the Chairman will be indemnified in relation to their actions in relation to the Code and the Procedure by the Irish Medtech Association.

## The Panel – Constitution and Procedure

2.4 The Panel is appointed yearly by a majority vote at the Irish Medtech Association AGM (upon nomination by the Board of the Irish Medtech Association) and may comprise of up to five, but not less than four independent experts. In the event that there are five, the areas of expertise should be categorised as follows: Legal, Company/Commercial, Clinical, Patient/Research, Public/Patient interest. In the event of less than five, they should be prioritised in the order above. The names and areas of expertise of the members of the Panel shall be published on the Irish Medtech Association Code of Ethical Business Practice website.

2.5 Panel members agree to serve for a minimum term of 3 years (from the date of adoption of the Procedure by the Board (12 December in 2013)) after which their position is to be filled by rotation in accordance with paragraph 2.4 above. From the outset two Panel members will serve for an initial period of 5 years (from the date of adoption of the Procedure by the Board (12 December in 2013)); those members to whom this pertains to be agreed amongst the Panel members, but the Chairman should be one of these. This extension to the initial period of tenure for two Panel members is required to ensure continuity of the Panel and to maximise the opportunity for rotation. In extenuating circumstances, a Panel member may resign before their term is complete by submitting their resignation in writing to the Chairman. Panel members may be nominated for a further term after the expiration of their initial term.

2.6 The Chairman shall be an independent barrister or solicitor with a minimum of 10 years post-qualification experience. A quorum of 3 Panel members is required for any Panel meeting which must include the Chairman. The Chairman has both an original and a casting vote (the casting vote only to be exercised in the event of a tie in the initial voting).

2.7 Rulings are made on the basis that a Complainant has the burden of proving their complaint on the balance of probabilities.

2.8 Appointees to the Panel must treat as confidential all information with which they come in contact as members. Members of the Panel will be required to sign a Confidentiality Agreement, which will survive their tenure as members of the Panel.

2.9 Panel members are required to declare any conflict of interest with regards to any case which comes before the Panel and to excuse themselves from the case in question in the event of such a conflict. In the event that the Chairman of the Panel has a conflict, the Board of the Irish Medtech Association will appoint another member of the Panel to act in the role of Chairman.

2.10 Panel members will be required to sign an agreement ("the Panel Agreement") which will detail their appointment to the Panel and their duties and terms. This agreement will be counter-signed by the chairman of the Board of the Irish Medtech Association.

2.11 The Panel may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel, but have no voting rights. Each such expert shall also be required to confirm that they have no conflict of interest in providing expert assistance on any particular case.

2.12 A complaint made under the Code and the Procedure should not be initiated, or should be suspended, in case of initiation of formal court, arbitration or other tribunal proceedings with respect to the same subject matter. Where a governmental or regulatory investigation or criminal proceedings are either initiated, or threatened, against a Complainant or a Respondent with respect to the same subject matter, that party shall notify the Chairman of the same in confidence, and the Chairman shall then have the discretion whether or not to suspend any relevant proceedings under the Procedure.

2.13 At any time during a complaint handling process the Chairman or the Panel shall be entitled to refer questions of interpretation of the Code, in writing, to the MedTech Europe Compliance Panel. The MedTech Europe Compliance Panel may, at its discretion, either decline to entertain the matter if it is felt that no question of principle is at issue, or it may accept the interpretation referral and review and provide guidance on the interpretation of the Code. Where such a request has been made, the Chairman and the Panel shall be obliged to follow and apply any such guidance provided by the MedTech Europe Compliance Panel, unless so doing would conflict with Irish law. For the avoidance of doubt the MedTech Europe Compliance Panel shall not rule on the merits or facts of any particular complaint but only on questions of interpretation of the Code.

# 3. Complaints Procedure

## Action on Complaints

3.1. NOTE: Prior to lodging a formal complaint against a Respondent under the Procedure, a Complainant company shall first comply with the dispute resolution procedure outlined in paragraph 3.2 below with the Respondent and, if necessary, enter into mediation. Mediation shall be a pre-condition before a complaint can be progressed to the Panel utilising the Procedure and any such Complainant shall adduce sufficient evidence to the Panel Administrator or the Chairman to prove such mediation has been undertaken.

3.2. If a dispute arises between companies in connection with an alleged contravention of the Code, the Managing Directors or equivalent of the respective companies, with authority to settle the dispute will, within 14 days (or such other time as may be agreed between the parties) of a written request from one company to the other(s), meet in a good faith effort to resolve the dispute.

3.3. If the dispute is not resolved at that meeting, the companies involved will, unless otherwise agreed, attempt to settle the dispute by mediation in accordance with the Centre for Effective Dispute Resolution ("CEDR") Model Mediation Procedure. Unless otherwise agreed between the companies, the mediator will be nominated by CEDR. To initiate the mediation a company must give notice in writing ("Mediation Notice") to the other company to the dispute requesting mediation. The mediation will start not later than 30 days, (or such other time as may be agreed between the parties and the mediator), after the date of the Mediation Notice.

3.4. No Complainant may commence any court, arbitration or tribunal proceedings in relation to any dispute arising from the Code until it has attempted to settle the dispute by negotiation in accordance with paragraph 3.2 above and/or mediation in accordance with paragraph 3.3 above and either the negotiation or the mediation has terminated or the Respondent has failed to participate in the negotiation or mediation, provided that the right to issue proceedings is not prejudiced by a delay (e.g. by the Statute of Limitations).

3.5. Where the Complainant is an individual, they must initially attempt to contact the Respondent to resolve the complaint. They can do so by utilising that company's internal or external whistleblowing and/or dispute resolution procedures, if available. If no amicable resolution of the complaint can be reached through such means within a reasonable timeframe, the Complainant shall be entitled to pursue the matter further directly via this Procedure.

3.6. Any individual or company making a complaint under the Procedure that is not a member of the Irish Medtech Association shall be required, for the duration of the Procedure, to undertake to abide by the provisions of the Procedure as a pre-condition before a complaint can be made utilising the Procedure.

3.7. Three hard copies of the complaint (draft template available online www.irishmedtechassoc.ie/ethics[2] ) to be dealt with by the Panel shall be submitted in writing, in English and in hard copy to the Panel Administrator (at Irish Medtech Association Code of Ethical Business Practice Panel Administrator, Irish Medtech Association, Ibec, 84-86 Lower Baggot Street, Dublin 2), by way of registered post and shall include at a minimum:-

- the name in full, description and address of the Complainant and Respondent;
- proof of compliance with paragraph's 3.1 to 3.3 or if applicable, paragraph 3.5 above;
- detailed description of the nature and circumstances of the dispute giving rise to the complaint(s);
- reference to the provisions of the Code allegedly infringed (except in the case of an individual Complainant, where the Panel will examine the complaint and determine which clauses of the Code have been breached);
- detailed reasoning explaining the nature of the alleged infringement;
- a statement of the relief sought (except in the case of an individual Complainant, where the Panel will examine the complaint and determine the appropriate relief); and
- supporting documentary evidence.

3.8. Having checked that the documentation is fully complete, the Panel Administrator will forward the complaint to the Chairman in the first instance. The date of the receipt of the complaint shall be the date of confirmed receipt of the complaint by the Panel Administrator.

3.9. The Chairman shall undertake an initial review of the complaint and will determine (if appropriate, in consultation with the Complainant and/or Respondent)

2. Check before finalising.

whether there is a prima facie case to answer. The Chairman will complete the initial review within 15 days or such other time as may be agreed between the parties and the Chairman. When determining whether to proceed with anonymous complaints, the Chairman will follow the process set out in paragraph's 5.6 and 5.7 below.

3.10. If, in the view of the Chairman, a complaint does not show that there has been a prima facie breach of the Code, the Complainant and the Board of the Irish Medtech Association shall be so advised. The Chairman's decision in this regard shall be final.

3.11. In the event that the Chairman determines that there is a prima facie case to answer, then the Chairman shall write to the Managing Director or equivalent of the member company against whom the complaint has been made requesting that that member company ("the Respondent") provide a complete response to the complaint.

3.12. The Respondent shall provide a response in writing to the Chairman within 30 working days or such other time as may be agreed between the parties and the Chairman. If no such response is provided by the Respondent within these timescales then the Panel shall make its ruling on the basis of the information provided by the Complainant only.

3.13. Following receipt by the Chairman of the Respondent's response, the case shall be referred to the Panel to rule whether or not there has been a breach of the Code.

3.14. To assist member companies in ensuring that a complete response is submitted, the Chairman may suggest relevant supporting material to be supplied, although it is the responsibility of the Respondent to ensure that a full response is submitted.

3.15. In addition, the Chairman may request (whether at the suggestion of the Complainant or Respondent or at the behest of the Panel) such further clarifications or documents from either the Complainant (except in the case of anonymous complaints) or the Respondent, or any third party within such reasonable timescale as he shall deem prudent and necessary to assist the Panel in making its ruling or when assessing whether there is a prima facie case to answer in accordance with paragraph 3.9 above.

3.16. The Panel may, at its sole discretion, join several complaints into a single procedure, if the Panel decides that the subject matter of the complaints is identical or sufficiently connected.

# 4. Panel Rulings

4.1. Where the Panel rules that there has been a breach of the Code, the Panel shall advise the Complainant and the Respondent, and the Board of the Irish Medtech Association of such ruling in writing and give their reasons for the ruling. The Respondent must pay, within thirty working days, an administrative charge based on the costs incurred in respect of the Panel meetings, and including the cost of expert advice (if any) as required by the Panel.

4.2. The Respondent must also provide to the Panel Administrator a written undertaking within thirty days or such other time as may be agreed between the parties and the Chairman, that the breach of the Code in question (if not already discontinued) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the Managing Director or equivalent of the Respondent and must be accompanied by details of the actions taken by the Respondent to implement the undertaking, including dates and timings and training undertaken or planned completion dates.

4.3. Where the Panel rules that there is no breach of the Code, the Panel shall advise the Complainant and the Respondent, and the Board of the Irish Medtech Association of such ruling in writing and give their reasons for the ruling.

4.4. In addition to the foregoing, the Panel may impose sanctions on the Respondent (in the event of its breach of the Code) or the Complainant (in the event of no breach of the Code and the company is a member company) as appropriate in respect of any particular complaint. The Panel may:

- issue a formal letter of reprimand to the member company;
- issue a formal letter of reprimand to the member company and also direct the Board of the Irish Medtech Association to suspend that member company from membership of the Irish Medtech Association for a specified period and/or to impose conditions for readmission;
- request the Board of the Irish Medtech Association to expel the offender from the Association.

4.5 Rulings of the Chairman or the Panel in relation to any complaint coming before him or it, and the sanctions to be imposed, shall be final and not subject to any appeal, or review, under the Code.

Note: The Panel will notify the Board of the Irish Medtech Association of the imposition by it of any sanction under the Code.

The Board of the Irish Medtech Association will notify the membership of the Irish Medtech Association in the event that a member company is suspended or expelled from membership of Irish Medtech Association.

# 5. General Provisions

## Amendments to Time Periods

5.1. The Chairman shall, in extenuating circumstances and at his discretion, be entitled to grant any party to this Procedure an extension in time or amend any timescales specified in this Procedure to the extent that to do so would be fair and reasonable in the circumstances.

## Withdrawal of Complaints

5.2. A complaint may be withdrawn by a Complainant with the consent of the Respondent company up until such time as the Panel makes a ruling but not thereafter. In such case, the Complainant shall pay an appropriate administrative charge.

## Charges

5.3. The administrative charge referred to in paragraph 4.1 above is determined by the Chairman based on the costs of formally convening the Panel and in dealing with the complaint.

5.4. Where two or more companies are ruled in breach of the Code in relation to a matter involving a joint activity, each company shall be separately and jointly liable to pay any administrative charge that is payable.

5.5. Failure to pay any of the administrative charges must be reported by the Panel Administrator, to the Board of the Irish Medtech Association.

## Anonymous Complaints

5.6. While anonymous complaints are accepted at the discretion of the Chairman, the weight to be attached to any evidence may be adversely affected if the source is anonymous, and thus in many instances it will not be possible for such a complaint to proceed. The Panel Administrator will first forward the complaint to the Chairman who will undertake an initial review to assess whether or not to accept the complaint. This will involve assessing whether there is a prima facie case to answer and if there is enough evidence and/or information available to fully adjudicate on the complaint. The process set out in Paragraphs 3.8 to 3.16 will also apply to anonymous complaints.

5.7. The Chairman will consider the following factors when determining whether to accept an anonymous complaint:

- the significance/seriousness of the complaint;
- whether sufficient information has been provided to assess the anonymous complaint and respond appropriately;
- the potential to obtain independent information; and
- the potential for ongoing risk if the anonymous complaint is not assessed.

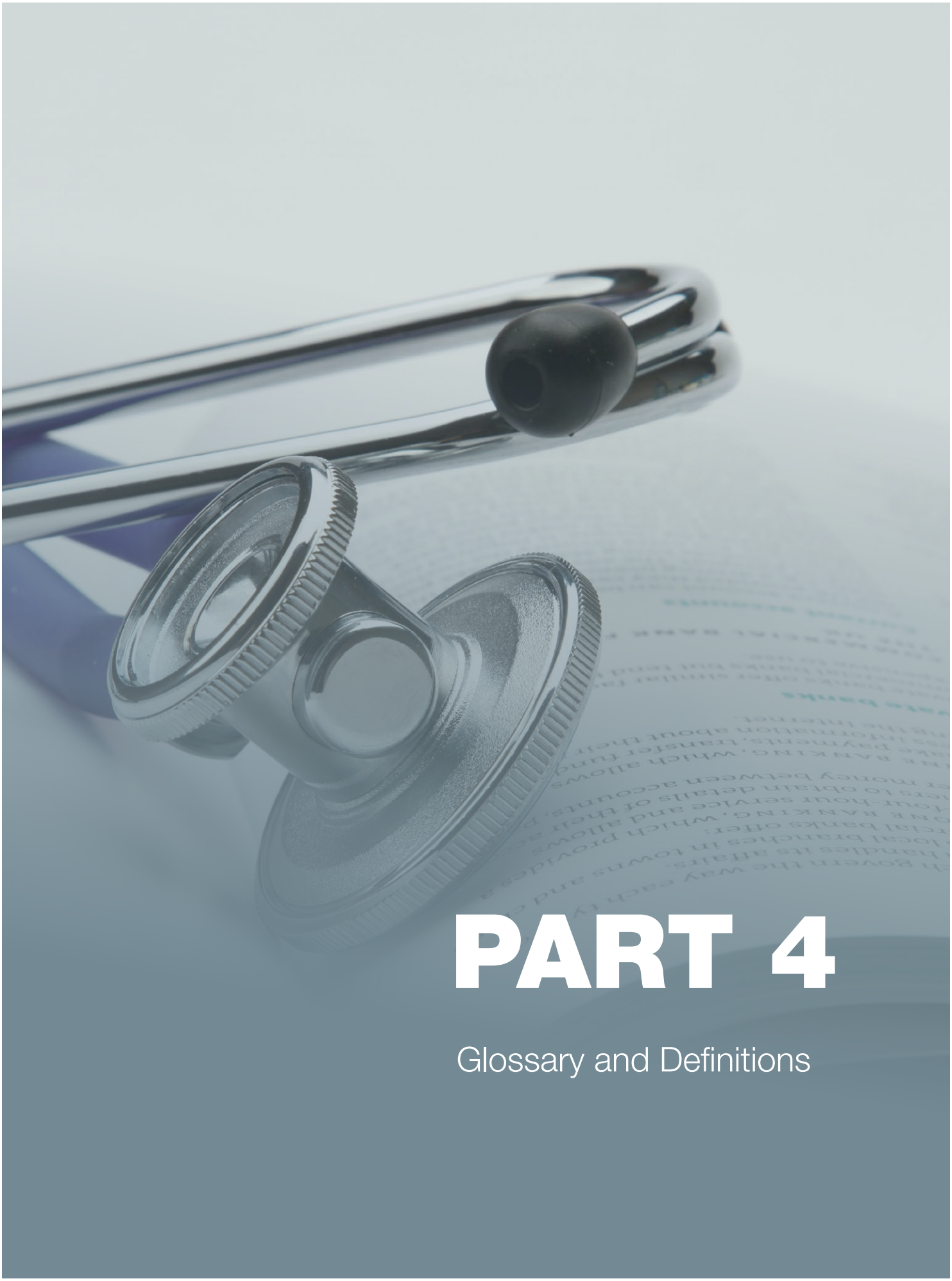
5.8. Anonymous Complainants do not have the right to challenge the outcome of either the Chairman or the Panel's decision or be kept informed of the progress of the Complaint.

## Amendments to the Code and the Procedure and Governing Law

5.9. The Code and the Procedure may be amended by a simple majority of those present and voting at a Board meeting of the Irish Medtech Association.

5.10. The Chairman and/or the Panel may, in the light of their experience, make recommendations for amendment of the Code and the Procedure.

5.11. The Code and the Procedure are governed by, and subject to, the laws of the Republic of Ireland.



# PART 4

## Glossary and Definitions

**Charitable Donations:** means provision of cash, equipment, company product or relevant Third Party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made on an unrestricted basis and to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

**Company Events:** means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the Member Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organisations.

**Conference Vetting System (CVS):** means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: http://www.ethicalmedtech.eu.

**Code:** means this Irish Medtech Association Code of Ethical Business Practice (including the incorporated Questions and Answers), the Disclosure Guidelines and the Complaints Procedure and Panel Constitution.

**Disclosure Guidelines:** means the Code provisions setting out the public disclosure requirements under the Code.

**Demonstration Products (Demos):** means either single-use or multiple-use products provided free of charge by or on be- half of a Member Company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

- Samples;
- Evaluation Products;
- Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

**Educational Grants:** means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.

**Employer Notification:** means the prior written notification provided to a Healthcare Organisation (e.g. hospital administra- tion), a Healthcare Professional's superior or other locally-designated competent authority of any interaction, collaboration or other matter concerning any Member Company and any Healthcare Professional, the purpose and/or scope of which requires notification under this Code.

**Entertainment:** Entertainment includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute Entertainment.

**Evaluation Products:** means either single-use or multiple-use products and/or equipment provided free of charge to a health- care institution by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose, as per the authorisation in the country where the supply occurs. Evaluation Products do not include the following:

- Demos;
- Samples;
- Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

**Event:** means either a Company Event or Third Party Organised Educational Event.

**Faculty:** means a podium speaker, moderator and/or chair, who presents during a Third Party Organised Educational Event. Poster- and abstract-presenters are not considered to be Faculty.

**Financial Hardship:** means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisa- tion's funds or other matters within its control is not considered to be financial hardship. Financial Hardship must be documented and objectively substantiated.

**Grants:** means either an Educational Grant or a Research Grant, or both.

**Guests:** means spouses, partners, family or guests of Healthcare Professionals, or any other person who does not have a bona fide professional interest in the information being shared at an Event.

**Healthcare Organisation (HCO):** means any legal entity or body (irrespective of its legal or organisational form) that is a

-healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription,

-recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching -in- stitution or learned or professional society (except for patient organisations); or through which one or more Healthcare -Profes- sionals provide services.

**Healthcare Professional (HCP):** means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services.

**Members:** means all member companies of the Irish Medtech Association.

**Professional Conference Organiser (PCO):** a for-profit company or organisation which specialises in the management of congresses, conferences, seminars and similar events.

**Product and Procedure Training and Education Event:** means a type of Company Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:

- The safe and effective use of medical technologies, therapies and/or related services, and/or
- The safe and effective performance of clinical procedures, and/or
- Related disease areas.

In all cases the information and/or training directly concern a Member Company's medical technologies, therapies and/or related services.

**Research Grants:** means the provision by or on behalf of a Member Company of funding, products/equipment and/or in kind services to any organisation that conducts research which is made for the sole, restrictive purpose of supporting the development or furtherance of bona fide, scientifically valid and legitimate research by the recipient the purpose of which is to advance medi-cal, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve patient outcomes.

**Sales, Promotional and Other Business Meetings:** means any type of Company Event the objective of which is to effect the sale and/or promotion of a Members Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use and/or commercial terms of supply.

**Samples:** means single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:

- Demos;
- Evaluation Products;
- Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

**Scholarships and Fellowships:** means Educational Grants provided to a Healthcare Organisation by or on behalf of a Mem- ber Company to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). "Scholars" and "Fellows" shall be understood accordingly.

