



# STAGO GROUP CODE OF BUSINESS ETHICS

July 2017 version



## 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.**



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## 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 equal environment and advancement opportunity for all qualified individuals. The diversity of our Employees is a strength that we will continue to promote and support throughout 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, disability.

### **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 behaviors, 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 labeled 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 labeled "confidential" as well as information that is not labeled 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, personnel information, contracts and related information.

Employees shall 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, labeled, 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.

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 eagerly service 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 Partners 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 having 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: <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx>;
- 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 <http://www.bis.doc.gov/complianceandenforcement/liststocheck.htm> ;
- France draws up a synthetic table of the existing restrictive measures per country which can be accessed on: [http://www.tresor.economie.gouv.fr/8465\\_tableau-recapitulatif-des-mesures-restrictives-par-pays](http://www.tresor.economie.gouv.fr/8465_tableau-recapitulatif-des-mesures-restrictives-par-pays);
- 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: [http://www.tresor.economie.gouv.fr/5061\\_Liste-electronique-consolidee-des-sanctions-financieres](http://www.tresor.economie.gouv.fr/5061_Liste-electronique-consolidee-des-sanctions-financieres).

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.

## 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 from 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 favor to Stago or to show disfavor 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 behavior.

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 directly 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, 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

Disregarding or failing to comply with this Code may lead to disciplinary action where authorized by applicable law.

The Stago Ethics Committee, along with local Compliance Officers, coordinate the business ethics and compliance programs and are a resource to assist Stago Employees with questions or interpretations of the Stago Code of Business Ethics and related issues. They are also a resource for supervisors in managing compliance issues.

Stago Employees are encouraged to talk to supervisors, managers or the Stago Ethics Committee members about any unethical behavior or when such Employees are in doubt about the best course of action in a particular situation, in order to enable Stago to try and solve the problem.

With regards to reporting a known or alleged Code violation, no retribution or retaliation will be taken against any person who has filed a report based on a good faith belief that an employee of Stago has engaged in conduct in violation of this Code. Additionally, retaliation is prohibited against any individual who cooperates in an investigation pertaining to a potential Code violation.

Any person who takes (or attempts to take) retaliatory action against another employee, for reason of a good faith report by this employee, will be subject to appropriate disciplinary action.

If a Stago employee reports a concern which he/she knows to be untrue or with sole intent to harm somebody, then such Stago employee will expose him/herself to disciplinary action.

**Please refer to the country-specific supplement to this Code for identification of the members of the Stago Ethics Committee and for a detailed description of the procedure to be followed with regards to reporting an alleged Code violation.**

# TCOAG IRELAND CODE OF BUSINESS ETHICS

Local supplement for Ireland

December 2017

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 ANTICORRUPTION**

The Irish Prevention of Corruption Acts 1889 - 2010 (the "Prevention of Corruption Acts") prohibits corrupt practices in Ireland. The Prevention of Corruption Acts prohibit three offences, which apply to both private sector and public sector bribery.

The first offence is corruptly accepting a gift (passive bribery). It is an offence for an agent or any other person to corruptly, accept, agree to accept, or agree to obtain, a gift, consideration or advantage, for himself or any other person, as an inducement, reward or on account of the agent doing any act, or making any omission, in relation to the agent's office or position, or his principal's affairs or business.

The second offence is corruptly giving a gift (active bribery). In this case, it is an offence for a person to corruptly, give, agree to give or offer, a gift, consideration or advantage, to an agent or any other person, as an inducement to, or reward for, or otherwise on account of the agent doing any

act, or making any omission, in relation to his office or his principal's affairs or business.

The third offence is making a false statement. A person will be guilty of an offence if they knowingly give to any agent, or an agent knowingly uses with intent to deceive his or her principal, any receipt, account or other document which contains any statement which is false or erroneous or defective in any way, and which to that person's knowledge is intended to mislead the principal.

A definition of 'corruptly' was introduced in 2010 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.

The term 'agent' is broader than the common-law understanding of agent and includes domestic and foreign nationals employed by or acting on behalf of both private and public bodies as well as employees, or persons acting for another.

Importantly, the Prevention of Corruption Acts do not take the value or type of gift, consideration or advantage into account when determining if an offence has been committed. Such gifts will fall within the scope of prohibited acts if provided "corruptly".

## 2 ENTERTAINMENT AND GIFTS

Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices as transposed in Ireland by S.I. No. 304/2001 European Communities (In vitro Diagnostic Medical Devices) Regulations 2001 as amended, 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.

### 2.1 IMDA 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 IMDA Guidelines on Interactions with Healthcare Professionals – Code of Ethical Business Practice (the "**IMDA Guidelines**", appended hereto at Appendix 2). The IMA has also published Guidelines on Interactions with Healthcare Professionals – Guidance Document (the "**Guidance Document**", appended hereto at Appendix 3). MedTech Europe published a new Code of Ethical Business Practice (the "**MedTech Europe Code**", appended hereto at Appendix 4) in January 2017 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 IMDA Guidelines and Guidance Document as well as the MedTech Europe Code applicable at the time the proposed entertainment / gift is being considered. Broadly, the IMDA Guidelines and Guidance Document cover the following:

- 2.1.1 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.
- 2.1.2 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 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.
- 2.1.3 As of January 1, 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.

- 2.1.4 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.

## 2.2 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 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.”*

## 2.3 Ethics in Public Office Acts

The Ethics in Public Office Acts 1995 and 2001, prohibit any gifts to employees of public offices which are over €650 in value. **However, Stago 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

## 3.1 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 STAGO 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 Public Procurement Code, without:

- first verifying their reputation, skills and activities using the Procedure available on Tcoag's Intranet site "Pre-verification, selection and dealings with Business Partners";
- formalising through a written contract the terms and conditions of the business relationship and verifying that this contract includes the clauses listed in the Procedure referred to above.

The "Pre-verification, selection and dealings with Business Partners" 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 "Pre-verification, selection and dealings with Business Partners" Procedure.

The provisions of this article as well as the "Pre-verification, selection and dealings with Business Partners" Procedure do not apply to all contracts regulated by the Public Procurement Code.

### **3.2 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 "Pre-verification, selection and dealings with Intermediaries" 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 "Pre-verification, selection and dealings with Intermediaries" Procedure.