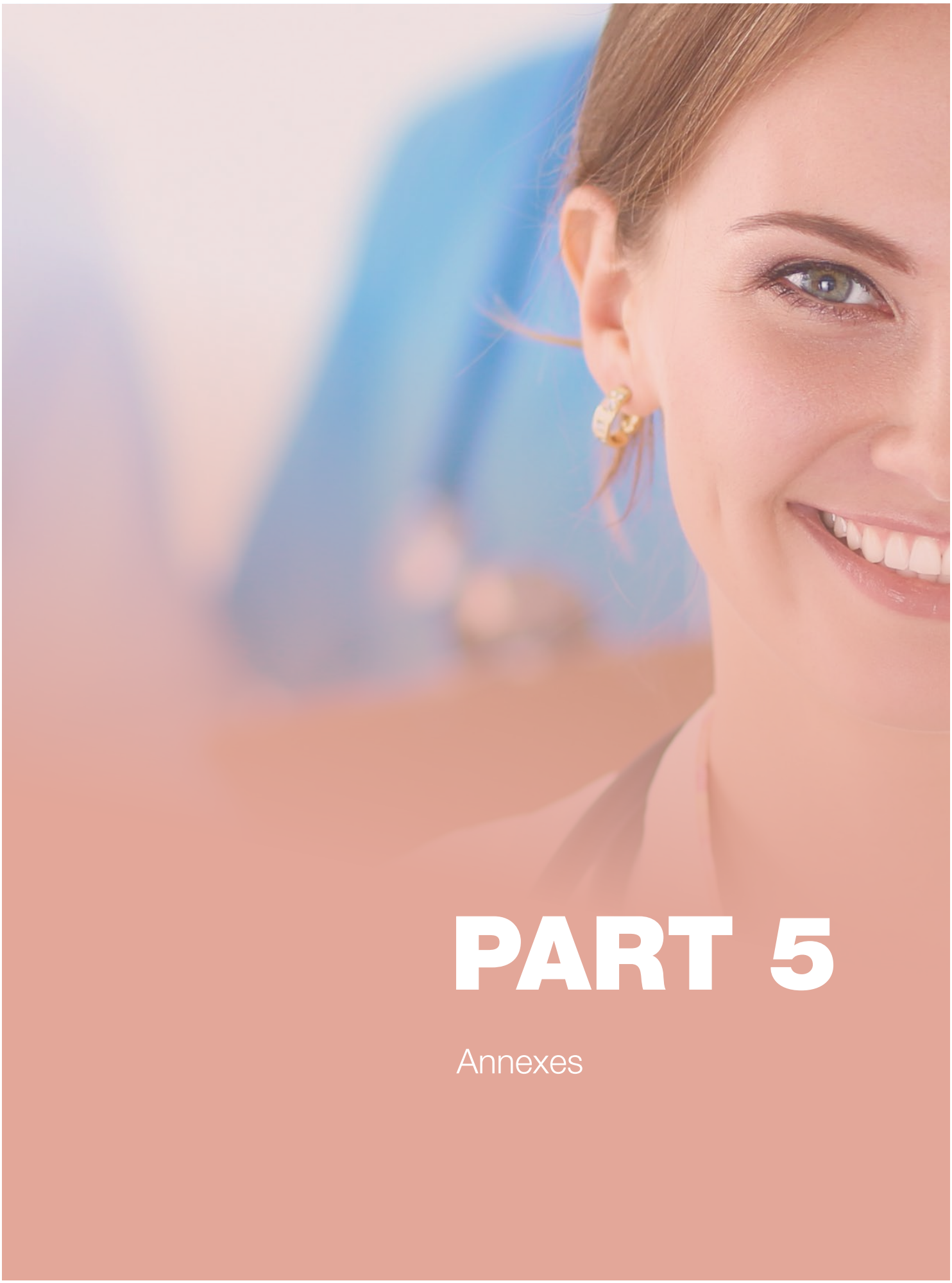
**Third Party Organised Educational Events:** means activities of any type that are planned, budgeted, managed and ex- ecuted in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.

**Third Party Organised Educational Conferences:** means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, Professional Conference Organisers (PCOs), patients organisations or accredited -continuing medical education providers.

**Third Party Organised Procedure Training:** means a type of Third Party Organised Educational Event that is primarily in- tended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third Party Organised Procedure Training.



# PART 5

## Annexes

# ANNEX I (added in October 2016)

## CVS scope: When are CVS assessments required?

| WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS? | | **NATIONAL**<br><br>Third Party Organised Educational Events attended by delegates which are local HCPs only) | **INTERNATIONAL**<br><br>(Third Party Organised **MedTech Europe** Geographic Area[1],[2]) | **INTERNATIONAL**<br><br>(Third Party Organised Professionals registered and practising in the **MedTech Europe** Geographic Area[3]) | **INTERNATIONAL**<br>(Third Party Organised Educational Events to which no Healthcare Professionals registered and practicing in the **MedTech Europe** Geographic Area attend, neither as speakers or delegates) |
|---|---|---|---|---|---|
| EDUCATIONAL GRANTS[4] PROVIDED | Educational Grant to support the general running of a conference | 2017 – Allowed[5]<br>2018 – Allowed | 2017 – Allowed.<br>Not subject to CVS decision<br>2018 – Subject to CVS decision | 2017 – Allowed.<br>Not subject to CVS decision<br>2018 – Allowed. Subject to CVS decision | Out of scope of the application of the Code[6] |
| TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE | Educational Grants that includes funds to support HCP attendance to the conference | 2017 – Allowed<br>2018 – Allowed | 2017 – Allowed.<br>Not subject to CVS decision<br>2018 – Subject to CVS decision | 2017 – Allowed.<br>Not subject to CVS decision<br>2018 – Allowed. Subject to CVS decision | N/A |
| | Educational Grants that includes funds to support Faculty | 2017 – Allowed<br>2018 – Allowed | 2017 – Allowed. Not subject to CVS decision<br>2018 – Subject to CVS decision | 2017 – Allowed.<br>Not subject to CVS decision<br>2018 – Allowed. | N/A |
| | Consultancy agreement for speakers in satellite symposia | 2017 – Allowed<br>2018 – Allowed | 2017 – Allowed.Not subject to CVS decision<br>2018 – Subject to CVS decision | Not subject to CVS decision<br>2017 – Allowed.<br>Not subject to CVS decision | N/A |
| COMMERCIAL ACTIVITIES | Booths/ advertising | 2017 – Allowed<br>2018 – Allowed | 2017 – Allowed. Not subject to CVS decision<br>2018 – Subject to CVS decision | 2018 – Allowed.<br>Not subject to CVS decision | Out of scope of the application of the Code |
| | Direct sponsorship of HCPs as delegates (passive participation) | 2017 – Allowed<br>2018 – Not allowed | 2017 – Subject to CVS decision<br>2018 – Not allowed | Not subject to CVS decision<br>2018 – Allowed.<br>Not subject to CVS decision | N/A |
| DIRECT SPONSORSHIP OF HCPs REGISTERED AND PRACTISING IN the **MedTech** Geographic Area | Direct sponsorship of HCPs as Faculty (active participation) | 2017 – Allowed.<br>2018 – Not allowed | 2017 – Allowed.<br>Not subject to CVS decision[7]<br>2018 – Not allowed | 2017 – Subject to CVS decision<br>2018 – Not allowed | N/A |
| | | | | 2017 – Allowed. Not subject to CVS decision<br>2018 – Not allowed | |

1. **MedTech Europe** Geographic Area includes the countries in the European Economic Area (EEA), as well as those other countries where Member Associations are located.
2. Formerly referred to as "Cross-border Events".
3. For avoidance of doubt, in 2018, this category of "Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practicing in the **MedTech Europe** Geographic Area" has to be understood as covering only Healthcare Professionals from the **MedTech Europe** Geographic Area benefiting from an Educational Grant.
4. Educational Grants: means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.
5. Allowed means no CVS decision is required but the provisions of the **MedTech Europe** Code of Ethical Business Practice and national laws and regulations still apply.
6. Out of scope: Means the Code does not apply given that the situation does neither involve a Member Company interacting with an HCP or HCO registered and practicing in the **MedTech Europe** Geographic Area nor does the activity take place in the **MedTech Europe** Geographic Area.
7. Please note that although international/cross-border Events are eligible to be submitted in CVS, the decisions rendered by CVS in 2017 will only pertain to the direct sponsorship of HCPs to Third-Party Organised Events.

## ANNEX II (added in May 2016)

Disclosure Guidelines Template Example*

| Full HCO Name | HCO/PCO 1 | HCO/PCO 2 | etc. |
|---|---|---|---|
| HCOs: city where registered | | | |
| Country of Principal Practice / Activity | | | |
| Registered Address | | | |
| Unique country local identifier | | | |
| A. Educational Grants to Support Third Party Organised Events /or to Support HCP Participation at Third Party Organised Educational Events) | Yearly amount | Yearly amount | Yearly amount |
| Object (Optional) | Optional | Optional | Optional |
| B. Other Educational Grants to HCOs (including Scholarships, Fellowships and Grants for Public Awareness Campaigns). | Yearly amount | Yearly amount | Yearly amount |
| Object (Optional) | Optional | Optional | Optional |

* Please note that this template is for illustrative purposes only. The template to be used for reporting purposes is available in the Transparent **MedTech** website.

# ANNEX III (added in May 2016)

## Example of Disclosure Guidelines Methodology Note

**STRUCTURE**

1 - Introduction

2 - Executive summary of the methodologies used for disclosure purposes and countries specificities

3 - Definitions
- Recipients
- Types of Educational Grants

4 - Disclosure scope and timelines

5 - Disclosures in case of partial performance or cancellation

6 - Cross-border activities

7 - Specific considerations:
- Multi-year agreements
- Consent management (please note that some jurisdictions may require the legal entity's consent for publication of data)
- Consent collection
- Management of recipient consent withdrawal
- Management of recipient's request
- Partial consent

8 - Disclosure Form
- Date of submission
- Currency in case of aggregated payments made in different currencies
- VAT included or excluded and any other tax aspects

9 - Disclosure financial data and amount of Educational Grants provided

10 - Calculation rules

Disclaimer: This Methodology note is provided as a template to support Member Companies in the implementation of these Disclosure Guidelines. Any other template may be equally valid provided it complies with the general requirements set out in Section 2.4 Methodology.

# ANNEX IV (added in November 2016)

## MedTech Europe Geographical Area

**The MedTech Europe Geographic Area currently includes**

D) countries with National Associations:

- Austria,
- Belgium,
- Bulgaria,
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- the countries where Mecomed is active
- The Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- The United Kingdom

E) countries party to the European Economic Area agreement without a MedTech Europe National Association:

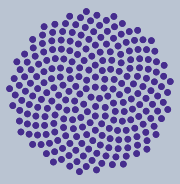
- Croatia
- Cyprus
- Estonia
- Iceland
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta.

3OHDVH QRWH WKDW Fountries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, are not currently under the scope of the Disclosure Guidelines.

## Notes

## Notes

## Notes



Irish Medtech Association

Ibec


**Irish Medtech Association**
84/86 Lower Baggot Street
Dublin 2
T: + 353 1 605 1500
E: info@irishmedtechassoc.ie
W: www.irishmedtechassoc.ie

**Ibec Head Office**
84/86 Lower Baggot Street
Dublin 2
T: + 353 1 605 1500
E: membership@ibec.ie
W: www.ibec.ie/membership

**Galway**
Ross House
Victoria Place
Galway
T: + 353 91 561109
E: galway@ibec.ie
W: www.ibec.ie/west

**Cork**
Knockrea House
Douglas Road
Cork
T: + 353 21 4295511
E: cork@ibec.ie
W: www.ibec.ie/cork

**Brussels**
Avenue de Cortenbergh
89, Box 2
B-1000 Brussels
BELGIUM
T: + 32 (0)2 512.33.33
F: + 32 (0)2 512.13.53
E: europe@ibec.ie
W: www.ibec.ie/europe

**Limerick**
Gardner House Bank
Place Charlotte Quay Limerick
T: + 353 61 410411
E: midwest@ibec.ie
W: www.ibec.ie/midwest

**Donegal**
3rd Floor, Pier One Quay Street
Donegal Town Donegal
T: + 353 74 9722474
E: northwest@ibec.ie
W: www.ibec.ie/northwest

**Waterford**
Waterford Business Park
Cork Road Waterford
T: + 353 51 331260
E: southeast@ibec.ie
W: www.ibec.ie/southeast


Extend Ireland's global reach. Join the conversation.

**@ibec_irl**
**www.linkedin.com/company/ibec**
**www.ibec.ie**

# Appendix 3. MedTech Europe Code

MedTech Europe
from diagnosis to cure

# MedTech Europe Code of Ethical Business Practice

**March 2022**

MedTech Europe
from diagnosis to cure

# About MedTech Europe

MedTech Europe's mission is to make innovative medical technology available to more people, while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations. It also promotes medical technology's value for Europe focusing on innovation and stakeholder relations, using economic research and data, communications, industry events and training sessions.

MedTech Europe started as an alliance in October 2012 formed by two organisations – EDMA, representing the European in vitro diagnostic industry; and Eucomed, representing the European medical devices industry.

Promoting a balanced policy environment
MedTech Europe engages with EU regulators, politicians and other decision-makers to help shape policies to promote innovation for our growing healthcare needs and expectations.

Demonstrating the value of medical technology
MedTech Europe promotes to its members and the wider industry value-based innovations that support more sustainable healthcare systems.
We use economic research to show the benefits of medical technology and we organise many initiatives to explain the value we bring to healthcare systems in Europe. We bring stakeholders together to discuss trends, issues and opportunities.

# Table of Contents

# Scope

# 1. Applicability of the Code

**1.1.** This Code only applies to the Member Companies of MedTech Europe, who are manufacturers of Medical Technology.

As provided by the Statutes of MedTech Europe, Member Companies must comply with the Code (as amended from time to time), as a minimum standard when:

- Member Companies interact with Healthcare Professionals and Healthcare Organisations registered and practising in MedTech Europe Geographic Area irrespective of where the activity takes place; and/or
- Activities take place in MedTech Europe Geographic Area, irrespective of where Healthcare Professionals and Healthcare Organisations are registered and practising.

The MedTech Europe Geographic Area includes the countries in the European Economic Area as well as those countries where Member Associations are located.

**1.2.** The Code shall be directly applicable to all activities of Member Companies and their affiliated companies that carry on activities in the Medical Technology sector in the MedTech Europe Geographic Area within the scope applicability defined in Section 1.1. above. If such affiliated company of a Member Company is also in its own name a member of a Member Association, the respective code of such Member Association shall apply to activities of such affiliated company in addition to the Code, which sets out the minimum standards appropriate to the various types of activities carried out by the Members.

Any activity or interaction described in Section 1.1. above and conducted by an affiliated company of a Member Company located outside the MedTech Europe Geographic Area will be deemed attributable to said Member Company.

**Q1** Is the Code applicable to activities of an affiliate of a Member Company located outside the MedTech Europe Geographic Area?

**A1** With regards to activities of an affiliate of a Member Company located outside of the MedTech Europe Geographic Area the Code is not applicable whenever they:

- support an Event taking place outside the MedTech Europe Geographic Area except if they are supporting participation of Healthcare Professionals registered or practising inside the MedTech Europe Geographic Area to attend the Event, or
- interact with Healthcare Organisations located, or Healthcare Professionals registered or practising outside the MedTech Europe Geographic Area.

However, in the interest of increased transparency, it would always be preferable for the affiliate of the Member Company based in the MedTech Europe Geographic Area to handle support for Healthcare Professionals attending Events held in the MedTech Europe Geographic Area

**Q2** How does the Code apply to members with company platforms that include different business units e.g., medical devices, pharmaceuticals, research only products? How can educational grants be applied in such organizational structures?

**A2** The Code applies to all Member Companies' interactions linked to Medical Technologies. Ensuring compliance with the Code may be more challenging for companies with platforms combining different business units, however Member Companies are required to comply with the Code as a minimum standard for all interactions linked to Medical Technologies independent of their organizational set up.

For example, if a Member were to have Medical Technology marketed under or linked to their pharmaceutical business unit, the interactions with Healthcare Professionals and Healthcare Organisations in relation to this Medical Technology would be governed by the Code irrespective of the business unit that pays for or manages the interaction. In this respect, the Member Company cannot circumvent the Code's requirements by using its pharmaceutical business/affiliate to directly support a Healthcare Professional to attend a Medical Technology-related Third Party Organised Educational Conference as this would amount to a violation of the Code.

For the avoidance of doubt, the Code will not apply to Member Companies' interactions linked exclusively to non-Medical Technology products or services such as medicinal products or research only products, without any link to Medical Technology products. However, this does not mean that different business units can be used to circumvent Code requirements as explained above.

In case an interaction or activity is linked in part to Medical Technology products or services, the Code shall apply.

## 2. Transposition Obligations

### 2.1 New Member Companies

At the time an applicant becomes a Member, it must begin to take all the necessary steps required to meet all membership obligations, including the obligation to comply with the Code.

MedTech Europe recognizes the complexities involved in this process and the time needed to make changes associated with these new obligations. As a result, Corporate Members have one year from the date of membership ratification by the MedTech Europe Board of Directors to fully comply with the Code. This one-year membership transition period does not include an exemption from the Code's ban on direct sponsorship. From the date of membership ratification by the MedTech Board of Directors direct sponsorship of Healthcare Professionals is prohibited (please see Chapter 2 for more information).

As soon as a Member Company transposes the Code internally it shall notify the MedTech Europe Secretariat, specifying the date on which such transposition became effective. The MedTech Europe Secretariat shall appropriately document and maintain records of all such notifications for statistical purposes.

For the avoidance of doubt, this section 2.1 shall also be applicable to membership transition following mergers and acquisitions.

As soon as a Member Company has full control of an acquired company (or part of it) that is not a member of Medtech Europe or any Member Association, or as soon as a Member Company merges with such a company, it shall ensure that no new commitments of direct sponsorship for Healthcare Professionals to attend Third Party Organised Conferences are entered into, and that pre-existing direct sponsorhip arrangements are not renewed.

If there are pre-existing commitments all direct sponsorship of Healthcare Professionalsthe Member Company shall terminate all such agreements when contractually viable.

No direct sponsorship of Healthcare Professionals may take place after one year of the formal date of acquisition or merger, including when the commitment pre-dates the acquisition or merger.

### 2.2 New Association Members

Association Members have one year from the date of membership ratification by the MedTech Europe General Assembly to transpose the Code.

For avoidance of doubt, where an Association membership modifies the MedTech Europe Geographic Scope, as provided by the Code, either by changing its own geographic scope or



when a new Association becomes a member of MedTech Europe, MedTech Europe Corporate Members have one year to comply with the Code in these new territories from the date of the date of the change of the geographical scope of an existing Association or the relevant ratification of membership by the MedTech Europe General Assembly..

After the passage of one year from the date of the relevant General Assembly ratification, all Members must fully comply with all obligations under the Code.

# Administering the Code

Part 2 of the Code includes procedures designed to provide an effective and efficient complaint-handling process, at national and MedTech Europe level, to ensure compliance with the Code. MedTech Europe's dispute handling system is based on the principle that disputes are generally national in nature and are therefore best resolved at national level.

For complaints between Member Companies, mediation should be considered seriously before further pursuit of the matter via any formal complaint handling process, either at national or MedTech Europe level.

The principles outlined in Part 2: Complaint handling and dispute resolution also aim at supporting Member Associations when setting up or amending their national dispute-resolution mechanisms. They are based on principles of proportionality, speed, due process, fairness and transparency and have been established under the guidance of the MedTech Europe Compliance Panel, acting independently of MedTech Europe.

The Code shall be reviewed when required and at a minimum every five (5) years, in accordance with the governance rules of MedTech Europe.

## 1. The Conference Vetting System

The Conference Vetting System is an independently-managed system which reviews the compliance of Third Party Organised Educational Events with the Code.

Conference Vetting System (see the Glossary) has been established as the online, binding and centralised decision-making process to help Member Companies review the compliance of relevant Third Party Organised Educational Events with the Code. It is managed independently of the MedTech Europe Secretariat and Members and is under the supervision of the MedTech Europe Compliance Panel.

The Conference Vetting System approval is required for Members to support Third Party Organised Educational Events which fall within its scope, as provided in Annex I.

Where there is a Conference Vetting System decision in relation to a specific Third Party Organised Educational Event, this decision is binding upon all Member Companies.

## 2. MedTech Europe Code Committee

The MedTech Europe Code Committee shall assist Member Associations and Member Companies to comply with their obligations under the Code, including the dispute resolution principles set out in Part 2 of the Code.

As a key part of its role, the MedTech Europe Code Committee shall promote the Code, monitor the adoption of compliant national codes, including preparation of updates to the MedTech Europe Board and assist Member Companies and Member Associations to share best practice and harmonised interpretation of the Code and its dispute resolution principles.

The MedTech Europe Code Committee will be composed of:

- at least one (1) but up to three (3) representatives of the MedTech Europe Legal Affairs Committee, elected in accordance with its own procedures, with a preference for the members of the MedTech Europe Legal Affairs Committee's Steering Committee
- nine (9) representatives of the MedTech Europe Ethics & Compliance Committee, elected in accordance with its own procedures
- the Chair of the MedTech Europe Ethics & Compliance Committee
- at least one (1) but up to three (3) representatives from Member Associations, elected in accordance with its own procedures

- In addition, the Code Committee may co-opt up to four (4) other members from the MedTech Europe Legal Affairs Committee and the MedTech Europe Ethics & Compliance Committee, where the Code Committee is satisfied that the concerned members will positively enhance the representativeness, operation and objectives of the Code Committee.
- Only one representative from a Member may be a member of the Code Committee at any given time
- The MedTech Europe Compliance Panel and the Conference Vetting System officers shall automatically be non-voting members of the Code Committee
- The Code Committee may invite external lawyers as standing non-voting members, as needed.

The Code Committee will elect its Chair from among the members of the group for renewable periods of two years, or until the Chair ceases to be a member of the Code Committee. The Chairs of other MedTech Europe committees are not eligible to be at the same time Chair of the Code Committee.

## 3. MedTech Europe Compliance Panel

**1. Tasks**

The MedTech Europe Compliance Panel shall have the following tasks:

- Supervise the MedTech Europe Conference Vetting System.
- Review consistency with the Code of interpretations of national panels of nationally applicable codes of conduct, upon request of the MedTech Europe Code Committee;
- Provide guidance to Member Associations on the dispute resolution principles set out in Part 2 of the Code;
- Interact, upon request of the Secretariat, with relevant MedTech Europe groups to further develop the Code and guidance documents;

The MedTech Europe Board may allocate additional tasks to the MedTech Europe Compliance Panel as deemed appropriate.

As an independent body, the MedTech Europe Compliance Panel shall be entitled to report to the MedTech Europe Code Committee any concerns that it might encounter in the exercise of its functions.

**2. Composition**

The MedTech Europe Compliance Panel will be composed of at least three individuals.

These shall include not only persons having industry experience but also for obvious reasons of independence, transparency and expertise, persons whose knowledge will contribute to the proper functioning of the MedTech Europe Compliance Panel, such as other relevant stakeholders and whose position may not raise potential conflicts of interest, in particular as regards complaint handling processes.

The chair of the MedTech Europe Compliance Panel must have a legal background. Neither the chair nor any member of the Compliance Panel can be employed by, or be contracted as a consultant for, a Member Company or an entity affiliated to a Member Company or by a Member Association or a company member of such Member Association. For avoidance of doubt, holding a position on the Board of Directors of a Member Association without any consulting or employment relationship with a Member Company shall not be considered a consultant or employee relationship with the concerned Member.

If for any reason a potential conflict of interest of a member of the MedTech Europe Compliance Panel occurs, then the concerned member shall refrain from participating in the specific complaint handling and decision process.

The term of office of the MedTech Europe Compliance Panel members will be three years, renewable twice. The chair shall appoint two other individuals for the MedTech Europe Compliance Panel, after consultation with and consent of the MedTech Europe Code Committee and the MedTech Europe Secretariat. The term of office of the two other MedTech Europe Compliance Panel members will also be three years and may be renewed twice by the chair, after consultation with and consent of the MedTech Europe Code Committee and the MedTech Europe Secretariat.

Notwithstanding the foregoing, the MedTech Europe Board may decide on different terms of office in order to ensure a staggered rotation of the three MedTech Europe Compliance Panel members, provided, however, that the MedTech Europe Compliance Panel member has given his/her consent.

**3. MedTech Europe Compliance Panel Internal Procedural Rules**

The MedTech Europe Compliance Panel may develop, after consultation with and consent of the MedTech Europe Code Committee, Internal Procedural Rules to hear and decide on disputes or questions of interpretation. These Internal Procedural Rules shall be based on the principles of Part 2 of the Code.

# 4. Interpreting the Code

The use of capital letters indicates that a word or expression is a defined term, the meaning of which is set out in the Glossary.

Any phrase introduced by the terms: including, include, in particular, or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.

# Introduction

## Promoting an Ethical Industry

MedTech Europe is the only European trade association representing the medical technology industry from diagnosis to cure. We represent in-vitro diagnostics and medical devices manufacturers operating in Europe. Our mission is to promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders.

MedTech Europe recognises that compliance with applicable laws and regulations as well as adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the medical technology industry.

The Code sets out the minimum standards appropriate to the various types of activities carried out by the Members. The Code is not intended to supplant or supersede national laws or regulations or professional codes (including industry, Member Company and HCP codes) that may impose more stringent requirements upon Members and all Members should independently ascertain that their activities comply with all current national and local laws, regulations and professional codes.

## Key Legislation

The medical technology industry in Europe, in common with other industries, is subject to national and supranational laws which govern many aspects of their business operations. MedTech Europe underlines compliance with the following laws and regulations as having particular relevance to the medical technology industry:

- Safety, Quality and Performance Laws;
- Advertising and Promotion Laws;
- Data Protection Laws;
- Anti-corruption Laws;
- Environmental Health and Safety Laws;
- Competition Laws.

National and European Union (EU) competition legislation applies not only to Members in their business operations, but also to MedTech Europe, each of the alliance's working groups

and any sub-group within the associations, irrespective of size and name. Liability under competition laws may be strict and a Member may become liable for the infringement of such laws by other Members of an association group in which it participates. Accordingly, Members must make every effort to observe EU and national competition laws in all their interactions.

## Aims and Principles of the Code

The interaction between Members and Healthcare Professionals and Healthcare Organisations is an important feature in achieving MedTech Europe's mission to make safe, innovative and reliable technology and related services available to more people. For example:

- **Advancement of Medical Technologies**
  The development of innovative MedicalTechnologies and the improvement of existing Medical Technology require collaboration between Member Companies and Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of Medical Technologies and/or related services.

- **Safe and Effective Use of Medical Technology**
  The safe and effective use of Medical Technology and related services requires Member Companies to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support.

- **Research and Education**
  Member Companies' support of bona fide medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new Medical Technologies and/or related services.

In each such interaction Member Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry. To achieve this aim, the Code provides guidance on the interactions of Member Companies with both Healthcare Professionals and Healthcare Organisations, based upon the following underlying principles:

- **The Principle of Image and Perception**: Member 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 Organisations.

• **The Principle of Separation**: Interaction between industry and Healthcare Professionals/ Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies' Medical Technology or related services.

• **The Principle of Transparency**: Interaction between industry and Healthcare Professionals/ Healthcare Organisations must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, Member Companies shall nevertheless maintain appropriate transparency by requiring prior written notification to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction.

• **The Principle of Equivalence**: Where Healthcare Professionals are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must be commensurate with, and represent a Fair Market Value for, the services performed by the Healthcare Professional.

• **The Principle of Documentation**: For interactions between a Member Company and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a Member Company, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Member Company. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the Member Company for a reasonable period of time to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

**Q3** Must a Member Company require Employer Notification to be given whenever Company personnel meet HCPs at an HCO?

**A3** No. Unless the Member Company's interaction with an HCP entails a transfer of value or raises a potential conflict of interest there is no requirement for Employer Notification. However, Member Companies must comply with any access requirements imposed by HCOs to visiting Member Company personnel.

# Chapter 1: General Criteria for Event

Member Companies may directly finance the costs of Healthcare Professionals that are Delegates to Company Organised Educational Events and Third Party Organised Procedure Training meetings provided this is in accordance with local professional codes, laws and regulations, and the requirements in Chapters 1, 2 and 3 of the Code.

Member Companies may also support attendance of Healthcare Professionals as Delegates and Faculty to other Third Party Organised Educational Events through Educational Grants in accordance with the rules of Chapters 1, 2 and 4 of the Code. They may also purchase promotional and advertising space at Third Party Organised Educational Events in accordance with the the requirements of Chapter 2 of the Code.

Member Companies may also finance the attendance costs of Healthcare Professionals attending as Faculty at satellite symposia at Third Party Organised Educational Events, as well as of Healthcare Professionals providing speaker services at Company Organised Events provided this is in accordance with the rules of Chapter 5: Consulting Agreements.

The principles and criteria set out in this Chapter 1 shall apply to all such Events supported in any way by Member Companies, irrespective of who organises the Event.

# 1. Event Programme

The Event programme should directly relate to the specialty and/or medical practice of the Healthcare Professionals who will attend the Event or be sufficiently relevant to justify the attendance of the Healthcare Professionals.

The detailed programme should be available in sufficient time prior to the Event, present a clear schedule with no gaps during the sessions in the case of in-person Events, including hybrid events, (e.g., the minimum duration for a full day for an in-person Event should be 6 hours or 3 hours for a half day for an in-person Event including refreshment breaks).

The Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.

For Third Party Organised Educational Events, the agenda should be under the sole control and responsibility of the third party organiser.

A Member Company shall not organise Events which include social, sporting and/or leisure activities or other forms of Entertainment, nor support such elements where part of Third Party Organised Educational Events. For Third Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the Third Party Organised Educational Event.

# 2. Event Location and Venue

The Event location and venue should not become the main attraction of the Event. For the location and the venue, Member Companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an Entertainment venue.

**Q4** Do the minimum duration requirements of Section 1 of Chapter 1 apply to Virtual Events?

**A4** No, Virtual Events are not affected by the duration requirements of Section 1, Chapter 1 of the Code.

**Q5** Can a Member Company organise or support an Event at a hotel or resort that offers significant leisure facilities such as golf, casino or ski/ water sports?

**A5** In principle no. It is not appropriate for a Member Company to organise or support Events at hotels or resorts renowned for their entertainment facilities or centred around recreational or sporting activities such as golf, private beach or ski/water sports. Exceptions might be considered for venues well adapted to business meetings in an otherwise compliant geographic location where there is a compelling need to use the chosen venue, for example, a lack of alternative venues or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the Third-Party Organised Event venue might be required for compliance.

Where an exception is considered, the Event's promotional material should not feature or promote the on-site leisure aspects of the conference venue and the Event's agenda should be arranged in such a way that attending Healthcare Professionals would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals. For reasons of perception, cruise ships or hotels with on-site casinos are under no circumstances compliant with the Code, either as an Event venue or for accommodation for Healthcare Professionals.

- The Event location and venue should be centrally located when regard is given to the place of residence of the majority of invited participants.
- The need for ease of access for attendees.
- The Event location and venue should be in or near a city or town which is a recognised scientific or business centre, suitable for hosting an Event which is conducive to the exchange of ideas and the transmission of knowledge.
- Member Companies must take into account the season during which the Event is held. The selected time of year must not be associated with a touristic season for the selected geographic location.

## 3. Guests

Member Companies are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for Guests of Healthcare Professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the Event.

**Q6** Under the Code, what is meant by "ease of access" in relation to Event location and venue?

**A6** When the originating location of the majority of attendees is considered, Event location and venue need to be in close proximity to an airport and / or train station with appropriate international connections, with associated reliable ground transportation infrastructure to the venue.

**Q7** Under the Code, how does the "season" impact evaluation of Event location?

**A7** Even assuming a location or venue meets all other applicable requirements under the Code, geographic locations renowned primarily as seasonal vacation or holiday destinations (for example, ski-, island-, or beach resorts) are still not appropriate locations during the season in question. For this purpose, in Europe, the ski season is considered to run from December 20 - March 31 and the summer season from June 15 - September 15. Equivalent, seasonally adjusted dates apply in other regions of the world. Member Companies must not support or organise Events at these locations if they take place during those seasons, even if only in part.

**Q8** What does the term "facilitate" mean where used in connection with Guest expenses?

**A8** The term "facilitate" refers to the prior arrangement, organisation or booking of meals, travel or accommodation by or on behalf of a Member Company on behalf of a Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in their own right, irrespective of who pays. Such actions are open to misinterpretation. If Healthcare Professionals attending the Event wish to be accompanied by a Guest who does not have a professional interest in the information being shared, the Healthcare Professional must take sole responsibility for the payment and organisation of the Guest's expenses.

**Q9** In the event that a Healthcare Professional is accompanied by a Guest at the Event, may this Guest be admitted to any Company Event, or Third Party Organised Educational Events?

**A9** It is not appropriate for a Guest of a Healthcare Professional to attend either Company Events (including satellite symposia) or Third Party Organised Educational Events (unless the individual qualifies as a participant in their own right), nor is it appropriate, in the interest of maintaining scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches, industry booths and coffee breaks) even when the Healthcare Professional pays for the Guest's expenses.

## 4. Reasonable Hospitality

Member Companies may provide reasonable hospitality to Healthcare Professionals in the context of Company Events and Third Party Organised Educational Events when they are attending the Event in person, but any hospitality offered must be subordinate in time and focus to the Event purpose (no home delivery is permitted, for example through catering or food delivery services to the HCPs' home). Member Companies must in any event meet the requirements governing hospitality in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the Event is being hosted.

The Code seeks to find a balance between the courteous and professional treatment of Healthcare Professionals by Member Companies, with the desire to avoid even the appearance that hospitality may be used by Member Companies as a means to induce Healthcare Professionals to purchase, prescribe or recommend Member Companies' Medical Technology or related services.

Accordingly, Member Companies must assess what is "reasonable" in any given situation and regional variations will apply. As a general guideline, "reasonable" should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations and professional codes of conduct. The term "hospitality" includes meals and accommodation and it is important that Member Companies differentiate between "hospitality" which is permitted and Entertainment which is not. Please refer to the Glossary for the definition of Entertainment.

Member Companies may not pay for or reimburse Healthcare Professionals' lodging expenses at top category or luxury hotels. For the avoidance of doubt, if the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Member Companies to offer participants meals and accommodation at the same hotel. However, accommodation and/ or other services provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event, unless when required by travel arrangements in relation to Company Organised Events arranged around Third Party Organised Educational Events (See section 3 of Chapter 2).

Member Companies, however, may financially support Third Party Organised Educational Events which offer extra-curricular programmes / activities beyond the scientific, educational or training sessions for Guests of Healthcare Professionals (such as touristic activities and hospitality), always provided that such an extra-curricular programme/activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, facilitated or reimbursed by, a Member Company.

**Q10** Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a Healthcare Professional for a specific amount to cover all or part of the Healthcare Professional's travel or accommodation expenses for attendance at the Event?

**A10** It is not acceptable to make an advance payment to a Healthcare Professional to cover prospective expenses. Payments should generally be made to the supplier/ vendor or intermediary agency. Alternatively Member Companies may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts.

## 5. Travel

Member Companies may only pay or reimburse for reasonable and actual travel. Travel provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event, unless when required by travel arrangements in relation to Company Organised Events arranged around Third Party Organised Educational Events (See section 3 of Chapter 2).

For air travel, in principle, this means that Member Companies can only pay or reimburse economy or standard class unless the flight time is of a duration of greater than 5 hours including connection flights, in which case business class can be considered. First class is never appropriate.

## 6. Transparency

Member Companies must ensure full compliance with national laws or regulations with regard to the disclosure or approval requirements associated with support and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, as a minimum, by requiring Employer Notification (as defined in the Glossary) be made prior to the Event whenever a Member Company engages a Healthcare Professional or whenever a member makes a financial contribution to the Healthcare Professional's medical education.

Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest promotional items related to the Healthcare Professional's practice or for the benefit of patients, do not require Employer Notification.

## 7. Virtual Events

Virtual Events must comply with any part of the Code that is by its nature applicable to them. Therefore, Member Companies may provide financial and/or In Kind support (e.g. Member CompanyMedical Technology) to Virtual Events in accordance with the rules of Chapters 1, 2, 3 and 4 of the Code.

**Q11** Are members required to provide additional written notification under the Code to the hospital administration, Healthcare Professional's superior (or other locally-designated body) for Member Company/ Healthcare Professional interactions in countries where notification or approval before the Event is required by local laws or regulations?

**A11** No. Only the compulsory notification before the Event is required. Additional notification under the Code is not required in countries where specific notification requirements of law or regulation govern the transparency of interactions between industry and Healthcare Professionals prior to the Event. The transparency provisions of the Code apply only in countries where there is an absence of equivalent national transparency laws and regulations.

**Q12** When making Employer Notification, are Member Companies required to provide details of the proposed financial contribution Member Companies will make to the Healthcare Professional in exchange for the services rendered?

**A12** The written notification must comply with national laws, regulations and professional codes of conduct. In countries where specific provision is not made, there is no requirement to notify employers of the amounts involved. Under the Code, Member Companies must ensure that the level of remuneration is commensurate with the services provided and not greater than a fair market value. However, the purpose of the Employer Notification is to provide transparency on the nature of the interaction between the Member Company and the Healthcare Professional and to enable the employer to raise objections if they perceive a potential conflict or have other issues concerning the interaction.

**Q13** Can a celebration dinner or other type of social Event be supported?

**A13** No. Social events, such as anniversaries, Christmas dinners or other similar events may not be supported by Member Companies, neither as stand-alone events nor as part of Third Party Organised Events. For the avoidance of doubt, Member Companies may also not invite Healthcare Professionals to attend such an event at the Member Company's expense.

# Chapter 2: Third Party Organised Educational Events

Member Companies may provide financial and/or In Kind support (e.g. Member Company products) to Third Party Organised Educational Events in accordance with the rules of this Code. Such Events include:

- Third Party Organised Educational Conferences; and
- Third Party Organised Procedure Training meetings.

# 1. Third Party Organised Educational Conferences

Member Companies may support Third Party Organised Educational Conferences (see the Glossary) with cash and/or In Kind provided these comply with:

- Chapter 1: General Criteria for Events; and
- Where applicable, have approval via the Conference Vetting System (see the Glossary).[1]

Where permitted under national laws, regulations and professional codes of conduct, Member Companies may provide financial and/or In Kind support to Third Party Organised Educational Conferences (always provided that the Third Party Organised Educational Conference has been approved via the Conference Vetting System, where appropriate) through grants and other types of funding, such as:

**a) Educational Grants**
Please refer to Chapter 4: Charitable Donations and Grants for guidance on Educational Grants.

**b) Promotional Activity**
Member Companies may purchase packages that may include promotional and advertising services, for example, advertisement space and booth space for company displays. Member Companies should ensure that the overall image projected by the promotional activity at Third Party Organised Educational Conferences is perceived as professional at all times. It should never bring discredit upon or reduce confidence in the medical technology industry.

**c) Satellite Symposia**
Member Companies may purchase satellite symposia packages at Third Party Organised Educational Conferences and provide presentations on subjects that are consistent with the overall content of the Third Party Organised Educational Conference. Member Companies may determine the content of these satellite symposia and be responsible for speaker selection.

1) For scope of application of CVS please refer to: http://www.ethicalmedtech.eu

**Q14** What is meant by "In Kind support" as used in Chapter 2, Section 1 of the Code in connection with "Third Party Organised Educational Conferences"?

**A14** "In Kind support" can be provided to Healthcare Organisations but Member Companies should take care to ensure such In Kind support does not, nor is perceived to, circumvent the prohibition against Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third Party Organised Educational Conferences. For example, it would not be appropriate for Member Companies to directly handle the conference registration, travel, or accommodation arrangements for individual (and identifiable) HCP delegates at a Third Party Organised Educational Conference. Examples of "In Kind support" which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements.

**Q15** Please provide examples of appropriate booth activities which will be perceived as professional?

**A15** Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies' Medical Technologies and/or related services and related literature. Therefore other activities should be limited and reasonable and in principle only soft drinks and snacks should be served.

**Q16** Can a Member Company for example be present via a satellite symposium, rent booth space at a Third Party Organised Educational Conference which was assessed as non-compliant by the Conference Vetting System (CVS)?

**A16** Please refer to Annex I for a detailed visualisation of the scope of CVS and its impact on commercial activities.

**Q17** Can Member Companies directly support attendance by Healthcare Professionals engaged to speak only at satellite symposia at Third Party Organised Educational Conferences, e.g. registration fee, travel and/or accommodation?

**A17** Member Companies must ensure all aspects of the arrangement comply with the Code, including entering into a consulting agreement with Healthcare Professionals engaged to speak at satellite symposia. The consulting agreements may provide for payments to be made in respect of travel and/or accommodation for the purpose of delivering the speaker services. Where payment of a registration fee is required in order for speakers to access satellite symposia, Member companies may also pay for the registration fee.

# 2. Third Party Organised Procedure Training

Member Companies may support Third Party Organised Procedure Training either via Educational Grants (in accordance with Chapter 4: Charitable Donations and Grants) or by providing financial support directly to individual Healthcare Professionals to cover the cost of attendance at Third Party Organised Procedure Training sessions in accordance with the following rules:

- Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events. Member Companies may therefore pay travel, hospitality and the registration fee.
- Where applicable, the Third Party Organised Procedure Training has approval via the Conference Vetting System (see the Glossary)[2].
- For financial support to Third Party Organised Procedure Training meetings Member Companies must apply the requirements governing conduct and attendance at such meetings in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the meeting is being hosted
- Should the participants' practical, hands-on portion of a Third Party Organised Procedure Training be cancelled or made virtual, the Event itself would no longer qualify as a Third Party Organised Procedure Training. As such, Member Companies would only be able to support such Event via Educational Grants and registration fee/access to the recording to such Events. Under no circumstances may travel expenses be paid in such a situation.