Furthermore, Tcoag Employees shall undertake not to proceed with or accept payments made in breach of the "Pre-verification, selection and dealings with Intermediaries" Procedure.

### **3.3 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

- 4.1 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 (formerly the National Public Policy Procurement Policy Unit (NPPPU) of the Department of Finance), 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.

In particular regard should be had to the monetary thresholds in relation to public contracts, i.e. for contracts under €5,000 oral offers may be accepted; for contracts between €5,000 - €25,000 (or €50,000 for 'works' contracts) a brief email/fax must be sent to a number of suppliers (at least 3); and for contracts over €25,000 (or €50,000 for 'works' contracts) a formal tender document must be drawn up and advertised to prospective suppliers on the public website [www.etenders.gov.ie](http://www.etenders.gov.ie).

- 4.2 Above these thresholds there are EU rules on Public Procurement which must be adhered to.

## 5 COMPETITION LAW

- 5.1 Tcoag Employees must at all times act in a manner which does not contravene Irish Competition Law. The Competition Act 2002 - 2014 (the "2002 Act") prohibits and renders 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 2002 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).

- 5.2 Furthermore the 2002 Act prohibits the abuse of a dominant position. It is important to recognise that it does not prohibit a dominant position - only its abuse.

- 5.3 The 2002 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 2002 Act will expose both Tcoag and its executives to criminal sanctions and civil actions for damages by ‘victims’ of anti-competitive behaviour in breach of the 2002 Act. The criminal sanctions for breach of the 2002 Act include fines ranging from €5,000,000 to 10% of Tcoag’s annual turnover, while directors and managers are liable to both fines of this level and/or imprisonment of up to ten years as well as personal civil liability.

## 6 WHISTLE-BLOWING MECHANISM

Any Tcoag Employee who suspects a breach of the Group Code of Ethics or Irish Code of Ethics is urged to exercise their right to report by going straight to their immediate superior or the Compliance Officer or the Group Ethics Committee, in accordance with the “Whistle-blowing Mechanism” described below.

### 6.1 Definition and purpose of the whistle-blowing mechanism

Tcoag Employees are encouraged to report any conduct that they believe clearly breaches the Group Code of Ethics and/or the Irish Code of Ethics.

**Employees can report conduct, either directly to their immediate superior or to the Compliance Officer or to the Group Ethics Committee.**

The whistle-blowing mechanism is optional. As such, Employees who do not exercise their right to report will not face any disciplinary action.

### 6.2 Scope of the professional whistle-blowing mechanism

The whistle-blowing mechanism enables any Tcoag Employee to exercise – in good faith – their right to report any conduct that is contrary to the provisions of the Group Code of Ethics, the Irish Code of Ethics, any serious and obvious breach of an international undertaking duly ratified and approved by Ireland, a unilateral act of an international organization taken on the basis of such an undertaking or current laws or regulations, or any threat or serious harm to the public interest, of which they have personal knowledge.

Information or documents, regardless of their form or medium, which are protected by national defense secrecy, medical confidentiality or lawyer-client privilege are excluded from the whistle-blowing system.

### 6.3 Exercising one’s right to report

Contact Persons

Employees who wish to report conduct must speak with their direct or indirect superior or the Compliance Officer or the Group Ethics Committee.

Compliance Officer: Adrian Farrell

Group Ethics Committee:

The following individuals are members of the Group Ethics Committee:

- Patrick Monnot, Acting Vice-Chairman
- Fabienne Clarac, Group General Counsel
- Antoine Coulot, Group Chief Financial Officer

Reports must be submitted by:

(1) Designated email :

- [Complianceireland@tcoag.com](mailto:Complianceireland@tcoag.com) which can only be accessed by the Compliance officer;
- [Ethics@stago.com](mailto:Ethics@stago.com), which can only be accessed by the Group Ethics Committee

(2) Mail to the following address:

- Adrian Farrell  
Tcoag Ireland,  
IDA Business Park  
Southern Cross Road  
Bray, Co.  
Wicklow  
Ireland
- Stago Group Ethics Committee  
3 Allée Thérèse,  
92600 Asnières sur Seine,  
France

### 6.3 Contents of a report

To the extent possible, a report should consist of the following information:

- Name of the person or persons involved and, if possible, where they work,
- Description of the breach or the incident in question, including the date, place and means used,
- Name of any witnesses who may be useful to the internal investigation,
- Description and reporting of any written item or document related to the breach.

The author of the report shall also provide the elements allowing communication with the recipient of the report.

### 6.4 Whistle-blower identification

Each Employee can identify himself or herself when reporting conduct, since Tcoag guarantees that whistle-blowing will be treated with the utmost confidentiality, as detailed below.

## 6.5 Confidentiality of the report

Tcoag guarantees that the identities of the whistle-blower and the people named by the latter as well as the information gathered by all recipients of the whistle-blower report will remain strictly confidential.

If a Tcoag Employee wishes to report conduct through a written medium, the written report must be submitted in an envelope marked “Personal and Confidential”. Elements that identify the whistle-blowing Employee may not be disclosed without their consent, except to the judicial authority.

Elements that may identify the person implicated by the report may not be disclosed, other than to the police or a judicial authority, until the merits of the report are established.

The Compliance Officer or the Group Ethics Committee will only convey confidential information to the following people:

- Lawyers if necessary,
- The Police or the appropriate public or judicial authorities.

## 6.6 Internal Investigations

Only the Group Ethics Committee is authorised to conduct an internal investigation into an alleged or potential breach of the Group Code of Ethics, Irish Code of Ethics or any laws and regulations. He/She is entitled to legal assistance.

The author of the alert shall be informed of its receipt without delay by the Group Ethics Committee and of the reasonable and foreseeable time necessary for the examination of the admissibility of the alert.

The author will also be informed of the manner in which he/she will be informed of the actions taken on their alert.

Each report will result in a preliminary assessment that is dealt with confidentially by the Group Ethics Committee in order to determine, prior to any investigation, whether it falls within the scope of the reporting procedure. Any report that clearly falls outside the scope of the reporting procedure, lacks seriousness, initiated in bad faith or constitutes slander or false allegation, as well as any report based on unverifiable facts, will be immediately destroyed. The initiator of the report will be notified.

If the reported facts fall within the scope of the reporting procedure, the Employee or Employees involved will be informed, as soon as the information relating to them is recorded, that they are being investigated as part of such proceedings.