2) For scope of application of CVS please refer to: http://www.ethicalmedtech.eu

**Q18** What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings?

**A18** Both Third-Party Organised Educational Conferences (see the Glossary) and Procedure Trainings (see the Glossary) are a type of Third Party Organised Educational Event. Therefore, they must comply with Chapter 1. General Criteria for Events; and, where applicable, are subject to the Conference Vetting System (see the Glossary). However, unlike Third Party Organised Educational Conferences, Third Party Organised Procedure Trainings are not subject to the prohibition of direct support for the attendance of HCPs. Nonetheless, for Third Party Organised Procedure Trainings the following three criteria shall apply:

- Programme: Unlike Third Party Organised Educational Conferences which are theoretical in nature, Third Party Organised Procedure Trainings consist of practical, hands-on training, generally involving more than one provider/manufacturer/sponsor
- This must be evident from the programme for the Event. The programme, which is often referred to as a "course", rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or Medical Technologies). Examples may include courses aimed at acquiring or improving the Healthcare Professional's skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices; etc.

  The programme must also include practical demonstrations (and/or actual live surgeries, where allowed). Examples of practical demonstrations may include surgery simulations where Medical Technologies are used on cadavers; skin models; synthetic bones; cath labs; etc.
- Venue: Third Party Organised Procedure Trainings are typically organised in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, the adjective "clinical" includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.

  Examples of clinical environment include hospitals or clinics, where medical treatment on real patients may be given; as well as conference rooms which are appropriately set up to simulate medical procedures, for example with the presence of Medical Technologies to be used on cadavers; skin models; synthetic bones; etc
- Stand-alone event: Third Party Organised Procedure Trainings must stand alone. Where the majority of the training is not given in a clinical environment, for example, where the training is organised in connection with, adjacent to, or at the same time as, a larger Third Party Organised Educational Conferences, that training will not qualify as a Third Party Organised Procedure Training, as defined in the Code.

**Q19** Do Proctorships and Preceptorships require CVS approval before they can be provided and/ or supported by a Member Company?

**A19** Proctorships and Preceptorships normally take place on HCO premises and are not subject to CVS approval as it is not considered to be either a Third Party Organised Educational Event or a Third Party Organised Procedural Training.

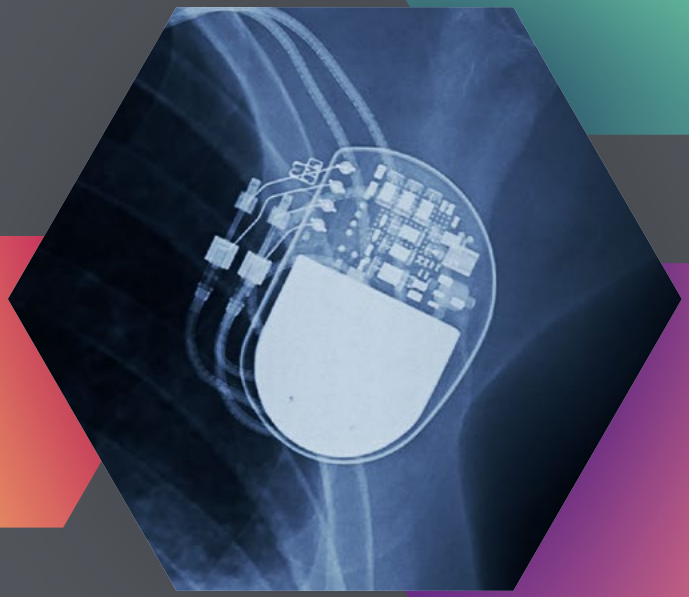
**Q20** Can a Member Company support a Third-Party Organised Educational Event, where the organisers are individual Healthcare Professionals without involvement of a legal entity, such as a Professional Congress Organiser, a Healthcare Organisation or a travel agency?

**A20** In no event can financial support be transferred directly to the bank account of an individual HCP.

In-Kind support may be provided to this kind of Event provided it complies with all the requirements of the Code. Such In Kkind support may include the (temporary) loaning of multiple use Medical Technologies, the provision of single-use Demonstration Products, but also the direct payment of catering, venue rental invoices, and/or speakers through Consulting / Speaker Agreements provided that these comply with all requirements of Chapter 5 of the Code.

This type of support carries significant risks for all parties involved, which need to be managed carefully, even where such an Event complies with all other aspects of the Code, including the prohibition of support for attendance of identifiable HCPs at Third Party Organised Educational Events.

# Chapter 3: Company Events



# 1. General Principles

Member Companies may invite and in some cases pay the costs of attendance of Healthcare Professionals at Company Events.

Examples of Company Events are, as defined in the Glossary:

- Product and Procedure Training and Education Events
- Sales, Promotional and Other Business Meetings

Company Events should comply with the principles mentioned in Chapter 1: General Criteria for Events.

Where there is a Legitimate Business Purpose, Company Events (including company plant or factory tours) may take place in Member Company's manufacturing plant or Healthcare Organisations used by the Member Company as reference centres, including in countries outside the country of residence of the Healthcare Professional provided the tour complies with the Code in all respects.

# 2. Product and Procedure Training and Educational Events

Where appropriate, in order to facilitate the safe and effective use of Medical Technologies, therapies and/or services, Member Companies should make product and procedure training and education available to relevant Healthcare Professionals. This may include paying the cost of attendance of Healthcare Professionals if allowed under local laws and regulations.

Member Companies shall ensure that personnel conducting the Product and Procedure Training and Educational Events have the appropriate expertise to conduct such training.

### 2.1 Company Organised Educational Events

Company Organised Educational Events are Company Events, whose objective is genuine and bona fide medical education, and the enhancement of professional skills.

The aim of Educational Events is to directly communicate information concerning or associated with the use of Member Companies' Medical Technologies, e.g. information

**Q21** Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Educational Events?

**A21** No. Cruise ships, golf clubs or health spas and venues renowned for their Entertainment facilities are not appropriate venues and should not be used. Appropriate examples include hospital, clinic or surgical centre laboratory, educational, conference, or other appropriate settings, including Member Companies' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required "hands on" training.

**Q22** What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Educational Events?

**A22** If the participants are primarily from one country, the venue should be in the specific country involved. If the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen. It is expected that the country selected will be the residence of at least some of the participants of a Product and Procedure Training and Education Event.

about disease states and the benefits of Medical Technologies to certain patient populations. In all cases the information and/or training must directly concern a Member Company's Medical Technologies, therapies and/or related services. This means that a Member Company must meet the following requirements when organizing such an Event in order to be compliant with the MedTech Europe Code:

The entire Event must comply with the criteria in Chapters 1 and 3;

a) The programme must be rigorous from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals who are attendees at the Event.

b) The programme must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective. This means that the educational part must fill most of the programme.

c) Information on the programme, clearly indicating the name of the Company organising the Event, should be made available sufficiently in advance in order for invited Healthcare Professionals to be able to make a reasoned judgment as to the rigor and quality of the programme, provided however that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality or nature of the programme.

d) The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day event, commences or ends at midday or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non-educational events or activities organized for the other part of the day. Furthermore, there should be no significant gaps in the programme which would permit Healthcare Professionals to engage in non-scientific or non-educational activities. For example, early morning sessions should not be followed by late afternoon or evening sessions with large blocks of free time in between.

## 3. Company Events taking place in the context of Third-Party Organised Educational Events

Member Companies cannot directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating in Company Events which take place during, around, or at the same time and in the same approximate location as a Third Party Organised Event.

However, Company Events—including fee-for-service arrangements like Advisory Boards and Clinical Investigator meetings—may be organised at or around a Third Party Organised

**Q23** Can a Member Company use a meeting venue outside Europe?

**A23** Yes, provided the participants are from multiple countries outside Europe. If the participants are primarily from within Europe, the venue should be in Europe. It is expected that the country selected (and the state, if the location is in the United States) will be the residence of at least some of the participants of the Product and Procedure Training and Education Event.



Educational Event for reasons of convenience and efficiency, given the attendance of Healthcare Professionals at that Third-Party Organised Educational Event.
If such an Event overlap occurs, the Member Company may only pay the contractual remuneration and expenses agreed for the provision of the services by the Healthcare Professional at the Company Organised Education Event itself. Under no circumstances may a Member Company pay for incremental costs relating to the Healthcare Professional's attendance at the Third Party Organised Educational Event, such as registration costs, hospitality, additional travel or accommodation.

Member Companies may provide flexibility in the Healthcare Professionals' travel arrangements—provided there is no additional or incremental cost involved (i.e. registration, hospitality, additional accommodation or travel).

The Healthcare Professionals must have an active role at such a Company Organized Event, rather than being mere passive attendees. For example, no support shall be provided by Member Companies to Healthcare Professionals attending a Company Organised Educational Event as a Delegate or trainee where this is organized at or around a Third Party Organised Educational Event.

**a. Specific rules for certain Company Events organized in the context of Third-Party Organised Educational Events**

Satellite symposia or booth speaker engagements taking place during the Third Party Organised Educational Event (i.e. as part of that Third Party Organised Educational Event):

- the Healthcare Professional's registration fee for the Third Party Organised Educational Event may be covered only if the Healthcare Professional's access to the satellite symposium or booth at the Third Party Organised Educational Event is conditional upon the payment of the registration fee. Where this applies the registration fee must, where possible, be prorated to the actual attendance required in order to deliver the required services. E.g. if the satellite symposium is held on a single day of the three-day event, and it is possible to choose a one-day registration, that option should be selected.
- the flight and accommodation costs can only be covered if the Healthcare Professional is not already benefiting from an Educational Grant covering their attendance to the Event.

**b. Hospitality at Company Events organised in the context of Third Party Organised Educational Events**

If a Member Company wishes to organise a legitimate business or scientific meeting which includes lunch or dinner with selected Healthcare Professionals in the context of a Third Party Organised Educational Event, the following conditions must be met before the Member Company may cover the hospitality costs:

- The meeting should have a legitimate business or scientific purpose and the lunch or dinner must not be the primary purpose of the invitation but must instead be clearly subordinate to the purpose of the meeting;
- The invitation to the lunch or dinner should only be made to a small number of participants, in order to ensure effective contribution by way of transfer of knowledge, discussion and exchange amongst the participants in line with the meeting's legitimate business or scientific purpose. Any such invitation should have regard to the rules of Chapter 4, Section 3, subsection a), point 1, "Support for HCP Participation at Third Party Organised Educational Events". In no case may a Member Company issue a blanket invitation to all the participants at the Third Party Organised Educational Event.
- The Member Company must ensure that the hospitality provided complies with all local laws and regulations, and with the MedTech Europe Code of Ethical Business Practice, in particular Chapter 1 (General Criteria for Events).

In all cases, Member Companies should pay special attention to instances where Healthcare Professionals may already be benefiting from an Educational Grant which covers all forms of hospitality; and be mindful of the impact that their interactions with Healthcare Professionals may have on the image and perception of the industry as a whole.

## 4. Sales, Promotional and Other Business Meetings

Where it is appropriate, Member Companies may organise sales, promotional and other business meetings where the objective is to discuss Medical Technology and related services features and benefits, conduct contract negotiations, or discuss sales terms.

In addition to the principles laid down in Chapter 3, Section 1, sales, promotional and other business meetings should also comply with the following more stringent requirements:

- Such meetings should, as a general rule, occur at or close to the Healthcare Professional's place of business;
- It is not appropriate for travel or accommodation support to be provided to Healthcare Professionals by Member Companies except where demonstrations of non-portable equipment are necessary.

**Q24** Can Member Companies directly support travel and/or accommodation of individual Healthcare Professionals at Company Events, which include new product launches, even if only portable equipment or solutions are being demonstrated?

**A24** Member Companies can pay for travel and/or accommodation of individual Healthcare Professionals to attend Company Events which include product launches provided that such Events fall within the scope of Chapter 3, Section2, of the Code ("Product and Procedure Training and Educational Events").

# Chapter 4: Grants and Charitable Donations

# 1. General Principles

a. While the Code does not cover Grants or Charitable Donations provided to patient organisations, MedTech Europe has published Patient Organisation Guidelines to support Member Companies when interacting with patient organisations. Research Grants are covered in the Code in Chapter 6: Research.

b. Grants and Charitable Donations (see the Glossary) shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by Member Companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. If Grants are provided on more than one occasion to the same recipient, Member Companies should be mindful that perception and contractual risks may arise. Member Companies should therefore establish internal controls and checks to mitigate these risks.

c. A Member Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying organisation or entity, as the case may be. Grants and Charitable Donations shall not be provided in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the qualifying organisation or entity and submits the request in writing on behalf of the qualifying organisation or entity.

d. The payment (or provision of other support) by way of any Grant or Charitable Donation shall always be made out in the name of the recipient organisation and shall be paid directly to the organisation. A Member Company shall not provide Grants or Charitable Donations in the name of any Healthcare Professional. In addition, all Grants and Charitable Donations shall identify the Member Company as the provider of the Grant or Charitable Donation.

e. In order to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a specific prospective recipient Member Companies shall implement an independent decision-making/review process with criteria that are not sales and/or commercially oriented. The Member Company's sales and/or commercial function shall not decide upon and/or approve decisions to provide Grants or Charitable Donations.. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.

f. Prior to deciding to provide a Grant or a Charitable Donation, the Member Company must evaluate the appropriateness of the award of the proposed Grant or Charitable Donation to the proposed recipient. It must in all cases be lawful under applicable national laws and regulations for the Grant or Charitable Donation recipient to receive and benefit of the particular type of Grant/Charitable Donation.

**Q25** Under the General Principles in Chapter 4. Grants and Charitable Donations, could you provide an example of an "independent decision-making/review process"?

**A25** Such a process could be led by a Member Company's legal, finance or compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria for review and decision-making.

Such an evaluation shall consider all the circumstances including consideration of the legal status and structure of the requesting (and/or prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation shall be documented and shall be based on information available to the Member Company, such as information or documentation available from public sources. For Educational Grants provided in relation to Third Party Organised Educational Events, this may also include information on how the funds have been applied by the recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of any previous Grant.

g. All Grants and Charitable Donations must be appropriately documented by the Member Company. Moreover, Grants and Charitable Donations shall only be provided in response to a written request submitted by the requesting organisation or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company, including, as a minimum a detailed description of the scope and purpose of the programme, activity or other project, which is proposed as the object of the Grant or Charitable Donation. It shall also contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties.

h. This section of the Code (Chapter 4: Grants and Charitable Donations) is not intended to address the legitimate practice by Member Companies of providing appropriate rebates, additional Medical Technoloy and/or service offerings, including free of charge, or other comparable pricing incentive mechanisms ("value adds") which are included in competitive and transparent centralised purchasing arrangements, such as, for example, tenders.

## 2. Charitable Donations

Member Companies may make Charitable Donations for charitable or other philanthropic purposes. Member Companies shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

Charitable Donations may be made only to charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes and which are objectively engaged in charitable or philanthropic activities. Charitable Donations shall always be made in accordance with the general principles set out in Chapter 4: Grants and Charitable Donations.

**Q26** Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?

**A26** No, a Member Company cannot make a Charitable Donation to support the general running of a hospital or other Healthcare Organisation. A Charitable Donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main objects. For the purpose of the Code and irrespective of their legal status, hospitals and Healthcare Organisations are considered to generally have health functions as their main purposes and accordingly are not generally considered to have charitable and/or philanthropic functions as their main purposes. It is not therefore appropriate to provide Charitable Donations to support their general running.

Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship (see Glossary), provided the Charitable Donation benefits patients, is limited to specific needs identified in advance, or is explicitly permitted by applicable national laws.

This section of the Code (Chapter 4: Grants and Charitable Donations– Charitable Donations) is not intended to address legitimate commercial transactions by Member Companies in the form of leasing of stands or booth space at Third Party Organised Educational Events and/or at any conference or event organised by a charity or other philanthropic organisation. Such activity is considered to be part of Member Companies' normal marketing activity. Member Companies should, however, always consider the appropriateness of the location, venue and the general arrangements for any such events and the impression that may be created by the arrangements in order not to bring the industry into disrepute.

**Fundraisers**

Charitable Donations made by Member Companies may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organization. The Member Company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the Member Company shall not invite Healthcare Professionals to attend such an event at the Member Company's expense. Furthermore, the Member Company is not permitted to suggest to the sponsoring organisation, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the Member Company's table.

## 3. Educational Grants

Member Companies may provide Educational Grants (see the Glossary) for the advancement of medical education. Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement. A Member Company shall also ensure that the Educational Grant agreement with the recipient organisation includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.

Member Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines.

**Q27** Is it permissible for a Member Company to specify restrictions in relation to the final use of a Charitable Donation where a Member Company wishes its Charitable Donation to be applied as part of a specific aid programme or as part of the relief effort following a specific natural disaster, such as a major earthquake in a particular country?

**A27** Member Companies may specify the broad, general purpose for which a Charitable Donation shall be applied, such as the relief of a specific disaster in a particular country (e.g. for use to aid reconstruction and/or re-equipping of healthcare facilities following an earthquake in that country). However, Member Companies must take care that such specifications do not amount to control over the specific, final use of the Charitable Donation by the recipient which is not allowed under the Code.

**Q28** Is it permissible for a Member Company to make a Charitable Donation to a Healthcare Professional's designated charity in instances where the Healthcare Professional has requested the Member Company to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the Member Company?

**A28** No. Under the Code it is not appropriate for a Member Company to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional irrespective of the underlying reasons. No exception can be made for sport events, such as payment of the registration charge to participate in a charity run.

**Q29** What are the differences between an Educational Grant and a commercial sponsorship?

**A29** Commercial sponsorships in the context of Third Party Organised Educational Events would involve objective consideration, such as access to the participants for marketing purposes, advertising opportunities or booth space.

On the other hand, an Educational Grant is exclusively provided for the advancement of medical education in situations where the Member Company neither requests, expects nor receives any consideration for the support.

Public notes or mentions thanking the providers of Educational Grants do not amount to consideration for these purposes .

Member Companies may provide Educational Grants for the following (non-exhaustive) purposes:

**a. Support for Third Party Organised Educational Events:**

As a general principle, any Third Party Organised Educational Event supported by way of an Educational Grant from a Member Company to a Healthcare Organisation must:

- Comply with Chapter 1. General Criteria for Events; and
- Where applicable, have approval via the Conference Vetting System (see the Glossary)[3]

**1) Support for HCP Participation at Third Party Organised Educational Events:**

Where the Educational Grant is provided for the purpose of supporting Healthcare Professionals' attendance at Third Party Organised Educational Events, the Healthcare Organisation receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement.

For the avoidance of doubt, Educational Grants to support HCP participation at a Third Party Organised Educational Event may, subject to local laws and regulations, cover matters such as travel, accommodation and hospitality, including meals. Member Companies should however be mindful of any specific notification or disclosure requirement linked to support of hospitality.

When providing an Educational Grant to Support Healthcare Professionals' participation at Third Party Organised Educational Events, Member Companies should not proactively seek to receive the names of the Healthcare Professionals benefiting from the Educational Grant. Generally, when a Third Party Organised Educational Event is supported by more than one company, all companies should receive the same attendance list, from which it should not be possible to identify which Healthcare Professionals have benefited from a particular Member Company's Educational Grant.

However, where required by law, a Member Company may, in accordance with the applicable legal requirements, request and obtain the names of the Healthcare Professionals participating in the Event, who are benefiting from that Company's Educational Grant.

For purposes of auditing, compliance and monitoring by relevant Company functions, it may be necessary for a Member Company to request and receive the names of the Healthcare Professionals and their respective Healthcare Organisation, who have

3) For scope of application of CVS please refer to: http://www.ethicalmedtech.eu

**Q30** Can a small Healthcare Organisation receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events?

**A30** Yes, in principle. There are no size limits for HCOs to receive Educational Grants; however, Member Companies must ensure that the final beneficiaries of the Educational Grant cannot be identified beforehand. For example, HCOs composed of a single Healthcare Professional will in practice not be allowed to receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events as the final beneficiary is known upfront.

**Q31** Can an Educational Grant or funds earmarked for education be provided to a specific hospital or department or specify individual hospital or department as criteria for HCOs and/or PCOs?

**A31** One of the guiding principles in the Code is that Member Companies should not receive or be able to determine the names of the ultimate HCP beneficiaries. The inclusion of a criterion specifying an individual hospital or hospital department is not prohibited under the Code. However,Member Ccompanies should bear in mind that the smaller the hospital or department the greater will be the risk that Member Companies will be able to identify individual beneficiaries if making use of such critera inappropriate under the Code. In addition, Member Companies should be mindful of any proximate or ongoing tender proceedings with a specific hospital, as such tenders may raise additional red flags.

**Q32** How can Member Companies in practice ensure that Educational Grants are only made available for Third Party Organised Educational Events which receive a positive review from CVS (where this is required under the Code)?

**A32** It is the responsibility of Member Companies to individually ensure compliance with this Code obligation. For example, Member Companies may themselves consider submitting relevant Third Party Organised Educational Events for CVS review or they may decide to include appropriate contractual obligations making it a pre-condition for an Educational Grant that the Third Party Organised Educational Event be submitted and positively assessed via the CVS, for example by the prospective Grant recipient or by a third party.

benefited from the Educational Grant provided by the Member Company after the Event has taken place.

In either of the above cases, unless required by law, such Healthcare Professional names should never be received by the Member Company until the Educational Grant agreement has been signed and the independent selection process of the Healthcare Professionals has been completed.

**2) Support for Third Party Organised Educational Events:**

Where the prospective beneficiary of an Educational Grant is the organiser of the Third Party Organised Educational Event and is also a Healthcare Organisation, the recipient Healthcare Organisation shall be solely responsible for:

- The programme content;
- The selection of Faculty; and
- The payment of Faculty honoraria, if any.

Member Companies shall not have any detailed involvement in determining the content of the educational programme for selection of Faculty (see Glossary) and this shall be reflected in the written Grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme.

**3) Support for Third Party Organised Events via commercial organisations not involved in the organisation of the Event (or of all of the Events)**

Member Companies must bear in mind that certain compliance risks may rise from working with intermediary companies for the management of Educational Grants, and must therefore take all necessary actions to mitigate these risks.

In particular, Member Companies must ensure that any company receiving funds for the management of Educational Grants manages those funds in accordance with the Code. To the extent the managing company will select particular HCPs to benefit from the Grant, the Member Company must ensure that the managing company has sufficient experience and expertise to make an appropriate selection. Additionally, Member Companies must include appropriate and specific compliance-related criteria in all contractual arrangements relating to management of Educational Grants, to ensure that the funds are used appropriately and in accordance with ethical standards and local rules and regulations.

The contractual arrangements should include appropriate provisions to provide the Member Companies the right to monitor and audit the activity of the companies managing the Educational Grants.

**Q33** Can Member Companies give criteria for HCOs and/or PCOs to allocate their Educational funds?

**A33** Yes, objective criteria for HCOs and/or PCOs to select HCPs to benefit from Educational funds may be provided as long as such selection criteria are relevant to the HCPs' educational needs and are not so specific that it would effectively select individual HCPs. Examples of criteria for selecting Educational Grant recipients are Healthcare Professionals' specialty, years of practice, country, city/region of practice and/or academic criteria such as number of publications, participation in clinical trials in a given pathology, or specific hospital, provided the HCP beneficiaries are not identifiable (see Q&As 31 and 32).

**Q34** Does Chapter 4: Donations and Grants – Educational Grants of the Code apply to requests received by Member Companies in the context of public procurement processes for educational support for Third Party Organised Educational Events from Healthcare Organisations and purchasing bodies?

**A34** No. Such requests and any subsequent financial or other support provided by a Member Company are not considered to be Educational Grants for the purpose of the Code. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice.

**Q35** In the event that a commercial organisation, such as a Professional Conference Organiser organises a Third Party Organised Educational Event independently of any Healthcare Organisation, is it appropriate for Member Companies to sponsor such events and what rules shall apply?

**A35** Member Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser that is organising a Third Party Organised Educational Event and acting independently of any Healthcare Organisation. However, such arrangements do not fall within the definition of Educational Grant as Professional Conference Organisers are for-profit organisations. Sponsorship arrangements are therefore commercial in nature and Member Companies should consequently document these in a written commercial agreement in accordance with normal business practice and the requirements of the Code (Chapter 2: Third Party Organised Educational Events). Where a Member Company provides funds earmarked for the advancement of genuine educational purposes to a Professional Conference Organiser, acting independently of any Healthcare Organisation, , all the Code provisions governing Educational Grants shall apply. For example, if a Member Company provides funding to a Professional Conference Organiser to fund Healthcare Professional Delegate places and expenses at a Third Party Organised Educational Conference, such Event, where applicable, must have CVS approval and the Member Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines.

Member Companies may not provide an Educational Grant or funds for education to a third party travel agency directly. For the avoidance of doubt, a Member Company may provide an Educational Grant to a Healthcare Organisation or funds earmarked for education to a Professional Conference Organizer which has arrangements in place so that payments for travel, accommodation and registration (where applicable) are remitted directly by the Member Company to a third party travel agency on behalf of the HCO / PCO, which is the recipient of the Educational Grant or the funds earmarked for education.

In these circumstances the Member Company may choose to establish a tri-partite contract, with the HCO/ PCO and the third party travel agency. Such a third party travel agency could in principle include a third party travel agency also used by the Member Company for its own internal travel arrangements provided this is not a Company-internal function or Company-owned entity.
Where a Member Company decides to use any such arrangement involving funding for, or payments to, a third party travel agency to arrange travel, accommodation and/ or registration (when applicable) it is important that the Member Company carries out appropriate, prior due diligence on a country-by-country and case-by-case basis in order to evaluate and mitigate the particular compliance risks and practicalities where such an arrangement is considered.The Member Company must include in all of the contractual arrangements appropriate and specific compliance-related criteria and conditions for the HCO/PCO to outsource travel arrangements to a third party travel agency, which should include appropriate provisions to allow effective monitoring and control of the activity of the third party travel agency.

### b. Scholarships and Fellowships

Member Companies may provide Educational Grants in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the Glossary). Only Healthcare Organisations where Healthcare Professionals are in training shall be eligible to request and/or receive such Educational Grants. A Member Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this shall be reflected in the written Grant agreement between the Member Company and the recipient HCO.

A Member Company may not additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow attending a Third Party Organised

**Q36** Is it appropriate for a Member Company to provide an Educational Grant to a Healthcare Organisation for the limited purpose of covering, in whole or in part, the cost of some form of peer-to-peer, general public or patient education or training? If so, under what circumstance can such Grants be provided and which criteria would need to be applied?

**A36** As a matter of principle, Member Companies should not cover an HCO's normal overhead or routine costs of operation ("overheads"). These routine costs are to be understood as those costs that would fall under the normal budgeting of a particular HCO. Different types of HCOs may have different kinds of routine costs and whether an activity and its costs are to be understood as "routine" for a particular HCO must be assessed on a case-by-case basis. For the avoidance of doubt, where a particular activity cannot be run due to lack of funding, it does not necessarily mean that such activity is not routine activity and cost for that type of HCO as per the definition of "overheads" above. It may be helpful to consider previous experiences with that HCO or similar HCOs to assess whether such activity would usually be internally funded.If so, the activity would typically be considered a routine activity. As an exception to the above and provided that local laws do not prohibit such setups, Member Companies may support peer-to-peer or public/patient training/education via Educational Grants under the following conditions:

1. If part of a lawful tender, which include internal educational set-ups as "value adds" which would cover, in whole or in part, hospital overheads where these are related to the requirements of that specific tender;

2. Fellowships and Scholarships, in accordance with the provisions of the Code;

3. Support of legitimate educational programs which benefit the delivery of care, and/or provide specific expertise to either an internal or external audience. For such educational support, Member Companies must, however, consider the following to ensure appropriate safeguards against conflicts of interest between the aims of the Member Company and the aims of the HCO, particularly in relation to procurement and competition:

- the purpose and scope of the support should be transparent and fully disclosed to the hospital administration as well as, where required, any other locally-designated competent authority;
- such support should be limited in time and not renewed for indeterminate periods;

The supported programme/activity should genuinely aim to improve patient safety and/or clinical outcomes. As such, it must go above and beyond supporting normal hospital capacity and capability, considering the primary purpose of the hospital. It would not be appropriate to support routine or administrative capacity. This support should be brand-agnostic," meaning that it should not promote specific Member CompanyMedical Technology. Additionally, while respecting the need for transparency, it should not promote the specific HCO.

Educational Event. Such costs shall be included in the Educational Grant supporting the Scholarship or Fellowship if it is intended that the Grant should extend to such attendance.

**c. Educational Grants for general medical education topics**

Member Companies may support genuine medical education for Healthcare Professionals on general healthcare-related topics through Educational Grants in accordance with the rules of this Chapter.

The topic must directly relate to the Member Company's area of business, Medical Technologies, therapies or related services. The Event must be conducted in accordance with, and meet the other requirements of Chapter 3 of the Code.
Additionally, Member Companies can also support genuine medical training on general healthcare-related topics through Member Ccompany-organised Product and Procedure Training and Education Events.

**d. Grants for Public Awareness Campaigns**

Member Companies may also provide Educational Grants to Healthcare Organisations for the legitimate purpose of providing information, promoting awareness and/or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member Company is interested and/or involved.

Additionally, a Member Company may provide an Educational Grant to support the provision of high quality information, promoting awareness and/or educating patients, carers, and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved.

Such disease awareness campaigns must not, however, be designed or used to promote the use of Member Company therapies, products or specific HCOs.

# Chapter 5: Consulting Arrangements

# 1. General Principles

Member Companies may engage Healthcare Professionals and Healthcare Organisations to provide consulting and other services to fulfil a Legitimate Business Need, including research, participation on advisory boards, presentations at Company Events and product development. Member Companies may pay Healthcare Professionals and Healthcare Organisations reasonable remuneration for performing these services. In all cases, Consulting Arrangements must be permitted under the laws and regulations of the country where the Healthcare Organisation is established, or where the Healthcare Professional is licensed to practise and be consistent with applicable professional codes of conduct in that country.

The principles in this chapter are applicable to all Consulting Arrangements between Healthcare Professionals or Healthcare Organisations and Member Companies including where a consultant Healthcare Professional or Healthcare Organisation declines a fee for provision of their services.

Consulting Arrangements shall not be contingent in any way on the prospective consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services.

When selecting consultants, Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with use of consultants. This process shall include a documented, prior evaluation of any such associated risks and of the relevant background information concerning each prospective consultant. For example, the decision to engage a specific Healthcare Professional or Healthcare Organisation as a consultant for sales reasons does not constitute a Legitimate Business Need. If it is necessary for a Member Company's sales function to be involved in decisions to engage specific Healthcare Professionals or Healthcare Organisations, the independent decision-making/review process should ensure decision-making is exercised to fulfil Legitimate Business Needs.

## 2. Criteria for genuine Consulting Arrangements with Healthcare Professionals and Healthcare Organisations

In addition to the general principles above, the arrangements which cover genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a. Consulting Arrangements must be entered into only where a Legitimate Business Need for the services is identified in advance, prior to the selection of the consultant(s).

b. The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified Legitimate Business Need.

c. Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified Legitimate Business Need. Some examples of these qualifications include the years of experience, geographic location, practice setting, clinical research experience, podium presence, speaking and publication experience, or experience with, usage of, or familiarity with a specific Medical Technology,. The volume or value of business generated by a prospective consultant is not a relevant criterion.

d. Consulting Arrangements with Healthcare Professionals or Healthcare Organisations must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the services to be provided and the basis for compensation for the performance of those services.

e. When engaging a Healthcare Professional or Healthcare Organisation as a consultant, Member Companies should be mindful of any potential conflict of interest that might arise from the specific project or from the engagement of that specific Healthcare Professional or Healthcare Organisation in particular.

f. The engaging of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.

g. The compensation for the services rendered must be reasonable, comply with local laws and regulations imposing limits on it and reflect the Fair Market Value of the services provided.

h. Member Companies must maintain records and documentation of the services, and associated work products, provided by the consultant and of the use made of those services by the Member Company. Examples of the documentation include the presentation, invitation letter, agenda, attendance list, minutes, etc.

i. The venue and other arrangements (e.g., hospitality, travel etc.) for Member Company meetings with consultants shall follow the rules for Events set out in Chapter 1: General Criteria for Events.

## 3. Compensation and Fair Market Value

The compensation paid to Healthcare Professionals and Healthcare Organisations engaged as consultants by Member Companies shall reflect Fair Market Value for the services provided and shall be determined by Member Companies based on a documented internal method to determine FMV. Amongst other matters, this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company. It shall not be in any way contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure in the course of their own professional practice and/or business operations.

All payments made for services must comply with all applicable tax and other legal requirements. Member Companies may pay for documented and actual expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation expenses incurred by consultants if attending meetings with, or on behalf of Member Companies. Such expenses must comply with local laws and regulations. The written consulting agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the Member Company.

## 4. Disclosure and Transparency

Member Companies shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with the use by Member Companies of Healthcare Professionals as consultants.

All required consents and approvals shall be obtained prior to commencement of the services, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable.



Where no such national requirements apply, Member Companies shall nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the Consultancy Arrangement

Member Companies shall impose appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the Member Company and their involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation.

# Chapter 6: Research

## Introduction

Member Companies may engage Healthcare Professionals to conduct Member Company-initiated research, support investigator-initiated research through Research Grants, or through collaborative research in accordance with the specific rules of this chapter and any general rule applicable to the interactions with Healthcare Professionals and having regard to the general principles of the Code.

## 1. Member Company-Initiated Research

Where there is a Legitimate Business Need to do so, Member Companies may initiate, conduct, manage and finance scientifically valid research to generate data, whether pre- or post-market. In this context, Legitimate Business Needs for data include medical needs, including patient safety; research and development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post-market clinical or performance follow up (PMCF/PMPF), vigilance, safety, or reimbursement and health economic, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making.

Where a Member Company uses a Healthcare Professional as a consultant - for example to lead a study on the Member Company's behalf (i.e. act as principal investigator); to provide advice as an advisory committee member or adverse event committee member – the Member Company shall ensure that such Consulting Arrangements comply fully with Chapter 5: Arrangements with Consultants.

In accordance with the Documentation Principle, any arrangements made by a Member Company to procure research-related services shall be set out in a written agreement which shall reference a written research protocol; written schedule of work and provide for all required consents, approvals and authorisations to be obtained prior to the commencement of the study.

Member Companies must ensure that their research activities comply with all applicable national laws, regulations and researchers' own professional codes of conduct, as well as with applicable Good Clinical Practice guidelines, if relevant.

In accordance with the Principles set out in the Introduction: Aims and Principles of the Code, Member Companies shall also ensure appropriate clinical trial transparency in relation to their research activities and results. This shall include appropriate disclosure of information

**Q37** What is an example of an external public register for clinical trial transparency?

**A37** Examples of an external public register for clinical trial transparency are www.clinicaltrials.gov or www.who.org

about Member Companies' clinical trials, for example in external public registries and peer-reviewed journals, and having regard to local transparency laws and regulations.

Where Member Companies engage third party intermediaries for research (e.g. contract research organisations (CROs)), they shall ensure that the contractual arrangements impose obligations on the third party intermediaries to ensure that the research conducted by these third parties on behalf of the Member Company is carried out in accordance with all applicable legal and ethical requirements, including the applicable requirements of the Code.

## 2. Member Company Post-Market Product Evaluation

Where there is a legitimate business need to do so, Member Companies may initiate, post-market third party evaluation of their Medical Technology, therapies and/or related services and may therefore provide Evaluation Products under a written contract in order to obtain defined user evaluation by Healthcare Organisations in relation to the Evaluation Products. Evaluation Products may be provided on a no charge basis in return for the requested user feedback from Healthcare Professionals at the Healthcare Organisation, which shall be formally described in a written protocol or questionnaire forming part of the contract.

Where the Evaluation Products are multiple-use Evaluation Products the defined period of time necessary for the evaluation and feedback to occur will depend on the frequency of anticipated use; the nature of the user evaluation feedback requested; the duration of any required training and similar considerations that should be reasonable in the context. Member Companies shall in all cases ensure that they retain title to multiple-use Evaluation Products and that they have a process in place for promptly removing such multiple use Evaluation Products and/or any unused single-use Evaluation Products from the Healthcare Organisation's location at the conclusion of the evaluation period, unless these are purchased or leased by the Healthcare Organisation.

Provision of Evaluation Products and/or related services must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or related services. Any offer and/or supply of Evaluation Products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct and ethicalrequirements.

## 3. Third Party-Initiated Research: Research Grants

Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide Research Grants (see the Glossary) to support clearly defined third party-initiated research studies for Clinical or non-Clinical Research programmes in therapeutic areas in which the Member Company is interested and/or involved. Research Grants may include In Kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the limited duration of the research.

Member Companies providing Research Grants shall ensure that they do not unduly influence the research. However, Member Companies shall clearly specify the intended research scope and purposes for which the Grant is requested and shall ensure that the written Grant agreement with the recipient organisation includes rights for the Member Company to verify that the Grant is applied solely for the agreed intended research use. Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research.

All requests for Research Grants from prospective Grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorisations or approvals. Bearing in mind that the investigator is at all times responsible with regards to compliance with local laws and regulations a Member Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project.

Research Grant agreements shall include provisions relating to adverse event reporting where appropriate and shall require full disclosure of the Member Company and of the Grant by the Grant recipient organisation and the lead-investigator in all oral or written presentations of the results.

## 4. Collaborative Research

Where there is a need to do so, and provided it is allowed by local laws and regulations, Member Companies and non-industry partners may collaborate to develop and/or conduct scientific research, provided this has a legitimate purpose. Collaborative research may be conducted before, during or after regulatory approval of a drug, Medical Technology, therapy or related service.

**Q38** Can Member Companies support the participation of Poster or Abstract Presenters in Third Party Organised Educational Conferences?

**A38** Poster or Abstract Presenters at Third Party Organised Educational Conferences are not to be considered asFaculty, as defined in the Code (“Glossary’). As such, if Member Companies want to support their participation in the Third Party Organised Educational Conference, such support may be provided through an Educational Grant (if it complies with the requirements of the Code, specifically those of Chapter 4). Alternatively, the support can be included in a Research Agreement, whether it relates to Member Company initiated or third party initiated research.

However, if the support is included in a research agreement, Member Companies may only support attendance of poster and abstract presenters to Third Party Organised Educational Conferences provided the following considerations are met:

- The selection of the poster or abstract presenters is done independently by the third party organiser of the Event,
- The support envisioned must be specific and detailed in the research agreement between the Member Company and the Healthcare Organisation, and
- The Member Company is not directly involved in the selection of the specific investigator who would benefit from the support (for the avoidance of doubt principal investigators with whom a company might have a direct relationship would be eligible to receive support for the dissemination of the research results). Member Companies should also consider including in the research agreement a clause which stipulates that funds will be made available only once the poster or abstract presenter has been selected independently by the third party organiser of the Event.

**Q39** What is the difference between Member Company-initiated research, yhird party-initiated research (Research Grant) and collaborative research?

**A39** Member Company-initiated research is sponsored by the Member Company, it is the Member Company who is responsible for all aspects of the research and who owns the data (e.g. used for regulatory purposes). Member companies may contract researchers to conduct the research on their behalf (i.e a fee-for-service agreement).

Third party-initiated research (investigator-initiated) is sponsored by the third party and it is the third party who is responsible for independently managing all aspects of the research. Member Companies may support the research e.g. financially (Research Grant).

Collaborative research is usually sponsored by a third party investigator, but may also be sponsored by a Member Company, so that there is a pooling of skills, experience and/or resources from all the parties that jointly complement the objectives of the collaborative research project as a shared commitment.

The scope of the collaboration must be agreed in advance by the Member Company and third party or parties (collaborative research agreement).

Each collaborator must actively contribute significant skills, experience and/or resource complementary to the collaboration, for example study objectives and design, methodology, protocol development, study conduct, statistical analysis plan, clinical study report and publication . Before engaging in research collaborations, it is critical for Member Companies to take into account key considerations such as the review and approval/authorisation process; due diligence criteria; budgeting and contracting processes; permissible interactions during the execution of the research and other relevant considerations. Items within scope and out of scope of the collaborative research should be clearly defined to justify the treatment of a research project as collaborative research as opposed to Member Company-initiated research or third-party-initiated research (for which a Research Grant is appropriate).

In accordance with the Documentation Principle, any arrangements made by a Member company to conduct collaborative research shall be set out in a written agreement to define roles and responsibilities transparently and in accordance with the study protocol. Examples include identification of the study [initiator and] sponsor; intellectual property ownership; financial support; transparency of involvement; reporting; rights to data; registration of publications; adverse event reporting procedures and dispute resolution.

Member Companies shall ensure that the pooling of all collaborators' skills, experience and/or resources is clear expressed in a collaborative research agreement and all activities falling within the scope of the Member Company's responsibility are performed in accordance with all applicable national laws and regulations, professional codes of conduct and ethical requirements as well as with applicable good practice guidelines.