This internal investigation shall be conducted in full compliance with applicable legislation. The Employee or Employees involved will be asked for their opinion on the reported facts. By the same token, Tcoag shall ensure that the information collected is sufficient, relevant and not excessive in relation to the purposes for which it is collected.

The Employee involved may be assisted by the person of their choice within Tcoag.

All Tcoag Employees are required to fully cooperate with the internal investigation. This includes cooperation during an interview by being honest and keeping all information and documents needed for the internal investigation confidential.

These provisions apply without prejudice to legal provisions governing internal investigations, in particular relating to preventing occupational hazards, workplace accidents or occupational illness, as well as harassment.

No sanctions or retaliation when whistle-blowing mechanism is used in good faith

The Employee who reports conduct in good faith may not claim any compensation and shall not be subject to any sanctions or retaliation, even if the facts prove to be inaccurate or are not acted on.

Any person who pursues sanctions or retaliation against a whistle-blowing Employee will face disciplinary action, including dismissal.

Tcoag Employees are encouraged to inform the Compliance Officer or the Group Ethics Committee of any action that they believe constitutes a sanction or retaliation.

The STAGO Group shall undertake to ensure that the Employee reporting conduct in compliance with the law is not penalised, dismissed or directly or indirectly discriminated against, including when it comes to compensation, training, redeployment, assignment, qualification, deployment, career advancement, transfer or contract renewal.

Any decision to the contrary shall be null and void.

However, a whistle-blower who self-servingly or in bad faith misuses the mechanism may be liable to disciplinary action as well as prosecution.

## 6.7 Information from people being reported

The person being reported shall be informed by Tcoag once the information relating to them is recorded, electronically or otherwise.

However, when provisional measures are needed, including to prevent the destruction of evidence related to the report, this person is not informed until these measures are adopted.

## 6.8 The rights of people being reported

In accordance with the Data Protection Acts 1988 and 2003, persons identified by the whistle-blowing mechanism have the right to access and modify the information relating to them; they can exercise this right by speaking with the Compliance Officer or the Group Ethics Committee. These people may also, for legitimate reasons, object to the processing of information relating to them.

## 6.9 Retention of the collected information

Report-related information will be destroyed, retained or archived in accordance with current legal provisions.

As soon as it is collected, information related to a report deemed not to fall within the scope of the mechanism will be immediately destroyed.

When the report is not followed by disciplinary or legal proceedings initiated by Tcoag, information related to this report (and particularly those enabling the identification of the author of the alert and of the persons affected by the alert) will be destroyed or archived within two months from the completion of the investigation. The author of the alert as well as the persons affected by the alert will be informed of the completion of the audit.

When disciplinary or judicial proceedings are commenced against the person involved or the initiator of a wrongful report, the information related to the report is retained by the organisation in charge of managing reports until proceedings are concluded.

## **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 and will come into force on December 1, 2017.

## 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's reputation and can have adverse implications for both the company, 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 their manager, 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. IMDA Guidelines

Guidelines on Interactions with Healthcare Professionals

# Code of Ethical Business Practice



Supported by

# Complaints Procedure and Sanctions

The Code of Ethical Business Practice complaints procedure and sanctions was formally ratified at IMDA's AGM on the 12 December 2013.

Compliance with the Code and with this Complaints Procedure and Panel Constitution is mandatory for members of IMDA. The Code is administered by a Panel Administrator and by a panel of independent individuals and the Panel is chaired by an independent solicitor/ barrister. The IMDA's Code of Ethical Business Practice Panel members include Mr Liam Downey (former Chairperson of the Health Service Executive) Mr Stuart Margetson, (consultant in commercial litigation and dispute resolution, Matheson), Ms Siobhán O'Daly (Network Development Manager, NCSRN Ireland, Irish Heart Foundation) and Professor W. Arthur Tanner (RCSI Council Member).

A full overview of complaints procedure and sanctions are available on [www.imda.ie/ethics](http://www.imda.ie/ethics)



These guidelines are intended to provide guidance on the interactions of Irish Medical Device Association (IMDA) members with individuals (Clinical or non-clinical, including but not limited to, physicians, nurses, technicians and research co-ordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' medical devices ("Healthcare Professionals").

The Irish Medical Devices Association Code of Ethical Business Practice consists of the Guidelines on Interactions with Healthcare Professionals and the Trade Associations' Guidelines and Competition Law.

This brochure contains only the Guidelines on Interactions with Healthcare Professionals.

*Members of the Irish Medical Devices Association recognise that adherence to ethical standards and compliance with applicable laws are critical to the medical technology/devices industry's ability to continue its collaboration with Healthcare Professionals.*

*All members should independently ascertain that their interactions with Healthcare Professionals comply with all current national and local laws, regulations and professional codes.*

## Preamble

There are many forms of interactions between the members of the Irish Medical Devices Association and healthcare professionals that advance medical science or improve patient care, including:

- **Advancement of medical technology:**

The development of innovative medical devices and the improvement of existing products require collaboration between members and Healthcare Professionals. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the facilities of medical device companies.

- **Safe and Effective use of Medical Technology:**

The safe and effective use of medical technology requires members to offer Healthcare Professionals appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.

- **Research and Education:**

Members' support of bona fide medical research, education, and enhancement of professional skills contribute amongst others to patient safety and increase access to new technology.

Members of the Irish Medical Devices Association recognise that adherence to ethical standards and compliance with applicable laws are critical to the medical technology/devices industry's ability to continue its collaboration with Healthcare Professionals.



Members must encourage ethical business practices and socially responsible industry conduct related to their interactions with Healthcare Professionals. Members must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment.

The guidelines are based on the following key principles:

- **The Principle of Separation:**

Interaction between industry and Healthcare Professionals 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 members' products.

- **The Principle of Transparency:**

Interaction between industry and Healthcare Professionals must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, members shall nevertheless maintain appropriate transparency by requiring prior written notification is made 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 to perform a service for or on behalf of a member, the remuneration paid by the member 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 and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a member, 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.

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 to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

Members should require that third party intermediaries, both sales intermediaries and other third party agents, including but not limited to, consultants, distributors, sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives, who interact with Healthcare Professionals in connection with the sale, promotion or any other activity involving members' products, comply with standards equivalent to these guidelines.

Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation imposes obligations upon the third party to comply with these or equivalent guidelines.