**Q40** What is meant by "legitimate purpose" in the context of collaborative research?

**A40** A collaborative research project must enhance patient care or be for the benefit of patients, or alternatively benefit the HCO and, as a minimum, maintain patient care. It must, therefore, always be ensured that none of the benefits of any collaborative research project go to individual HCPs or their practices. If there are benefits which are due to the HCO in the collaborative research project, these must go to the HCO or similar organization.

A collaborative research project shall not constitute an inducement to HCPs or other relevant decision makers to prescribe, supply, recommend, buy or sell a Member Company's Medical Technology or any related service. It shall be legitimate from a scientific and ethical viewpoint and ethical approval must be obtained where required by national laws and regulations, professional codes of conduct and ethical requirements as well as with applicable good practice guidelines and it shall be carried out in an open and transparent manner.

# Chapter 7: Royalties



Healthcare Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

A royalty arrangement between a Member Company and a Healthcare Professional should be entered into only where the Healthcare Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method, such that the Healthcare Professional would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations. The foregoing is without prejudice to Member Companies' obligations to comply with any applicable obligations to pay royalties which may arise under applicable laws and regulations in some countries.

Arrangements involving the payment of royalties by or on behalf of Member Companies to a Healthcare Professional must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations. For example, royalties paid in exchange for intellectual property should not be conditional on:

- A requirement that the Healthcare Professional purchase, order or recommend any product, services or Medical Technology of the Member Company or any product or technology produced as a result of the development project; or
- A requirement to market the product or Medical Technology upon commercialisation.

Subject to national regulations and requirements, Member Companies should exclude from the calculation of royalties the number of units purchased, prescribed, used, or ordered by the Healthcare Professional and/or members of the Healthcare Professional's practice or Healthcare Organisation.

# Chapter 8: Educational Items and Promotional Items

It is generally prohibited to provide gifts to Healthcare Professionals and Healthcare Organisations. Member Companies may exceptionally provide inexpensive educational items and/or promotional items, in accordance with national laws, regulations and industry and professional codes of conduct of the country where the Healthcare Professional is licensed to practise. Member Companies may only provide such educational items and/or promotional items in accordance with the following principles:

a. Educational items and/or promotional items may be provided but these must relate to the Healthcare Professional's practice, or benefit patients, or serve a genuine educational function.

b. No educational items and/or promotional items should be provided in response to requests made by Healthcare Professionals.

c. Educational items and/or promotional items must not be given in the form of cash or cash equivalents.

d. Educational items and/or promotional items must be modest in value, and can be branded or non-branded items.

e. Educational items and/or promotional items must not be given to mark significant life events (e.g., birthday, birth, wedding, etc.).

f. A Member Company may occasionally provide educational items of greater value to a Healthcare Organisation always provided that the item serves a genuine educational function for the Healthcare Professionals at that Healthcare Organisation and is of benefit to patients. Such items shall not be provided to Healthcare Professionals purely for their personal use. The item shall also be related to the therapeutic areas in which the Member Company is interested and/or involved. For higher value educational items, Member Companies must maintain appropriate records of their provision of such educational items to Healthcare Organisations. Such items should not be part of the Healthcare Organisation's normal overheads or routine costs of operation.

g. Provision of educational items and/or promotional items must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's Medical Technology or related services.

h. The educational items and/or promotional items shall not be intended mainly for personal use.

Member Associations shall provide guidelines on appropriate limits for educational and/or promotional items, in accordance with the principles above.

Prize draws and other competitions at Events are permissible if the prize awarded complies with Chapter 8. Educational Items and Promotional Items. In addition, it must comply with national laws, regulations and industry and professional codes of conduct.

**Q41** Under Chapter 8, what are examples of items of modest value that are "related to the Healthcare Professional's practice or for the benefit of patients".

**A41** Stationery items, calendars, diaries, computer accessories for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets are examples of modest value items that could be appropriately provided as promotional items to Healthcare Professionals provided their value falls within the maximum value prescribed under national laws, regulations and industry and professional codes of conduct. Food, alcohol and items which are primarily for use in the home or car are not appropriate as they are not related to the Healthcare Professional's practice nor are they for the benefit of patients.

**Q42** Where Healthcare Professionals engaged by Member Companies as consultants or speakers decline a professional fee for their services, would it be appropriate for the Member Company to show its appreciation by giving the Healthcare Professional a small gift such as a bottle of wine or a bouquet of flowers?

**A42** No, it would not be acceptable for the Member Company to make such a gift because to do so could be open to misinterpretation and would be likely to breach the Principle of Image and Perception. Moreover such gifts would not comply with Chapter 8.Educational Items and Promotionl Items as they neither relate to a Healthcare Professional's practice nor serve an educational function.

**Q43** Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?

**A43** Examples of educational items of greater value that can be provided may include medical textbooks or anatomical models, but only if those relate to the therapeutic areas in which the Member Company is interested and/or involved.



This Chapter is not intended to address the legitimate practice of providing appropriate Evaluation Products, Demonstration products or Samples. For guidance on how Member Companies may provide Evaluation Products, Demonstration products or Samples, please refer to Chapter 6: Research and Chapter 9: Demonstration Products and Samples, as applicable.

# Chapter 9: Demonstration Products and Samples

# 1. General Principles

Member Companies may provide their own Medical Technologies as Demonstration Products and/or Samples (see the Glossary) at no charge in order to enable Healthcare Professionals and/or Healthcare Organisations (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the Medica;l Technology and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the Medical Technology and/or service in the future.

Demonstration Products and/or Samples may be either single- or multiple-use products. Member Companies may also provide products from another company in conjunction with the Member Company's own Demonstration Products and/or Samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company.

Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct. Member Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Professionals and/or Healthcare Organisations, for example recording proof of delivery for any Demonstration Products and/or Samples provided and receipt of return for multiple-use Demonstration Products and/or Samples. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products and/or Samples no later than the time of the supply. The disclosure to Healthcare Professionals and Healthcare Organisations shall be in writing.

This Chapter is limited to the provision of Demonstration Products and/or Samples and related services at no charge and is not intended to apply to provision of products or related services under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of rebates or pricing incentives in a public procurement context. It is also not intended to cover the placement of capital equipment at a Healthcare Organisation's premises[4].

4) Please note MedTech Europe has issued the "MedTech Europe Guidance on Placement of Capital Equipment". It can be found in the Members Area or upon request to the Secretariat (only available to Members).

## 2. Demonstration Products (Demos)

Member Companies may provide examples of their products to Healthcare Professionals and/or Healthcare Organisations in the form of mock-ups (such as unsterilised single use products) that are used for Healthcare Professionals and patient awareness, education and training. For example, a Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product.

Demonstration Products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products no later than the time of the supply. It is recommended that the disclosure to Healthcare Professionals and Healthcare Organisations be in writing.

## 3. Samples

Member Companies may provide a reasonable number of Samples at no charge to allow Healthcare Professionals and/or Healthcare Organisations to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

For Samples, which are single-use products, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the Healthcare Professionals/Healthcare Organisation to acquire adequate experience in dealing with the products.

For Samples, which are multiple-use products, the specific length of time necessary for a Healthcare Professional to familiarise themself with the product will depend on the frequency of anticipated use; the duration of required training; the number of Healthcare Professionals who will need to acquire experience in dealing with the product and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple-use Samples and that they have a process in place for promptly removing such multiple use Samples from the Healthcare Professional's location at the conclusion of the familiarisation period.

# Chapter 10: Third Party Intermediaries

Member Companies must be mindful of the fact that they may be liable for the activities of Third Party Intermediaries who interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products and/or services.

Accordingly, where such arrangements are entered into, and provided local laws and regulations allow it, Member Companies shall ensure that the relevant contractual documentation imposes obligations upon the Third Party Intermediary to comply with provisions set out in the Code and other applicable guidelines, as well as appropriate oversight to ensure this is duly implemented.

**Risk Assessment**

Member Companies should evaluate the risk profile for proposed and utilised Third Party Intermediary arrangements, including, for example, assessing:

- Risk in the relevant country, as well as specific risk profiles of planned or utilised Third Party Intermediaries;
- Information concerning local market legal and ethics requirements;
- Information from the Third Party Intermediaries for potentially unusual arrangements ; and
- Information available from public sources or employees for potential risks associated with the Third Party Intermediaries.

**Due diligence**

Before engaging with a Third Party Intermediary, Member Companies should perform a robust due diligence process by establishing a risk-based pre-engagement and renewal due diligence programme to identify, prevent and mitigate risks relating to the market in which the Third Party Intermediary is engaged to operate, as well as any specific activities the Third Party Intermediary may deploy on behalf of the Member Company. Member Companies should also consider performing due diligence checks during the execution of the engagement to continuously update any relevant information regarding the Third Party Intermediary, and in any case whenever required by local laws and regulations.

**Training**

Member Companies should be mindful of current standards regarding onboarding and training of Third Party Intermediaries, and maintain and update their training materials accordingly.

It is therefore recommended Member Companies maintain an up-to-date assessment of the training needs of all individual Third Party Intermediaries with which a Member Company engages and to ensure that they are trained on a regular basis on new rules, requirements and standards applicable to the activity they perform for or on behalf of the Member Company. For example, Member Companies may consider providing access to relevant training materials (including internal Member Company) to small and medium sized enterprises or in general to Third Party Intermediaries that might have difficulties creating or accessing adequate training materials. Where practical, training should be done in local languages.

**Written Contract**

Member companies should encourage contract terms that require adequate controls and implementation of the Company's anti-corruption policy, such as the following:

- Compliance with applicable laws, industry or professional codes, best practice principles and Member Company policies;
- Right to conduct independent audits, including where possible access to relevant books and records;
- Rights for early termination for failure to comply with applicable laws, industry or professional codes, best practice principles and/or Member Company policies.

**Oversight**

Member Companies should, where applicable applicable, exercise reasonable efforts to perform risk-based, routine monitoring, auditing or other assessment of Third Party Intermediaries for compliance with applicable laws, industry and professional codes, best practice principles and Member Company policies and relevant contractual terms; and should request regular confirmation of Third Party Intermediaries' compliance with applicable laws, industry and professional codes, best practice principles and Member Company policies and relevant contractual terms.

**Appropriate Corrective Action**

Member Companies are encouraged to implement necessary and appropriate corrective measures, consistent with applicable local laws if a Third Party Intermediary fails to comply with applicable laws, industry or professional codes, best practice principles, Member Company policies and/or applicable contractual terms or engages in other impermissible conduct.

**MedTech Europe Code of Ethical Business Practice Part 2:**

# Complaint handling and dispute resolution

# 1. General Principles

The principles set out below are intended to design an effective and efficient complaint-handling process, the object of which is to ensure compliance with the MedTech Europe Code of Ethical Business Practice ("the Code") by Member Companies and the codes of conduct adopted by the Member Associations. It is based on principles of proportionality, speed, due process, fairness, and transparency.

- The general principles are that:
  a) Disputes are best resolved amicably and efficiently by conciliation, mediation or mutual settlement; and
  b) Disputes are generally best handled by national panels subject to exceptions laid down in section 2.4.

# 2. Complaint handling procedure

**2.1 Who can complain?**

- A complaint concerning an alleged breach by a MedTech Europe Member Company (together "Member Companies" or individually "Member Company") of the Code, can be lodged by any organisation or individual directly affected by the activities of MedTech Europe Member Companies, such as sickness funds, individual Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) or patients and Patient Organisations ("Complainants").
- In the event that the MedTech Europe Secretariat becomes aware of information or facts which could involve a breach of the Code by a MedTech Europe Member Company, the MedTech Europe Secretariat may itself file a complaint with the MedTech Europe Compliance Panel[5].

**2.2 Reception of Complaints**

Complaints may be lodged either with a Member Association or with the MedTech Europe Secretariat. Adjudication of complaints shall be a matter solely for Member Associations at a national level subject to exceptions laid down in section 2.4.

**2.3. Processing of complaints**

Complaints received by the MedTech Europe Secretariat shall be processed as follows:

i The MedTech Europe Secretariat will forward any complaints it receives (without commenting upon them) to the relevant Member Association(s), subject to the exceptions laid down in section 2.4.

ii The MedTech Europe Secretariat will send an acknowledgement of receipt to the complainant, indicating the relevant Member Association(s) to which the complaint has been sent for processing and decision.

iii In addition, upon receipt by the MedTech Europe Secretariat of multiple external complaints (i.e., several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), the MedTech Europe Secretariat will communicate these complaints to the Member Association either of the parent company or of the European subsidiary designated by the parent company.

5) Please refer to the Code's "Administering the Code" Chapter

iv For complaints for which the MedTech Europe Compliance Panel has jurisdiction, the rules of procedure are laid down in in this section as well as in the Internal Rules of Procedure.

v Complaints shall be handled confidentially by all parties involved in the procedure.

**2.4. Notwithstanding any provisions of this Code to the contrary, the MedTech Europe Secretariat shall refer the complaint to the MedTech Europe Compliance Panel that will render a decision in the first and last instance in the following cases:**

i there is no dispute resolution process in the territory concerned; or

ii a Member Company is not a member of a Member Association; or

iii more than one national compliance panel has or may have jurisdiction, but the parties to the dispute cannot agree on which one does. Referral may be made either by one of the parties or by a Member Association Secretariat or by the MedTech Europe Secretariat; or

iv the national panel having jurisdiction cannot take the case based on provisions of its national code or any other legitimate reason; or

v a complainant refuses the jurisdiction of a national panel for what it considers to be a legitimate reason. In such case, the matter shall be referred to the MedTech Europe Compliance Panel to determine, at its sole discretion, whether or not the reason is legitimate. If the MedTech Europe Compliance Panel determines that it is, then it shall resolve the complaint in the first and last instance; or

vi a party to a dispute believes that conciliation, mediation or mutual settlement is inappropriate due to the serious or repeated nature of the alleged infringement, and petitions the MedTech Europe Compliance Panel to waive the requirements as set out in the General Principles of this Part 2 or

vii a dispute concerns an alleged violation of the MedTech Europe Conference Vetting System or an alleged violation of the Code relating to a third party medical education conference which was eligible for assessment under the Conference Vetting System, whether or not it was actually assessed.

When deciding on such matters, the MedTech Europe Compliance Panel will act in conformity with the dispute resolution principles set out below and in the Internal Procedural Rules and will have the right to impose sanctions in line with the ones enumerated in section 4 below.

## 3. Dispute resolution principles and procedures

### 3.1 Principles for complaint handling and sanctions

Processing of complaints and sanctions by Member Associations as well as the MedTech Europe Compliance Panel shall follow the principles set out below:

i Member Associations and the MedTech Europe Compliance Panel shall ensure that industry and non-industry complaints are processed according to the same principles, without regard to who has made the complaint. National panels and the MedTech Europe Compliance Panel shall not receive or process anonymous complaints.

ii Member Associations and the MedTech Europe Compliance Panel may request any company, which is not a member of the Association and making a complaint under their codes, to undertake to abide by the provisions of their codes of conduct and their complaint handling principles as a pre-condition before processing the complaint.

iii For complaints and other matters that are handled by the MedTech Europe Compliance Panel, it shall apply the MedTech Europe Code and, at its sole discretion and, as it deems appropriate, Member Association codes in the event that both parties are also bound by them

iv In the event of a conflict between the provisions of a national code and the MedTech Europe Code, national panels shall apply their own national codes when rendering decisions on complaints, except when there is a contradiction with the MedTech Europe Code and the national code is less stringent, in which case the provisions of the MedTech Europe Code should be applied.

v A complaint handling procedure should not be initiated or should be suspended in case of a formal investigation by criminal law enforcement authorities or commencement of criminal proceedings or a proceeding at ordinary courts with respect to the same or a substantially similar subject matter. It is the responsibility of the parties to notify the national panels and the MedTech Europe Compliance Panel of such proceedings.

**3.2 Procedural steps for dispute resolution**

The procedural steps for dispute resolution should be as follows:

i The first stage of any dispute resolution procedure shall be the filing of a written complaint. Where a national panel or, where applicable, the MedTech Europe Panel considers a complaint fails to establish a prima facie case of violation of the Code or a national code, such complaint shall be dismissed with respect to that code.

ii The second stage of the dispute resolution procedure shall be based on the principle provided in section 1 above. To that end the following steps shall be considered by the Member Association and the MedTech Europe Compliance Panel:

- Within a reasonably short time frame of receipt of a written complaint by a Member Association or, where applicable, by the MedTech Europe Secretariat, if considered appropriate, a mediation should be attempted, involving an independent third party or mediator or, depending on the nature of the complainant, an attempt to reach an amicable solution.
- If no amicable resolution of the complaint can be reached within a time frame set by the Member Association Secretariat, the MedTech Europe Secretariat or the mediator, the mediator shall direct Complainant(s) to further pursue the complaint via the relevant complaints handling process, pursuant to which the national panel or, where applicable, the MedTech Europe Compliance Panel shall ensure that a final decision is taken promptly in relation to each case thus referred to it for consideration.

iii Member Associations may establish a national appeal procedure, pursuant to which either party may appeal in writing against a decision of the national panel.

iv National panels as well as the MedTech Europe Compliance Panel shall notify their decisions in writing to the parties by registered or certified mail with return receipt or other equivalent means of delivery.

v Decisions by the MedTech Europe Compliance Panel are final and no appeal is available.

## 4. Sanctions

**4.1 The potential sanctions available to the MedTech Europe Compliance Panel and Member Associations' national panels must be proportionate to the infringement, act as a deterrent, and be commensurate with the seriousness and/or persistence of the breach.**

Such sanctions may range from/to:

- A written reprimand;
- The requirement that the offender takes steps to conform with the national and/or the MedTech Europe code(s) (specific steps may be specified in whole or in part, and may be subject to time limits);
- The inspection and audit by a third party (at the offender's cost and expense) of the offender's relevant compliance systems;
- The requirement that the offender recovers items given in connection with the promotion of products and/or to issue a customer communication regarding future corrective practice;
- The requirement that the offender publishes or otherwise disseminates corrective or clarificatory information or statements;
- The prohibition against offending company representative(s) standing for elected office within the institutions of Member Association and/or MedTech Europe; suspension – with specific time limit and detail on conditions of 're-entry' - of membership of the Member Association and/or MedTech Europe; expulsion from membership of the Member Association and/or MedTech Europe;
- Publication of any decisions or sanctions imposed upon the offender.

**4.2 Notwithstanding the foregoing, Member Associations and MedTech Europe Compliance Panel shall ensure that any final decision (including any appeal decision) taken in an individual case shall be rendered in writing, detailing the reasons for reaching this decision and signed by the members of the respective panel. At the minimum, copies of such decisions shall be made available to the parties of a proceeding.**

Member Associations shall make available to both MedTech Europe Compliance Panel and the Code Committee summaries in English of the main facts and conclusions of the national decisions that have precedent or interpretative value and are of international interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest). Member Associations are encouraged to publish in English the full decision.

# MedTech Europe Code of Ethical Business Practice Part 3:

# Glossary and Definitions

- **Charitable Donations**: means provision of cash, equipment, Member Company product or relevant third party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

- **Clinical Research**: a type of research that studies tests and treatments and evaluates their effects on human health outcomes. This includes clinical investigations or interventional and non-interventional clinical performance studies where people volunteer to take part in order to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.

- **Company Events**: means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the Member Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organisations.

- **Conference Vetting System (CVS)**: means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: http://www.ethicalmedtech.eu.

- **Code**: means this MedTech Europe Code of Ethical Business Practice (including the incorporated Questions and Answers), the Disclosure Guidelines, and Part 2: Dispute Resolution Principles.

- **Consulting Arrangement**: means any provision of service by a Healthcare Professional or Healthcare Organisation for or on behalf of a Member Company. Consulting arrangements include, but are not limited to marketing and Clinical Research activities, providing technical expertise for the development, testing, etc. of Medical Technology, providing feedback in post-market evaluations and market research, providing speaking services at Events, teaching other Healthcare Professionals, providing training on how to use the Member Company's Medical Technology, participating in research-related meetings, etc.

- **Delegate**: means Healthcare Professionals that attend an Event neither as Faculty, nor as Healthcare Professionals providing services to Member Companies for the specific Event.

- **Disclosure Guidelines**: means the Code provisions setting out the public disclosure requirements under the Code.

- **Demonstration Products (Demos)**: means either single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:
    - Samples;
    - Evaluation Products;
    - Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

- **Educational Grants**: means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company solely for the support and advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved and where such support is provided solely for a specified intended purpose within this category.

- **Employer Notification**: means the prior written notification provided to a Healthcare Organisation (e.g. hospital administration), a Healthcare Professional's superior or other locally-designated competent authority of any interaction, collaboration or other matter concerning any Member Company and any Healthcare Professional, the purpose and/or scope of which requires notification under this Code.

- **Entertainment**: Entertainment includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute Entertainment.