These guidelines set out the standards appropriate to various types of relationships with Healthcare Professionals. These guidelines are not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon members or Healthcare Professionals who engage in certain activities in those countries.

All members should independently ascertain that their interactions with Healthcare Professionals comply with all current national and local laws, regulations and professional codes.

*Any hospitality should be reasonable in value, subordinate in time and focus to the educational purpose of the training and in compliance with the regulations of the country where the Healthcare Professional is licensed to practice.*

*Members may sponsor satellite symposia at third party conferences and provide presentations on subjects that are consistent with the overall content of the third party conference provided that all information presented is fair, balanced and scientifically rigorous.*



## Member - sponsored product, training and education

Where appropriate, members should make product education and training available to Healthcare Professionals to facilitate the safe and effective use of medical technology. Such education and training programmes should occur at appropriate locations taking account of the convenience of the attendees and the nature of the training. In particular:

Programmes and events should be conducted in clinical, laboratory, educational, conference, or other appropriate settings, including members' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required "hands on" training.

The training staff should have the appropriate expertise to conduct such training.

Members may provide attendees with reasonably priced meals in connection with the programme, and for educational programmes necessitating overnight stays, additional hospitality may be appropriate. Any hospitality should be reasonable in value, subordinate in time and focus to the educational purpose of the training and in compliance with the regulations of the country where the Healthcare Professional is licensed to practice.

Members may pay for reasonable travel and accommodation costs incurred by an attending Healthcare Professional, in compliance with the regulations of the country where the Healthcare Professional is licensed to practice.

Members are not permitted to facilitate or 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.

# Supporting third-party educational conferences

Bona fide independent, educational, scientific or policy-making conferences promote scientific knowledge, medical advancement and assist in the delivery of effective Healthcare. To these ends members may support such events provided the educational conference content promotes scientific knowledge, medical advancement and the delivery of effective Healthcare and is consistent with relevant guidelines established by professional societies or organisations for such meetings.

IMDA members may support such events by the provision of financial, scientific, technical, organisational and/or logistical assistance as follows:

- **Healthcare Professional Sponsorship**

Where permitted under national and local laws, regulations and professional codes of conduct, members may provide financial support to cover the cost of conference attendance by individual Healthcare Professionals. Such financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event.

Members must ensure full compliance with national and local laws with regard to the disclosure or approval requirements associated with such sponsorship and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, for example, by requiring prior written notification of the sponsorship is made to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority.

- **Advertisements and Demonstrations**

Members may purchase advertisements and lease booth space for company displays at conferences.

- **Conference Support**

Members may provide financial grants directly to the conference organiser to reduce the overall cost of attendance for participants and to cover reasonable honoraria, travel, meals and accommodation expenses of Healthcare Professionals who are bona fide conference faculty members. A written request must be made by the conference organiser, to the member and any sponsorship must be paid directly to the conference organiser or training institution. The conference organiser alone is responsible for the programme content and the faculty selection. Members may not have any detailed involvement in determining the content of the conference other than recommending speakers or commenting on the programme where requested to do so.

- **Satellite Symposia**

Members may sponsor satellite symposia at third party conferences and provide presentations on subjects that are consistent with the overall content of the third party conference provided that all information presented is fair, balanced and scientifically rigorous. Members may determine the content of these events and be responsible for faculty selection.

The arrangement must be documented by written contract and the support of the member must be disclosed in all materials relating to the satellite event.

- **Scholarships**

Members may also provide educational grants to training institutions, Healthcare institutions or professional societies for medical education programmes by providing financial support for fellowships and similar scholarship awards.

The selection of the grantee should be within the discretion of the institution at which they are enrolled or the teaching institution at which they will be trained. Grants must be provided to the teaching or professional institution, not to individual fellows, save at the prior written request of the institution. In no way should the funding be tied to an institution's purchase of a company's products, or otherwise be based on an institution's past or potential future use of the company's products or services.

*Members may pay for reasonably priced meals for Healthcare Professional attendees in an environment that is conducive to the exchange of information.*

*Consulting arrangements with Healthcare Professionals must be described in a written agreement, signed by the parties and must specify the services to be provided.*



## Sales and promotional meetings

In the countries where it is appropriate for members to meet with Healthcare Professionals to discuss product features, conduct contract negotiations, or discuss sales terms, these meetings should, as a general rule, occur at or close to the Healthcare Professional's place of business. In connection with such meetings, members may pay for reasonably priced meals for Healthcare Professional attendees in an environment that is conducive to the exchange of information.

Where plant tours or demonstrations of non-portable equipment are necessary, members may also pay for the reasonable travel and accommodation costs of Healthcare Professional attendees. However, members are not permitted to facilitate or 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.

## Arrangements with consultants

Healthcare Professionals may serve as consultants to members, providing meaningful bona fide services, including research, participation on advisory boards, presentation at member-sponsored training or third party educational conferences, and product development.

It is appropriate to pay Healthcare Professionals reasonable compensation for performing these services. The following factors support the existence of a bona fide consulting arrangement between members and Healthcare Professionals:

- Consulting agreements must be entered into only where a legitimate purpose for the services is identified in advance.
  - Selection of consultants must be on the basis of the consultant's qualifications and expertise to address the identified purpose and should not be on the basis of volume or value of business generated by the consultant.
  - Consulting arrangements with Healthcare Professionals must be described in a written agreement, signed by the parties and must specify the services to be provided.
  - Such arrangements must be consistent with the regulations of the country where the Healthcare Professional is licensed to practice.
  - The compensation paid to Healthcare Professionals engaged as consultants must be the fair market value for the services provided and must not be tied in any way to the value of medical devices which the consultants may use for their own practice. All payments made must comply with applicable tax and other legal requirements.
  - Members may pay for reasonable and actual expenses incurred by consultants in carrying out the subject of the engagement including reasonable and actual travel, meals and accommodation expenses incurred by consultants in attending meetings with, or on behalf of members. The written agreement should describe all expenses that can be claimed by the consultant in relation to the provision of the services.
  - Members must ensure full compliance with national and local laws with regard to the disclosure or approval requirements associated with members engaging Healthcare Professionals as consultants. Where no such national requirements are prescribed, members shall nevertheless maintain appropriate transparency by requiring prior written notification is made to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, disclosing the purpose and scope of the consultancy arrangement.
  - All consultancy arrangements with Healthcare Professionals must be documented in writing even where the Healthcare Professional does not require payment for services or where the arrangement involves a one-day event only.
  - The venue and circumstances for member meetings with consultants should be appropriate to the subject matter of the consultation. The meetings should be conducted in clinical, educational, conference or other suitable settings, including hotel or other available meeting facilities, conducive to the effective exchange of information.
  - Member-sponsored hospitality that occurs in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus for the primary purpose of the meeting.
  - When a member contracts with a Healthcare Professional acting as a consultant for research services, the written agreement described above must reference a written research protocol or written schedule of work as appropriate and all required consents and approvals should be obtained.
  - When a member contracts with a Healthcare Professional for the development of intellectual property, there must be a written agreement providing compensation at a fair market value. However, under no circumstances may the Healthcare Professional receive any financial compensation in respect of medical devices he/she has prescribed in the past or may prescribe in the future, including medical devices which contain the novel intellectual property.
- All required consents and approvals should be obtained, including from the hospital administration or the Healthcare Professional's superior (or locally-designated competent authority).

*Members should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisations.*

*Members may make donations for charitable or other philanthropic purposes. Donations may be made only to charitable organisations or other non-profit entities entitled to receive them under applicable national or local laws and regulations.*



## Gifts

Members occasionally may provide inexpensive, branded or non-branded items as gifts to Healthcare Professionals, if they are modest in value and in accordance with the national and local laws, regulations and industry and professional codes of conduct of the country where the Healthcare Professional is licensed to practice.

Gifts must relate to the Healthcare Professional's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents.

This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

## Provision of Reimbursement and other economic information

Members should support accurate and responsible billing to reimbursement authorities and other payors. In doing so, they provide economic efficiency and reimbursement information to Healthcare Professionals and third party payors regarding members' products.

This information should be limited to identifying appropriate coverage, coding or billing of member products, or procedures using those products, or to encouraging the economically efficient delivery of member products. This section is not intended to address the legitimate practice

of providing technical or other support intended to aid appropriate use or installation of the member's products.

# Donations for charitable and philanthropic purposes

Members may make donations for charitable or other philanthropic purposes. Donations may be made only to charitable organisations or other non-profit entities entitled to receive them under applicable national or local laws and regulations.

Donations may be made to support the general activities of a bona fide organisation or may be made to support general fund raising drives for projects undertaken by such an organisation.

Charitable donations must not be tied in any way to past, present or potential future use of the member's products or services. All donations to a charity or non-profit organisation should be appropriately documented. For example, a written request should be submitted by the charitable organisation, detailing the purpose of the charity and the nature of its activities. The payment should be made out in the name of the charity and paid directly to the charity. Charitable donations to a bona fide organisation should not be made in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the organisation and submits the request on behalf of the organisation.

It would not be appropriate for a member to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional. Members should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisations.

## Educational grants

Members may provide funds to support genuine independent medical research, advancement of medical science or education, or patient and public education.

However, it is important that support of these programmes and activities by members is not viewed as a price concession, reward to favoured customers or inducements to recommend, prescribe or purchase members' products or services. Therefore members should ensure that they

maintain appropriate documentation in respect of all educational grants made.

Educational grants must not be tied in any way to past, present or potential future use of the member's products or services. Educational grants may be made only to organisations or entities entitled to receive them under applicable national and local laws and regulations and should not be made to individual Healthcare Professionals. (For guidance on how members may support the education of individual Healthcare Professionals refer to Section III Supporting Third Party Educational Conferences). Examples of appropriate educational programmes and related considerations are as follows:

- **Scholarships**

Professional organisations, hospitals and universities where Healthcare Professionals are in training may be eligible to receive grants to support scholarships. For guidance on how members may support scholarships and similar awards refer to Section III Supporting Third Party Educational Conferences.

- **Advancement of Healthcare Education**

Members may support Healthcare Professional education by donating funds to institutions or organisations for either accredited or non-accredited Healthcare education. For further guidance on how members may support such education, refer to Section III Supporting Third Party Educational Conferences.

- **Research**

Research grants to support customer-initiated studies may be permitted for programmes involving clinical or non-clinical research in areas of legitimate interest to the member. The member may provide funds for documented expenses, in-kind services, or free product to support clearly defined bona fide research activities of Healthcare Professionals where permitted by national and laws, regulations and professional codes of conduct.

All requests for research grants must be in writing from the requestor stating the nature and objective of the research activity. No support should be provided until a written agreement is signed by both parties and said agreement should provide for adverse event reporting where appropriate. Full disclosure of the award must be made to the hospital administration, or the Healthcare Professional's superior, or other locally-designated competent authority as appropriate and the recipient of the grant shall be required to acknowledge the member's support of the research in all oral or written presentations of the results.

- **Public Education**

Members may make grants for the purpose of supporting education of patients or the public about important Healthcare topics.



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## Appendix 3. Guidance Document