- **Evaluation Products**: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose, as per the authorisation in the country where the supply occurs. Evaluation Products do not include the following:
    - Demos;
    - Samples;
    - Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

- **Event**: means either a Company Event or Third Party Organised Educational Event.

- **Faculty**: means a podium speaker, moderator and/or chair, who presents during an Event. Poster- and abstract-presenters are not considered to be Faculty.

- **Fair Market Value (FMV)**: means the value of the specified services (or products, if applicable) which would be paid by the Member Company to the other party (for example a Healthcare Professional or a Healthcare Organisation), each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.

- **Financial Hardship**: means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation's funds or other matters within its control is not considered to be Financial Hardship. Financial Hardship must be documented and objectively substantiated.

- **Grants**: means either an Educational Grant or a Research Grant, or both.

- **Guests**: means spouses, partners, family or guests of Healthcare Professionals, or any other person who does not have a bona fide professional interest in the information being shared at an Event.

- **Healthcare Organisation (HCO)**: means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of Medical Technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organisations); or through which one or more Healthcare Professionals provide services..

- **Healthcare Professional (HCP)**: means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe Medical Technologies or related services. This definition does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Member Companies' Medical Technologies or related services for or on behalf of medical or clinical personnel. For example, if a Member Company's Medical Technologies or related services are sold as part of the common merchandise of the retail outlet, interactions between the Member Company and the purchasing professional do not fall within the Code. However, where the Member Company's Medical Technologies or related services are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall within the Code.

- **In kind**: means the provision of Grants, Charitable Donations and other types of support in the form of goods or services other than money, including the provision of labour, lent or donated goods, or lent or donated services (e.g. catering services for Events, provision of venue space, company products and other services).

- **Legitimate Business Need**: means a current and actual business objective pursued by a Member Company such as the advancement of medical education, Clinical Research and/or the safe and effective use of the Member Company's Medical Technology . Engaging a Healthcare Professional or a Healthcare Organisation for the purpose of influencing the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of Medical Technologies or related services directly or indirectly by a Healthcare Professional or Healthcare Organisation is never deemed a Legitimate Business Need.

- **Medical Technology or Medical Technologies**: Within the framework of the Code, Medical Technology refers to Medical Devices and In Vitro Diagnostics medical devices as defined in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as amended from time to time.

- **Members**: means all full and associate corporate members ("Member Companies") of MedTech Europe as well as full and associate national association members of MedTech Europe ("Member Associations"), as defined in the MedTech Europe statutes and as applicable and amended from time to time.

- **Preceptorship**: means a type of clinician-to-clinician training funded by a Member Company where the supervising clinician oversees the procedural training of the trainee clinician and the trainee does not have primary responsibility for the patient undergoing the procedure.

- **Proctorship**: means a type of clinician-to-clinician training funded by a Member Company where the trainee clinician performs a procedure under the supervision of another clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure.

- **Professional Conference Organiser (PCO)**: a for-profit company or organisation which specialises in the management of congresses, conferences, seminars and similar events.

- **Product and Procedure Training and Education Event**: means a type of Company Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:
    - The safe and effective use of Medical Technologies, therapies and/or related services, and/or
    - The safe and effective performance of clinical procedures, and/or
    - Related disease areas.

  In all cases the information and/or training directly concern a Member Company's Medical Technologies, therapies and/or related services.

- **Research Grants**: means the provision by or on behalf of a Member Company of funding, products/equipment and/or In Kind services to any organisation that conducts research which is made for the sole purpose of supporting the development or furtherance of clearly specified bona fide, scientifically valid and legitimate research by the recipient the purpose of which is to advance medical, scientific and healthcare knowledge, Medical Technologies and/or clinical techniques designed to improve patient outcomes.

- **Sales, Promotional and Other Business Meetings**: means any type of Company Event the objective of which is to effect the sale and/or promotion of a Members Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use and/or commercial terms of supply.

- **Samples**: means single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:
    - Demos;
    - Evaluation Products;
    - products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

- **Scholarships and Fellowships**: means Educational Grants provided to a Healthcare Organisation by or on behalf of a Member Company to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). "Scholars" and "Fellows" shall be understood accordingly.

- **Third Party Intermediary**: means any legal entity or person that markets, sells, promotes or otherwise brings to end-users Member Companies' products or related services, and may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives.

- **Third Party Organised Educational Events**: means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.

- **Third Party Organised Educational Conferences**: means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and is consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, Professional Conference Organisers (PCOs), patients organisations or accredited continuing medical education providers.

- **Third Party Organised Procedure Training**: means a type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:
    - Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of Medical Technologies); and
    - Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

  For the avoidance of doubt, Proctorship and Preceptorship are not considered to constitute Third Party Organised Procedure Training.

- **Virtual Event**: A Virtual Event is a Third-Party Organised or Company Organised Event that is characterised by the participation of Healthcare Professionals Delegates who attend exclusively remotely. As a result, a Virtual Event is not connected in any way with a physical Third Party Organised Educational Event. For example, the filming of presentations, discussions, etc. taking place during a Third Party Organised Educational Event ("hybrid" events), and their broadcasting to audiences not present at the physically attended Event—whether contemporaneously or after the Event—do not qualify as a Virtual Event, and therefore need to comply with all requirements of (in person) Third Party Organised Events.

# ANNEX I

## CVS scope: When are CVS assessments required?

| | | PRIOR CVS SUBMISSION | | | |
|---|---|---|---|---|---|
| | | IN MEDTECH EUROPE GEOGRAPHIC AREA | | OUTSIDE MEDTECH EUROPE GEOGRAPHIC AREA | |
| **WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS?** | | **NATIONAL** Third Party Organised Educational Events attended by delegates which are local HCPs only) | **INTERNATIONAL** (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area[1,2]) | **INTERNATIONAL** (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area[3]) | **INTERNATIONAL** (Third Party Organised Educational Events to which no Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area attend, neither as speakers or delegates) |
| EDUCATIONAL GRANTS[4] PROVIDED TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE | Educational Grant to support the general running of a conference | Allowed[5]. | Subject to CVS decision | Allowed. Not subject to CVS decision | Out of scope of the application of the Code[6] |
| | Educational Grants that includes funds to support HCP attendance to the conference | Allowed | Subject to CVS decision | Subject to CVS decision | N/A |
| | Educational Grants that includes funds to support Faculty | Allowed | Subject to CVS decision | Allowed. Not subject to CVS decision | N/A |
| COMMERCIAL ACTIVITIES | Consultancy agreement for speakers in satellite symposia | Allowed | Subject to CVS decision | Allowed. Not subject to CVS decision | N/A |
| | Booths/advertising | Allowed | Subject to CVS decision | Allowed. Not subject to CVS decision | Out of scope of the application of the Code |
| DIRECT SPONSORSHIP OF HCPs REGISTERED AND PRACTISING IN THE MEDTECH EUROPE GEOGRAPHIC AREA | Direct sponsorship of HCPs as delegates (passive participation) | Not allowed | Not allowed | Not allowed | N/A |
| | Direct sponsorship of HCPs as Faculty (active participation) | Not allowed | Not allowed | Not allowed | N/A |

1) MedTech Europe Geographic Area includes the countries in the European Economic Area (EEA), as well as those other countries where Member Associations are located.

2) Formerly referred to as "Cross-border Events".

3) For the avoidance of doubt, in 2018, this category of "Third Party Organised Educational Events attended by Delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area" has to be understood as covering only Healthcare Professionals from the MedTech Europe Geographic Area benefiting from an Educational Grant.

4) Educational Grants: means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company solely for the support and advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved and where such support is provided solely for a specified intended purpose within this category

5) Allowed means no CVS decision is required but the provisions of the MedTech Europe Code of Ethical Business Practice and national laws and regulations still apply.

6) Out of scope: Means the Code does not apply given the situation involves neither a Member Company interacting with an HCP or HCO registered, practising and/or operating in the MedTech Europe Geographic Area nor does the activity take place in the MedTech Europe Geographic Area.

# ANNEX II Calculating the value of In Kind Educational Grants

### What is an In-Kind Educational Grant?

Please note that the Glossary includes a definition of Educational Grant, and Chapter 4 provides guidance as to how Member Companies can use them to support Third Party Organised Events or educational programs. The definition outlines two types of Educational Grants:

- Monetary grants which involve a transfer of funds to the organization
- In Kind grants which is a contribution that includes any other type of support

An In Kind Educational Grant is a non-monetary (i.e non-cash) contribution to an HCO to support an Event or educational program. Both Member Company and HCO should understand what constitutes an In Kind contribution as well as how to value this and this should be clearly documented.

### Types of In-Kind Educational Grant

An In Kind Educational Grant includes goods or services other than cash transfers, including where the In Kind support is provided by a third party and the payment is made directlyby the Member Company to the third party (i.e. no funds are transferred to the Educational Grant beneficiary). Any In Kind Educational Grant must always strictly comply with the general requirements for Educational Grants set out in the Code and shall have the purpose of advancement of genuine medical education.

For example:

- **Goods** such as computers, furniture, electronic equipment, Xray protection clothing, masks, office equipment, etc.
- **Services** such as meeting space, transportation, copy services, administrative services, the supply of access to digital platforms (Zoom, Teams...) etc
- **Expertise**: Members could provide skills, expertise and/or resource to an HCO, such as providing technical support/analysis/work (hours spent by Members' employees), which shall, if so, be provided solely for the purpose of supporting educational activities.
- **Member Company's products** including commercially available / saleable products, re-usable training products and equipment, which may be returned to the Member Company after use

### Value of In Kind Contributions

The Member Company should, whenever possible and practicable, determine the amount of the In Kind contribution and quantify the value in the Educational Grant agreement. The basic principle for valuation of In Kind contributions should be the cost to the Member Company, which should, whenever possible and applicable include logistics, documentation and training costs. For specific recommendations on how to value In Kind Educational Grants please refer to the table below.

| IN-KIND CATEGORY | EXAMPLES OF VALUES THAT CAN BE CONSIDERED, VAT EXCLUSIVE WHEN RELEVANT |
|---|---|
| Third Party Services | Contractual value or Fair Market Value |
| Services provided by Member Company Staff | The salary (inclusive social contributions), or a portion of the salary, for technical support provided by personnel employed by the Member Company (based on time spent and salary) |
| Goods (whether third party or Member Company-produced) | • Provision of used goods<br>  • Fair Market Value<br>  • Company book value<br>• Provision of new goods<br>  • For third party goods, the listing price.<br>  • Contractual value or Fair Market Value<br>  • Internal costs, whether relating to cost of manufacture or transfer price<br>• Loaned goods<br>  • Rental equivalent based on depreciation<br>  • Rental equivalent to highest-volume rate – NOTE: Rent cannot exceed accepted values if the equipment were to be donated or sold<br>  • Exception: if single used products are bundled, they should be separated and valued as a donation of equipment |

| | |
|---|---|
| Materials, technological infrastructure, components | • Fair Market Value |
| Licenses | • FMV for Member Company-owned licences<br>• For licences acquired from third parties for HCO's use in the educational project, the cost. |
| Software | • Copying costs<br>• Licensing costs<br>• Software technical support costs |
| Use of Facilities | • Internal costs for use of facilities with specialised equipment |

In-Kind Educational Grant do not include the following:

- Samples and Demonstration Products
- Products or services provided as part of a commercial deal (e.g. samples required to be provided pursuant to a public procurement procedure)
- Products and services that could be used for non-educational clinical activities
- Any Products or services that are for research purposes (see Chapter 6: Research).

# Annex III

## The Geographical Area where the Code applies as the minimum standard

The MedTech Europe Geographic Area currently includes

Countries with National Associations:

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- The Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- The United Kingdom

Countries party to the European Economic Area agreement without a MedTech Europe National Association:

- Iceland
- Liechtenstein
- Luxembourg
- Malta

Countries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, are not currently under the scope of the Disclosure Guidelines.

# Annex IV
## Verification Of The Use Of Funds

How can a Member Company verify that the Educational Grant is in fact used for the intended purpose as agreed in the Educational Grant agreement?

A Member Company should set up an internal verification process for the purpose of ensuring that the funds provided through an Educational Grant are used for the agreed intended purpose. For example, such a process could include verification of every single Grant provided by a Member Company or periodic verification of a selected sample of Grants, after the Event takes place or before any subsequent application for an Educational Grant.

Examples of the documents requested by Member Company for verification purposes could include, but are not limited to, the following:

Grant to support Healthcare Professionals' attendance at the Third Party Organised Educational Event:

- Attendance proof (e.g. hotel check out form, signed attendance list, a digital certificate issued by the Event organiser etc.)
- Travel proof (e.g. flight/train tickets)
- Copy of the receipts of taxi fares, meals, etc.
- Where allowed, pictures of the Event.

Grant to support the costs related to organisation of the Third Party Organised Educational Event:

- Budget breakdown listing the general expenses of the Event
- Accounting records, copies of invoices, receipts
- Verifications performed by company staff on-site during the Event
- Written confirmation from the Event Organiser that the funds were spent as intended
- Documentation of the speaker's presentation (e.g. slides)

Grant provided in a form of a Scholarship or Fellowship:

- Activity records of the educational programme
- Certification of enrollment from the institution or professor in charge
- Progress report by or of the beneficiary

If a Grant recipient fails to provide the requesting Member Company with the documents or if a Member Company determines that the Grant funds were not used as provided in the Grant agreement, the Member Company.

- Should take this into account when assessing any future funding request from the same Healthcare Organisation.
- May consider requesting MTE to withdraw the right to use the Logo, if the HCO/PCOs is a MTE "Chartered Organisation" under the Ethical Charter.

# Annex V

## Methodology Note Example

**Structure**

- Introduction

- Executive summary of the methodologies used for disclosure purposes and countries specificities

- Definitions

    - Recipients

    - Types of Educational Grants

Disclosure scope and timelines

Disclosures in case of partial performance or cancellation

Cross-border activities

Specific considerations:

    - Multi-year agreements

    - Consent management (please note that some jurisdictions may require the legal entity's consent for publication of data)

        - Consent collection

        - Management of recipient consent withdrawal

        - Management of recipient's request

        - Partial consent

- Disclosure Form

    - Date of submission

    - Currency in case of aggregated payments made in different currencies

    - VAT included or excluded and any other tax aspects

- Disclosure financial data and amount of Educational Grants provided

- Calculation rules

**Disclaimer**: This Methodology note is provided as a template to support Member Companies in the implementation of these Disclosure Guidelines. Any other template may be equally valid provided they comply with the general requirements set out in *Section 2.4 Methodology*.

# ANNEX VI Direct support to HCP participation in Events

| | | | Direct Support for HCP attendance | |
|---|---|---|---|---|
| **Event** | **Setting** | | **Faculty /Speaker** | **Delegates** |
| **Third Party Organised Educational Conference** | **Main Event / Independent Scientific Program** | | Not allowed | Not allowed |
| | **Satellite Symposium** | | Allowed (consulting agreement required) | Not allowed |
| | **Booth** | | Allowed (consulting agreement required) | Not allowed |
| **Third Party Organised Procedure Training meeting*** *The criteria for a Third Party Organised Procedure Training meeting can be found in Q&A 18 | | | Allowed | Allowed |
| **Company Events** | **Product and Procedure Training and Education Event** | **NOT** taking place at or about the same time as a **Third Party Organised Educational Event** | Allowed | Allowed |
| | | Taking place at or about the same time as a **Third Party Organised Educational Event** | Allowed | Not allowed |
| | **Sales, Promotional and Other Business Meeting** | **NOT** taking place at or about the same time as a **Third Party Organised Educational Event** | Allowed (consulting agreement required) | Not allowed (except for demonstration of non-portable equipment) |
| | | Taking place at or about the same time as a Third **Third Party Organised Educational Event** | Allowed | Not allowed |

**Description:**

**Delegate**: "Delegate" is any Healthcare Professional who is attending passively a Company Event or a TPOE and cannot be considered as "Faculty". For avoidance of doubt, poster- and abstract-presenters are considered to be Delegates.

**Satellite Symposium**: Common elements of Satellite Symposia are:

- It takes place at a Third Party Organised Event (TPOE) and it is part of the TPOE official programme (i.e. not focused on marketing of specific products);
- The Company is responsible for the content subject to review by the Organiser where required;
- It's open to any Delegate, not only to selected individuals;
- It has Company branding and the Company can promote the Satellite Symposia to customers.

**Speaker/Faculty**: "Faculty/speaker" in this chart is someone who is considered a speaker at an Event, for example someone who gives a presentation whether at a Company Event or a TPOE; someone who moderates/chairs a session and therefore needs to prepare ahead of the presentation/moderation.

**Guidance**:

In order to determine whether an event is a TPOE or a Company Event, the following aspects should be taken into account:

- Open events (not only Company's customers) are typical of a TPOE, and in this case, it is a thirdpParty chooses which HCPs attend or HCPs self-select;
- Who is the primary initiator of the Event: To what extent is the third pParty vs. the Member Company involved and who is determining the agenda?
- CME accreditation is an indication of a TPOE;
- TPOE generally have a broader focus than one or only a few products;
- Single-sponsored events are often Company Events.

# ANNEX VII

## The Criteria Applicable to Third Party Organised Procedure Trainings (Effective as of 3rd September 2018)

Third Party Organised Procedure Training, as defined in the Glossary of the MedTech Europe Code of Ethical Business Practice ("the Code") means a type of Third Party Organised Educational Event that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.

Chapter 2 of the Code provides that Member Companies may support Third Party Organised Procedure Trainings ("TPPT") either:

- via Educational Grants (in accordance with Chapter 4: Charitable Donations and Grants); OR
- by providing financial support directly to individual Healthcare Professionals ("HCP") to cover the cost of attendance at Third Party Organised Procedure Training sessions.

This exception is to be narrowly interpreted.

For cross-border and international Third Party Organised Events, it is the CVS Compliance Officers whose responsibility it is to determine whether or not a conference meets the criteria to be qualified as a Third Party Organised Procedure Training. In case the Event does not meet the TPPT criteria, it will be re-qualified as a Third Party Organised Educational Conference.

### CRITERIA FOR TPPT DETERMINATION

**1. Programme**:
Practical and hands-on activities must comprise the majority of the programme of TPPTs (unlike Third-Party Organised Educational Conferences which are theoretical in nature). TPPTs are often referred to as "courses", rather than "conferences" or "seminars". Examples may include courses aimed at acquiring or improving the HCP's skills in minimally invasive surgery, orthopaedic trauma surgery, or the implantation of cardiac rhythm devices, etc.

The programme must be focused on acquiring specific medical skills relevant to certain medical procedures as opposed to products, or medical technologies. The programme must include practical sessions.
In order to be considered a TPPT, the practical sessions must in all cases represent more than 50% of the full programme and hands-on sessions must represent at least one-third of the full programme. These requirements must be clearly indicated in the TPPT programme.

The following will be considered as examples of practical sessions:

- Hands-on sessions in which all attendees to the TPPT participate actively. In these sessions, attendees perform specific procedures on settings and environments appropriate for the practice of the relevant procedure. Examples of hands-on sessions may include surgery simulations where the technologies relevant to the specialty are practiced on cadavers, skin models, synthetic bones, cath labs; etc. To ensure that attendants are able to fully benefit from the active aspects of hands-on sessions, no "station" (model, cadaver, table, etc.) can in principle have more than four participants. For ethical considerations, when human cadavers are used, up to eight participants may share a "station".
- Streaming (e.g. video, 3D-rendering software, augmented reality) or demonstrations of live surgeries.
- Case study sessions when the trainees learn about procedure preparations and best practices from specialty expert(s). These sessions must be interactive and based on pictures, videos, animations, 3D rending software, augmented reality, etc.

**2. Venue**: TPPTs' hands-on sessions are typically organised in either a clinical environment or in places suitable for medical procedures. Examples of a clinical environment include hospitals or clinics, where medical treatment on real patients is given (f.ex. operating room, cath lab). Examples of simulation settings include conference or meeting rooms which are appropriately equipped with relevant simulation devices/systems, or experimental laboratories suitable for training on cadavers, skin models, synthetic bones, live animals in accordance to applicable regulations and ethical rules, etc.

**3. Stand-alone event**: TPPTs must be stand-alone. Where the majority of the training is not given in a clinical environment, for example where the training is organised in connection with, adjacent to, or at the same time as a larger Third-Party Organised Educational Conference, that training will not qualify as a TPPT as defined in the Code.

**4. Size**: Given the essential practical and hands-on element of a TPPT and given the fact that Member Companies would know the identity of the HCPs participating in the course, the size of such training is usually relatively small. However, provided that the above criteria are met, size may not be a determining factor.

# Appendix 4. Whistleblowing Mechanism

Pursuant to the Protected Disclosure Act 2014, as amended by the Protected Disclosures (Amendment) Act 2022 (together, and as may be amended from time to time, the "Act"), as well as the Code of Ethics of Tcoag Ireland Limited (hereinafter referred to as "Tcoag"), Tcoag Workers (as defined below in Section 1.2) are entitled to raise concerns within their workplace in relation to matters that are serious and of obvious concern to their workplace, amounting to relevant wrongdoings. Accordingly, this appendix sets out the whistleblowing mechanism, which is applicable to all Tcoag Workers, that should be followed when reporting such concerns.