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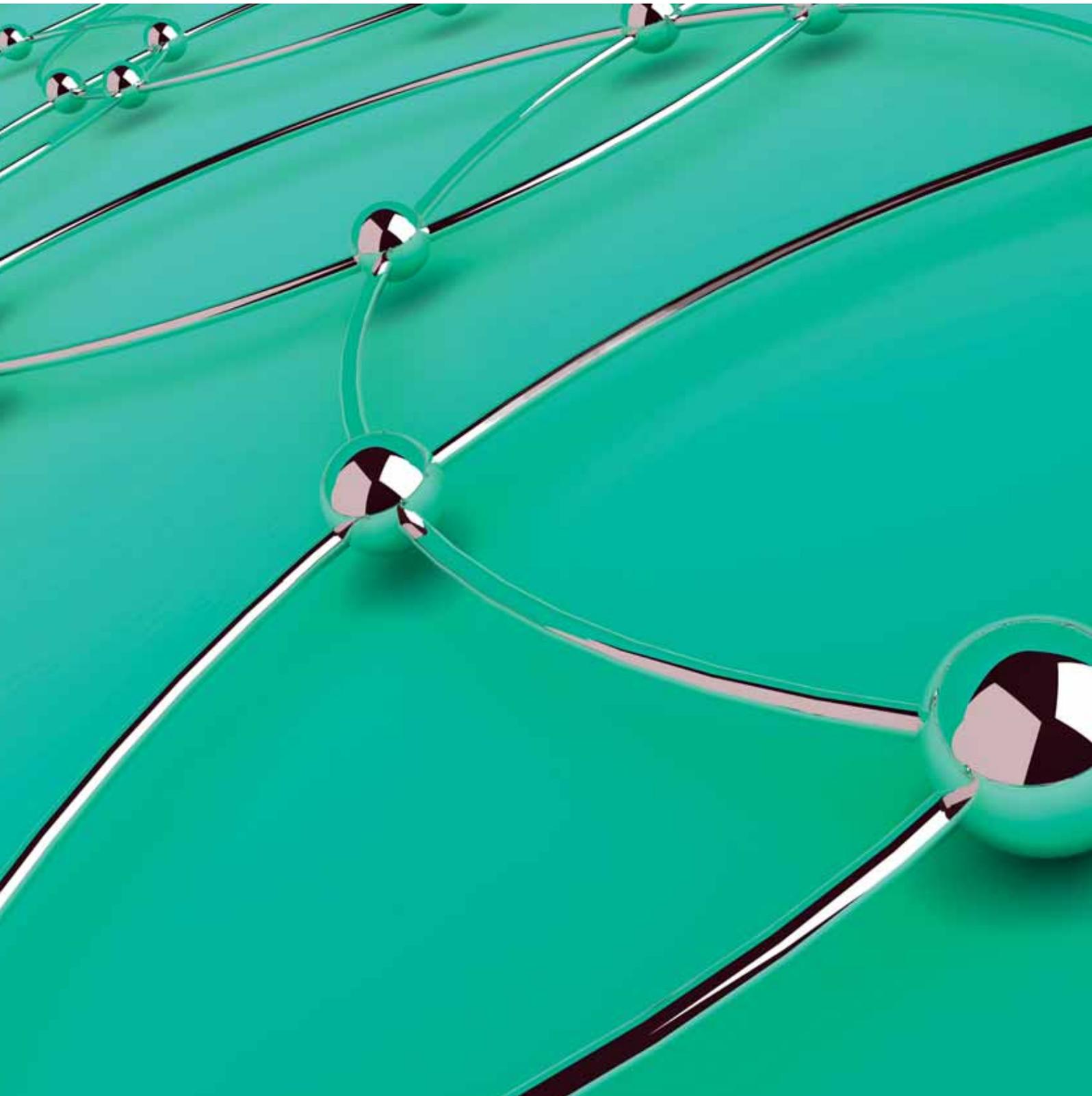
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## IRISH MEDICAL TECHNOLOGY INDUSTRY

GUIDELINES ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

# Guidance Document



## IRISH MEDICAL TECHNOLOGY INDUSTRY

### GUIDELINES ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

# Guidance Document

These guidelines are intended to provide guidance on the interactions of **Irish Medical Device Association (IMDA)** and **IMSTA** members with individuals (clinical or non-clinical, including but not limited to, physicians, nurses, technicians and research co-ordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' medical devices ("Healthcare Professionals").

# Guidance on Interactions with Healthcare Professionals

## Q1

Under the guidelines, is written notification to the Healthcare Professional's employer (or other locally-designated body) required for each interaction with a member? For example, is such notification required each time a member pays for a reasonably priced meal or gives a Healthcare Professional a gift which is otherwise in line with the requirements of the guidelines?

## A1

Written notification to the Healthcare Professional's employer (or other locally-designated body) is required whenever a member engages a Healthcare Professional as a consultant or whenever a member makes a financial contribution to the Healthcare Professional's medical training. 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 notification.

## Q2

Are members required to provide additional written notification under the Code to the Healthcare Professional's employer (or other locally-designated body) for member/Healthcare Professional interactions in countries where there are compulsory notification systems already in place?

## A2

No. Only the compulsory notification is required. Additional notification under the Code is not required in countries where specific 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 local transparency laws and regulations

## Q3

Under the guidelines, what is meant by the term "appropriate location"?

## A3

An "appropriate location" is a recognised institution, conference or business centre which is centrally located, providing ease of access when regard is given to the place of origin of the invited participants. The location selected should not become the main attraction of the event and members must consider at all times the image that may be projected to the public by their choice of location.

The appropriateness of the location applies irrespective of who organises the event and members should consider the location of the event and the image that may be projected to the public when supporting an event, whether this is by leasing booth space for company displays or any form of event sponsorship.

## Q4

What criteria should a member apply when considering the country location of product training or education?

## A4

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 meeting.

## Q5

Can a member use a meeting venue outside Europe?

## A5

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 meeting.

## I

# Guidance on Interactions with Healthcare Professionals

## Q6

Are hotels suitable venues for member-sponsored meetings with Healthcare Professionals?

## A6

Yes, hotels are suitable venues for member-sponsored meetings with Healthcare Professionals. The hotel selected should not become the main attraction of the event and members must consider at all times the image that may be conveyed to the public by their choice of hotel.

The hotel should not normally be a top category or luxury hotel in the country in which it is located nor be renowned for its entertainment facilities. An important factor in selecting a hotel is its suitability for business meetings, including the availability of conference facilities.

## Q7

Can a member use a hotel that offers leisure facilities such as golf, or water sports for member-sponsored training and education?

## A7

Many business hotels and conference centres provide leisure facilities and while it would not be reasonable to exclude these venues if otherwise appropriate, members must exercise caution. Members should arrange the meeting agenda such that Healthcare Professionals attending the meeting 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, members may not make such payments on behalf of the Healthcare Professionals.

## Q8

Are cruise ships or golf clubs appropriate venues for member-sponsored training and education?

## A8

No. Cruise ships, golf clubs or health spas and venues renowned for their entertainment facilities are not appropriate venues and should not be used.

## Q9

Under the guidelines, what do the terms 'reasonable' and 'hospitality' mean?

## A9

The guidelines seek to find a balance between the courteous and professional treatment of Healthcare Professionals by Irish Medical Devices Association (IMDA) and IMSTA members, with the desire to avoid even the appearance that hospitality may be used by members as a means to induce Healthcare Professionals to purchase, prescribe or recommend company products.

Accordingly, members 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 local laws, regulations and professional codes of conduct. If the meeting venue is a hotel which complies with the requirements of the guidelines, it would be acceptable for members to offer participants meals and accommodation at the same hotel.

The term 'hospitality' includes meals and accommodation. It is important that members differentiate between 'hospitality' which is permitted and 'entertainment' which is not. 'Entertainment' 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.