It supersedes and replaces the previous whistleblowing mechanism outlined at section 6 of the previous version of Tcoag Code of Ethics.

The whistleblowing mechanism provides for two distinct and independent procedures for reporting or disclosing information as:

- An internal report, via the internal whistleblowing mechanism that Tcoag shall implement as a company that employs more than 50 employees;
- An external report, by using the procedure set up by the Office of the Protected Disclosures Commissioner or by issuing a protected disclosure to any prescribed person listed in Protected Disclosures Act 2014 (Disclosure to Prescribed Persons) Order 2020.

## 1 Implementation of an internal whistleblowing mechanism by Tcoag

### 1.1 Scope

Pursuant to the Act, the internal whistleblowing mechanism covers Workers, as defined in section 1.2 below. Therefore, all Workers can:

- Report or disclose information relating to any infringement of the Group Code of Ethics and / or this local supplement (whilst noting that such an infringement may in some circumstances not amount to a "relevant wrongdoing" as defined below, for the purposes of the Act); and / or
- Make a "protected disclosure". A protected disclosure is a disclosure of information which, in the reasonable belief of the Worker concerned, tends to show one or more "relevant wrongdoing".

A relevant wrongdoing in this context is limited to the following:

(a) that an offence has been, is being or is likely to be committed;

(b) that a person has failed, is failing, or likely to fail to comply with any legal obligation (other than one arising under the Worker's contract of employment or terms of engagement);

(c) that a miscarriage of justice has occurred, is occurring or is likely to occur;

(d) that the health and safety of any individual has been, is being or is likely to be endangered;

(e) that the environment has been, is being or is likely to be damaged;

(f) that an unlawful or improper use of public money has occurred, is occurring or is likely to occur;

(g) a breach of an act of the European Union, which concern one or more of the areas of:

(i) public procurement;

(ii) financial services;

(iii) product safety and compliance;

(iv) transport safety;

(v) protection of the environment;

(vi) radiation protection and nuclear safety;

(vii) food and feed safety and animal health and welfare;

(viii) public health;

(ix) consumer protection;

(x) protection of privacy and personal data; and

(xi) security of network and information systems,

(h) oppression, discrimination, gross negligence or gross mismanagement by or on behalf of a public body; and

(i) concealment or destruction of information (or an attempt to do so) in relation to any of the above matters.

## 1.2 Conditions to be fulfilled to use Tcoag's internal whistleblowing mechanism

Given the importance of the issues that are raised, it is extremely important that such issues are brought to the attention of Tcoag as soon as possible after a reasonable belief has been formed that the relevant wrongdoing has been, is being or is likely to be committed.

In order to qualify as a protected disclosure, the report or disclosure must comply with the following conditions in order to assess the accuracy of the allegation and, if necessary, implement any means necessary to remedy the situation reported or disclosed.

1. Eligibility of the person reporting or disclosing the situation

The report or disclosure must have been raised by one of the following individuals:

- Tcoag employees at all levels and grades;
- Persons whose employment relationship with Tcoag has ended, when the information was obtained in the context of this relationship;
- Persons who have applied for employment with Tcoag, when the information was obtained in the context of this application;
- Tcoag shareholder(s);
- Tcoag Board members (including non-executive directors);

- External and occasional collaborators of Tcoag;
- Tcoag's co-contractors and their subcontractors;
- An individual who is a member of an administrative, management or supervisory bodies of an undertaking;
- Interns;
- Agency staff;
- Volunteers;
- Those on work experience; and
- Those who are training at Tcoag.

(collectively described as "Workers" in this appendix).

2. The nature of the information reported or disclosed

The information that is disclosed must have come to the Worker's attention in a work-related context.

Additionally, the reporting or disclosure of information will not qualify as a protected disclosure under the Act, to the extent that:

- It is the Worker's function to detect, investigate or prosecute the relevant wrongdoing to which the disclosed information relates; and
- the relevant wrongdoing does not involve an act or omission on the part of Tcoag.

In respect of any infringement of the provisions of the Group Code of Ethics and / or its local supplement, this information must: i) be related to events that have occurred or are very likely to occur in Tcoag; and ii) have been obtained in the context of the professional activity of the person who reports/discloses it and in this case, the information shall be related to facts of which she/he was personally aware or which were related to her/him. Nevertheless, such an infringement may in some circumstances not amount to a "relevant wrongdoing" for the purposes of the Act and provisions of the Act may not apply in such circumstances.

3. The exclusion of certain information

Facts, information and documents, whatever their form or nature, which do not meet the criteria to be a "protected disclosure" or is not an infringement of the Group Code of Ethics and / or its local supplement as detailed above, would not be investigated under this whistleblowing mechanism.

For example, the Group Ethics Committee will not investigate :

- concerns about a breach of a reporting person's own employment contract; or
- matter concerning interpersonal grievances exclusively affecting a reporting person, namely:
    - grievances about interpersonal conflicts between the reporting person and another worker; or
    - a matter concerning a complaint by a reporting person to, or about, his or her employer which concerns the worker exclusively.

Complaints relating to a Worker's own personal circumstances generally fall outside the scope of this whistleblowing mechanism and so are more appropriately processed in line with Tcoag's Grievance Policy.

If a Worker is unsure whether something is within the scope of this whistleblowing mechanism , or should more properly be dealt with under any other of Tcoag's policies, then the Worker

should seek advice from the Compliance Officer or the Group Ethics Committee, whose contact details are set out below.

4. There must be a reasonable belief that a relevant wrongdoing has occurred

While Workers are not expected to prove the truth of an allegation, they must have a reasonable belief that a relevant wrongdoing or breach of the Group Code of Ethics and / or its local supplement has occurred. As such, a Worker shall not report or disclose facts that she/he knows to be false, with or without the aim of causing any detriment to another Worker or person.

A disclosure that is made without any reasonable belief as to its accuracy may result in disciplinary action in accordance with Tcoag's Disciplinary Policy. Where a Worker has a reasonable belief that information tends to show a relevant wrongdoing or breach of the Group Code of Ethics and / or its local supplement, that Worker is free to disclose such information to the relevant contacts as described below without fear of penalisation or threat of penalisation.

Tcoag Employees and Tcoag Business Partners who believe they comply with the above conditions are encouraged to report/disclose any infringement using Tcoag's internal whistleblowing mechanism. Nevertheless, the use of this mechanism remains optional and its non-use will not expose the Tcoag Employee to any disciplinary sanction.

## 1.3. Persons to contact

Any Worker wishing to use the internal whistleblowing mechanism should contact the Compliance Officer or the Group Ethics Committee, whose contact details are as follows:

Whistleblowing shall be reported/ disclosed via:

(1) The dedicated email addresses:
- Complianceireland@tcoag.com, to which only the Compliance Officer has access;
- Ethics@stago.com, to which only the members of the Group Ethics Committee have access;

(2) Mail to the following postal address:
- Sean McGlynn
  Tcoag Ireland Limited
  IDA Business Parl
  Southern Cross Road
  Bray, Co.
  Wicklow
  Ireland

- Stago Group Ethics Committee
  3 Allée Thérésa,
  92665 Asnières sur Seine
  France

(3) The local telephone hotline
- Sean McGlynn: +353860497811

Compliance Officer and local designated person: Sean McGlynn

The Group Ethics Committee

The following people are members of the Group Ethics Committee :

- Jean-Claude Piel, President of Diagnostica Stago
- Fabienne Clarac, Group Legal Counsel
- Antoine Coulot, Group Chief Financial Officer and Deputy CEO of Diagnostica Stago
- Brigitte Crelier, Diagnostica Stago Coordination Manager

The members of the Group Ethics Committee actually have, by their position or status, the competence, authority and sufficient means to collect and process the reports transmitted. The Group Ethics Committee and the Compliance Officer have overall responsibility for this whistleblowing mechanism , and for reviewing the effectiveness of actions taken in response to concerns raised under the whistleblowing mechanism.

The Compliance Officer, acting as the local designated person, follows up, maintains communications and provides feedback to the Worker regarding any report or disclosure. Tcoag ensures that the Compliance Officer as local designated person (i) is competent to follow up on reports; (ii) maintain communication with the Worker; and (iii) where necessary, request further information from and provide feedback to that Worker.

In the event that the report is not transmitted to the Group Ethics Committee, the recipients of the report, including the Compliance Officer, are required to immediately transmit it to the Group Ethics Committee.

## 1.4. Anonymous Disclosures

A concern may be raised anonymously to the Compliance Officer or the Group Ethics Committee. An anonymous report, where possible, will be treated in the same manner as a report made by a reporting person who disclosed their identity. However on a practical level it may be difficult to investigate such a concern. Accordingly, Workers are encouraged to put their names to allegations in order to facilitate appropriate follow-up. This will make it easier for the Group Ethics Committee to assess the disclosure and take appropriate action including an investigation if necessary.

A Worker who is concerned about possible reprisals if his/ her/ their identity is revealed should come forward to the Compliance Officer and / or the Group Ethics Committee and appropriate measures should then be taken to preserve confidentiality.

## 1.5. The content of a report

Any concerns may be made orally or in writing. However, irrespective of whether a Worker raises a matter orally or in writing, it is imperative that he/she identifies their concern as one arising under this whistleblowing mechanism. This will enable Tcoag to deal with the concern in the appropriate fashion for a matter of such seriousness and in the manner set out in this appendix.

Where possible, a report should contain the following information:

- Name of the person or persons involved and, if possible, their place of work;
- The relevant details (insofar as is possible) including dates, place, sequence of events

and description of circumstances;
- Name of any witnesses who could be useful for the internal investigation;
- Description, and communication of any element or document relating to the alleged or potential breach;
- Any other element, whatever its form or mean, likely to support the report of facts that have occurred or are very likely to occur.

The Worker should also consider providing explicit consent to their identity being disclosed to those who are named in the report to ensure appropriate action can be taken by the recipient of the report.

Should a Worker raise a concern orally the competent person to whom that concern is raised should keep a written record of the conversation and provide the Worker with a copy after the meeting.

In addition, any Worker utilising these whistleblowing mechanisms has the possibility to identify herself/ himself when making a report as Tcoag guarantees the strict confidentiality of the Worker's identity subject to the conditions detailed in section 1.8. below. If she/he decides to identify herself/ himself, the Worker shall confirm when making her/his report any details that could allow the characterisation of which category of Worker she/he falls into (as defined above).

Nevertheless, it is important to mention that the Worker can also decide to remain anonymous, as outlined in section 1.4 above.

## 1.6. Internal investigation

The purpose of this whistleblowing mechanism is to ensure the whistleblowing mechanisms are operated in a secure manner which ensures: (i) the protection of the confidentiality of the identity or the reporting person (subject to limited exceptions); and (ii) the prevention of access by non-authorised persons. Only impartial members of the Group Ethics Committee have the power to carry out an internal investigation into an alleged or potential infringement. They have the option of being assisted by a third party as they deem appropriate.

Once a protected disclosure has been made, the Worker will be informed, within seven (7) working days, of the receipt of her/his report by the Group Ethics Committee. However, this provision is not applicable in the case of an anonymous report.

Each report will give rise to a preliminary assessment treated confidentially by the Group Ethics Committee in order to determine, prior to any investigation, whether there is prima facie evidence that a relevant wrongdoing may have occurred. Any report that clearly falls outside the scope of the whistleblowing mechanism will be closed or the matter may be referred to another applicable procedure e.g. the grievance procedure.Where the Group Ethics Committee decides that there is no prima facie evidence that a relevant wrongdoing may have occurred the report will then be closed and the Worker will be notified in writing, as soon as practicable of the decision and the reasons for it.

If, after the initial assessment, the Group Ethics Committee decides that there is prima facie evidence that a relevant wrongdoing may have occurred, they should take appropriate action to address the relevant wrongdoing, having regard to the nature and seriousness of the matter concerned. The Group Ethics Committee, in cooperation with the Compliance Officer, will provide feedback to the Worker on the actions taken, or envisaged to be taken, within three (3) months, and, if requested in writing, at three (3) month intervals until the procedure triggered by the report is closed.

Generally, the Group Ethics Committee, with the cooperation of the Compliance Officer, will communicate in writing to the Worker information on the measures envisaged or taken to assess the accuracy of the allegations made and, if necessary, to remedy the situation described in the report as well as their grounds. However, it is important to note that, from time to time, the need for confidentiality and legal considerations may prevent Tcoag from giving the Worker specific details of an investigation or any disciplinary action taken as a result. The Worker should treat any information about the investigation as confidential.

An internal investigation shall be carried out in strict compliance with the Act (where it is deemed that the report comes within the remits of the Act). In particular, the concerned employees will have her/his/their point of view on the reported facts checked or may be asked to clarify certain matters. Likewise, Tcoag ensures that the data collected are adequate, relevant and limited with regard to the purposes for which they are collected.

All Tcoag Employees have an obligation to cooperate fully with the internal investigation. It includes, among other things, cooperating in an interview by being honest, and keeping confidential all information and documents necessary for the internal investigation. Tcoag will not tolerate any Employee hindering or attempting to hinder a Worker from making a protected disclosure. If it is found that an Employee has prevented or attempted to prevent a Worker from making a report, this may result in disciplinary action being taken, up to and including dismissal.

When the allegations made by the Worker appear to be true, the Group Ethics Committee, with the cooperation of the Compliance Officer, will implement the means at its disposal to remedy the situation described in the report.

On the contrary, when the allegations made by the Worker appear to be unfounded or inaccurate, the Group Ethics Committee will close the report, destroy all data (or retain it for such period in accordance with the Act or by the applicable data protection legislation) and inform the Worker in writing (as referenced above). Where a concern is raised or a disclosure is made which in the reasonable belief of the Worker tends to show relevant wrongdoing in accordance with this whistleblowing mechanism , but is subsequently not upheld by an investigation, no action should be taken against the Worker making the disclosure and the Worker will be protected against any penalisation. However, as set out above, a disclosure that is made without any reasonable belief as to its accuracy may result in disciplinary action in accordance with Tcoag's Disciplinary Policy.

These provisions apply without prejudice to the legal provisions applicable to internal investigations, in terms of occupational hazards prevention, accidents at work or occupational diseases, and harassment. In certain circumstances, disclosures may, in the light of the seriousness of the matters raised, be referred immediately to the appropriate authorities. Likewise if urgent action is required (for example to remove a health and safety hazard), this action will be taken. It is important that the Worker feels assured that a disclosure under this whistleblowing mechanism is taken seriously.

## 1.7 If a Worker is not satisfied

Tcoag aims to deal with concerns in an appropriate way. By using this whistleblowing mechanism Workers can help us to achieve this.

If a Worker is not happy with the way in which his/ her concern has been handled, he/ she can raise it with the Compliance Officer or the Group Ethics Committee.

## 1.8. The confidentiality of the report

Tcoag guarantees, as far as possible, the strict confidentiality of:

- the identity of the Worker, the persons implicated in the report and any third party mentioned in the report;
- the information collected by all the recipients of the report.

The identity of the reporting person and the concern raised will be treated as confidential information and will only be shared with those authorised to receive and follow up on the disclosure, save as otherwise set out in this whistleblowing mechanism . Only the Compliance Officer and the members of the Group Ethics Committee will be able to access this information.

In line with legal requirements, except for limited exceptions, Tcoag should not disclose a Worker's identity (or any information from which the identity of the Worker may be deduced directly or indirectly) without explicit consent of the Worker. The focus will be on the wrongdoing rather than the person making the disclosure.

However, it is important to be aware that there are circumstances, as outlined in the Act, where confidentiality cannot be maintained - particularly in a situation where it may be necessary to disclose a Worker's identity for the purposes of follow-up of a report (however in those circumstances the Worker should be notified in writing with reasons before his/her identity or the information is disclosed). It should be understood that if engagement of the disciplinary process is considered appropriate follow-up, an Employee subject to such disciplinary process should in fairness know the case against him/her including the identity of the individual making the report on a confidential basis.

Consequently, in the event that a Tcoag employee wishes to make a report in written form, by post, the written report shall be sent in an envelope marked "Personal and Confidential".

The Group Ethics Committee will only disclose confidential information to the following people, if their communication is necessary for the report processing and in full compliance with the provisions relating to personal data protection and the confidentiality provisions of the Act:

- Legal counsel; and
- The Police or the competent public or judicial authorities.

## 1.9. No sanction or retaliatory actions if the whistleblowing mechanism is used in good faith

A Worker, as well as any facilitator or any other person, natural or legal, in connection with the Worker, who makes a disclosure, and has a reasonable belief that the information tends to show a relevant wrongdoing, will not be penalised by Tcoag, even if the concerns or disclosure turns out to be unfounded.

Penalisation for the purpose of this whistleblowing mechanism means any direct or indirect act or omission, which occurs in a work-related context, is prompted by the making of a report and causes or may cause unjustified detriment to the Worker.

This includes:

(j) suspension, lay-off or dismissal;
(ii) demotion;
(iii) disadvantage or unfair treatment;
(iv) reduction in wages or change in working hours;
(v) imposition of any discipline;
(vi) discrimination; and/or
(vii) harassment.

Any person who has penalised, threatened or attempted to penalise or takes or has taken sanctions or retaliatory actions against the Worker, including any facilitator or any other person, natural or legal, related to the Worker, may face disciplinary action, up to and including dismissal.

Tcoag employees are invited to inform the Group Ethics Committee of any measure that they consider to constitute, penalisation or any other sanction or retaliatory action. If substantiated, any act of penalisation will be deemed null and void.

On the other hand, the abusive use, in an interested way or in bad faith of the whistleblowing mechanism can expose the Worker to disciplinary sanctions as well as to legal proceedings in some circumstances.

## 1.10. Exercise of her/his rights by the persons identified in a report

Data processing of reports is implemented in accordance with the procedures put in place by and the GDPR.

In accordance with the GDPR, the persons identified within the framework of this whistleblowing mechanism have a right to access, to erasure when the personal data are no longer necessary with regard to the purposes for which they were collected, and to rectification of their information. They may exercise their rights by contacting the Group Ethics Committee.

## 1.11. Retention of collected data

Data relating to reports will be destroyed, stored or archived in accordance with the GDPR and the legal provisions in force.

As soon as they are collected, the data relating to a report considered as not falling within the scope of the whistleblowing mechanism are destroyed without delay.

When the report is not followed by a disciplinary or legal procedure initiated by Tcoag, the data relating to this report (and in particular the data allowing the identification of the Worker if she/he is identified, the data of the persons implicated in the report and the data of any third party mentioned in the report) are destroyed within two (2) months as from the end of the verification operations. The Worker, if she/he is identified, as well as the persons implicated in the report, are informed in writing of the end of the verification operations.

When disciplinary or legal proceedings are initiated against a person implicated in a report or against an identified whistleblower who made an abusive report, the data relating to the concerned report are archived by the body in charge of managing the reports until the end of the proceedings, prescription or exhaustion of the remedies according to the applicable regulations.

**Reports may only be kept for the time strictly necessary and proportionate to their processing and to the protection of the Worker, the persons they implicate and the third parties they mention.**

## 2 The possibility of turning to an external authority

The aim of this whistleblowing mechanism is to provide an avenue within Tcoag to deal with concerns or disclosures related to relevant wrongdoings. Tcoag strongly encourages Workers to report such concerns internally.

Tcoag acknowledges that there may be circumstances where a Worker wants to make a disclosure externally, and the Act provides for a number of avenues in this regard, even without having to first make use of the internal one.

In these circumstances, a Worker may turn to the following entities:

- Office of the Protected Disclosures Commissioner at https://www.opdc.ie/, who will receive and redirect the report to the appropriate competent authority;

- A prescribed person listed in Protected Disclosures Act 2014 (Disclosure to Prescribed Persons Order 2020). You may find this list at: https://www.gov.ie/en/collection/41798-protected-disclosures-whistleblowing-list-of-prescribed-persons/?referrer=http://www.gov.ie/prescribed-persons/

It is important to note that, if a Worker is considering an external disclosure, different and potentially more onerous obligations may apply depending on whom the disclosure is made.

Whistleblowing concerns usually relate to the conduct of Workers within Tcoag, but they may sometimes relate to the actions of a third party, such as a customer, supplier or service provider. In some circumstances the law will protect a Worker if he/she raises the matter with the third party directly. However, Tcoag encourages Workers to report such concerns internally first.

## 3 Review

Tcoag reserves the right to make changes and amendments to this whistleblowing mechanism at its sole discretion from time to time. The updated whistleblowing mechanism will be distributed to all Tcoag's Employees.

This whistleblowing mechanism does not form part of any employee's contract of employment.