## Q10



“ If Healthcare Professionals attending product training wish to be accompanied by a spouse/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 spouse’s/guest’s expenses. ”

Under the guidelines, what standard of air travel may a member provide a Healthcare Professional attending member-sponsored training?

### A10

Members may provide only economy or standard class air travel to Healthcare Professionals unless the flight time is of a duration of greater than 5 hours; in which case, it is appropriate to consider premium economy or business class provided this is permitted under the national and local laws, regulations and professional codes of conduct of the country where the Healthcare Professional is licensed to practise.

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### Q11

What does the term “facilitate” mean when used in connection with the guest or spouse’s expenses?

### A11

The term “facilitate” refers to the prior arrangement, organisation or booking of meals, travel or accommodation by a member on behalf of the spouse/guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in their own right.

If Healthcare Professionals attending product training wish to be accompanied by a spouse/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 spouse/guest’s expenses.

### Q12

In the event that a Healthcare Professional is accompanied by a spouse/guest at member-sponsored product training, may the spouse/guest be admitted to any member-related activity?

### A12

It would not be appropriate for the spouse/guest of a Healthcare Professional to be invited to attend any of the member-related activities, including associated meals even when the Healthcare Professional has paid for the spouse/guest expenses. Any uninvited appearance by a spouse/guest should be strongly discouraged.

---

### Q13

In connection with providing financial support to cover the cost of conference attendance by individual Healthcare Professionals, what are deemed to be reasonable travel, meals and accommodation?

### A13

Members must assess what is reasonable in any given location and regional and country variations will apply. However, as with member-sponsored training, the hospitality provided by members at third party educational events should not be of such a level as to become the main attraction of the event.

Accordingly, hotel accommodation should not normally be provided at top category or luxury hotels, air travel should be economy or standard class unless the duration of the flight extends beyond 5 hours (in which case premium economy or business class may be considered), and meals should be of a standard that Healthcare Professionals would routinely expect if they were paying for them out of their own pockets. A meal at the conference hotel with wine would normally be considered acceptable.

# Guidance on Interactions with Healthcare Professionals

## Q14

Is it appropriate for members to cover the full registration fee of third-party conferences where such fee covers the cost of a conference dinner and/or social or cultural activities?

## A14

Members must not pay for the expenses which relate to the purely social or cultural aspects of the conference. Modest and incidental gatherings such as the welcome cocktail are appropriate and members may cover these expenses.

Where the registration fee includes an element of entertainment members must request that these elements are separated in the registration fee and subsequently not pay for this element.

If the conference organiser is unable to separate the entertainment costs from the registration fee, members should assess the image that may be projected to the public and reconsider supporting the event.

For the avoidance of doubt, the conference dinner may be supported if it is expected that all delegates to the conference would normally attend and provided the dinner is otherwise in line with the requirements of the guidelines.

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## Q15

Please provide examples of the types of third party educational conferences where members may provide financial support to cover the attendance by individual Healthcare Professionals.

## A15

Where permitted under national and local laws, members may provide reasonable financial support to cover the cost of attendance (e.g. registration fee, travel, meal and accommodation) by individual Healthcare Professionals at third party scientific events such as medical congresses and symposia, seminars, training courses and therapy-orientated training.

## Q16

May a member provide financial support to cover the cost of conference attendance (including conference registration and reasonable travel, meals and accommodation) to HCPs who are conference faculty members?

## A16

Yes, a member may provide financial support to individual HCP who are conference faculty members to cover the cost of the conference attendance. The principles set out in the guideline in Section III relating to the HCP's sponsorship shall apply. Payment should generally be made to the conference organiser or the appropriate supplier/vendor or intermediary agency or alternatively members may reimburse the faculty members expenses against original invoices or receipts. Furthermore, in the interest of transparency, the faculty member should declare that he/she is the recipient of such sponsorship from a member company at the time he/she delivers a presentation at the conference.

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## Q17

Are members permitted to invite Healthcare Professionals to educational conferences, offering to cover their reasonable expenses, or are members only permitted to support Healthcare Professional attendance at conferences in response to unsolicited requests from Healthcare Professionals?

## A17

Members are permitted to invite Healthcare Professionals to attend educational conferences provided the selection is based upon the training and educational requirements of the individual Healthcare Professional and is in no way tied to the Healthcare Professional's past or potential future use of the member's products or services.

Members have to ensure that they comply with all national and local laws, regulations or professional codes of conduct with regards to transparency.



“ Each Healthcare Professional remains subject to the regulations of his/her own country, irrespective of where the event takes place. In the case of conflict, the member is recommended to apply the stricter rule. ”

In countries where specific provision is not made, Members must maintain appropriate transparency by giving prior written notification to the hospital administration, the HCP's superior (or other designated competent authority) expressly offering the possibility to comment and/or oppose the invitation or to designate an alternative HCP recipient.

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### Q18

**How does the Code apply where a member organises or sponsors an international meeting with Healthcare Professionals attending from various European countries?**

### A18

When organising or sponsoring international events, members must comply with the regulations on hospitality applicable to each Healthcare Professional in their respective countries and with the regulations in the country where the event takes place. Each Healthcare Professional remains subject to the regulations of his/her own country, irrespective of where the event takes place. In the case of conflict, the member is recommended to apply the stricter rule.

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### Q19

**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 a conference?**

### A19

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 members may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts.

### Q20

**May member companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the congress or other training programme attended?**

### A20

Generally, travel and accommodation support given by member companies to Healthcare Professionals should be strictly tailored to the duration of the congress or educational event. However, where the travel expenses incurred are significantly reduced by the Healthcare Professional travelling at alternate times, the travel arrangements may be extended. Any accommodation expenses relating to the extended stay must be met by the Healthcare Professional.

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### Q21

**May member companies organise the travel and accommodation arrangements of the spouse or other guest of a Healthcare Professional attending a third-party congress if the Healthcare Professional pays for the spouse or guest?**

### A21

No, unless that person qualifies as a proper delegate or participant at the meeting in their own right, it would not be appropriate for a member to organise the travel and/or accommodation arrangements of the spouse or guest of a Healthcare Professional, irrespective of who pays. Such actions are open to misinterpretation.

# Guidance on Interactions with Healthcare Professionals

## Q22

Is it permissible under the Code for member companies to sponsor the attendance of individual Healthcare Professionals on courses of further education, for example, masters degree courses or modules of such courses?

## A22

No, members may not sponsor individual Healthcare Professionals to attend courses of further education such as masters degree courses. Members may make educational grants available and provide such grants to the training institution but must have no role in the selection of the individual who will receive the grant.

## Q23

Is it acceptable for members to subsidise or pay for the attendance of Healthcare Professionals at events organised by medical device industry associations or by groups of companies (in both cases with or without the involvement of third parties)?

## A23

Yes this is acceptable provided the Healthcare Professional is likely to obtain an objective benefit from such attendance and there is no overt commercial promotion. For example, meetings arranged for the purpose of training Healthcare Professionals on the guidelines or gaining a better understanding of the industry in general, would be acceptable.

## Q24

Is it appropriate for members 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?

## A24

Yes it is appropriate for members 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 guidelines in all respects.

Accordingly, members should ensure that appropriate documentation is put in place, hotel accommodation is not normally provided at top category or luxury hotels, air travel is economy or standard class unless the duration of the flight extends beyond 5 hours (in which case premium economy or business class may be considered) and meals are of a standard that Healthcare Professionals would routinely expect if they were paying for them out of their own pocket.

## Q25

What general criteria need to be fulfilled for arrangements with Healthcare Professionals that are engaged to provide genuine consultancy services?

## A25

The criteria that should be adopted are as follows:

- a legitimate business need is identified in advance;
- the criteria for the selection of Healthcare Professionals are related to the identified need;
- a written agreement specifying the services to be provided is in place before the service is rendered;
- compensation for the service rendered is reasonable and according to fair market value;
- members document the work products generated by the Healthcare Professionals; and the arrangement is entered into without intention of using it as a means to induce the recommendation, purchase, prescription, supply or sale of medical products or services.



“ It is appropriate for members 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 guidelines in all respects. ”

## Q26

Under the guidelines, is it compulsory that a Healthcare Professional engaged as a consultant by a member obtains a written permission from the main Healthcare institution where the Healthcare Professional conducts his or her work to render services as a consultant for the member?

## A26

Under the guidelines, written permission is not required. However, interaction between industry and Healthcare Professionals must be transparent and comply with national and local laws, regulations and professional codes of conduct.

In countries where specific provision is not made, members shall nevertheless maintain appropriate transparency by giving prior written notification to the hospital administration or the Healthcare Professional's superior (or other locally-designated body), fully disclosing the purpose and scope of the engagement.

## Q27

According to the guidelines, would it be permissible for members to organise entertainment or other social or leisure activities in association with meetings with Healthcare Professionals who are engaged as consultants by the member?

## A27

No. Members should not provide or organise entertainment for Healthcare Professionals who are engaged as consultants by the member.

## Q28

Is it appropriate for members to cover the cost of meals, travel or other hospitality expenses of the spouse or guest accompanying Healthcare Professionals at member-sponsored consultant meetings.

## A28

No, it is not appropriate for members to pay for the meals, travel or accommodation of persons accompanying Healthcare Professional consultants at member-sponsored consultant meetings. Furthermore, members should not organise the travel or accommodation of such guests.

## Q29

When a member contracts with a group of Healthcare Professionals for the development of intellectual property, is it appropriate for each Healthcare Professional pertaining to that group to receive financial compensation in respect of the co-developed medical devices prescribed or used by the other co-developer Healthcare Professionals?

## A29

No. It is advisable that the Healthcare Professionals who co-develop one or more medical devices under an appropriate contract with a member do not receive financial compensation in respect of the co-developed medical devices used or prescribed by the other co-developer Healthcare Professionals.

# Guidance on Interactions with Healthcare Professionals

## Q30

Please provide some examples of items of modest value that are “related to the Healthcare Professional’s practice or for the benefit of patients”.

## A30

Mugs, 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 would be appropriate for use as gifts for Healthcare Professionals provided their value falls within the maximum value prescribed under national and local laws, regulations and industry and professional codes of conduct.

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.

## Q31

Are prize draws and competitions appropriate forms of promoting medical devices?

## A31

Prize draws and other competitions may be appropriate if the prize awarded complies with the guidelines on gifts and is in accordance with national and local laws, regulations and industry and professional codes of conduct.

## Q32

What are regarded as cash equivalents?

## A32

Items that have a specified cash value such as store vouchers, book tokens, music tokens or vouchers offering a discount or free gift are regarded as cash equivalents.

## Q33

May a member provide a small gift to a Healthcare Professional upon significant life events such as a marriage, birth, birthday or death?

## A33

The guidelines restrict the types of gifts 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 to determine the appropriateness of making a tasteful gift as a mark of respect.

## Q34

May a member give gifts to staff of a Healthcare Professional who are not themselves Healthcare Professionals?

## A34

Gifts given to the staff of a Healthcare Professional should be treated as though they were given to the Healthcare Professional and accordingly must comply with the provisions of the guidelines in all respects.

## Q35

Can a member make a charitable donation to a non-profit organisation in the name of a Healthcare Professional?

## A35

No. All contributions made with a member’s funds must represent the member as the provider of the donation.



“ Charitable donations made by members 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 charity or other eligible entity. ”

### Q36

Can a member buy a stand or booth at a conference organised by a charity?

### A36

Yes, but this activity would not be considered to be a charitable donation. It would be considered a legitimate commercial transaction as a normal part of marketing activity but members should consider the appropriateness of the location and the general circumstances of the event from the perspective of maintaining the reputation of industry.

### Q37

Under the guidelines, may a member make a charitable donation such as the purchase of a table of dinner invitations at a fundraising dinner?

### A37

Yes, charitable donations made by members 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 charity or other eligible entity.

However, the member should not invite Healthcare Professionals to attend the event at the member's expense. The member may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring organisation for use as the sponsoring organisation sees fit.

Furthermore, the member 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's table.

### Q38

Can a member pay a research grant to a Healthcare Professional for a clinical study where the member is named as the sponsor of the study?

### A38

No. Clinical investigators participating in a member-sponsored study are regarded as providing a consultancy service and arrangements should follow Section V Arrangements with Consultants.

### Q39

Do the guidelines apply to requests for educational support made by medical institutions and group purchasing bodies in the context of public tender offerings.

### A39

No. Such requests and the subsequent financial support made are not considered to be “educational grants” for the purpose of these guidelines. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice.



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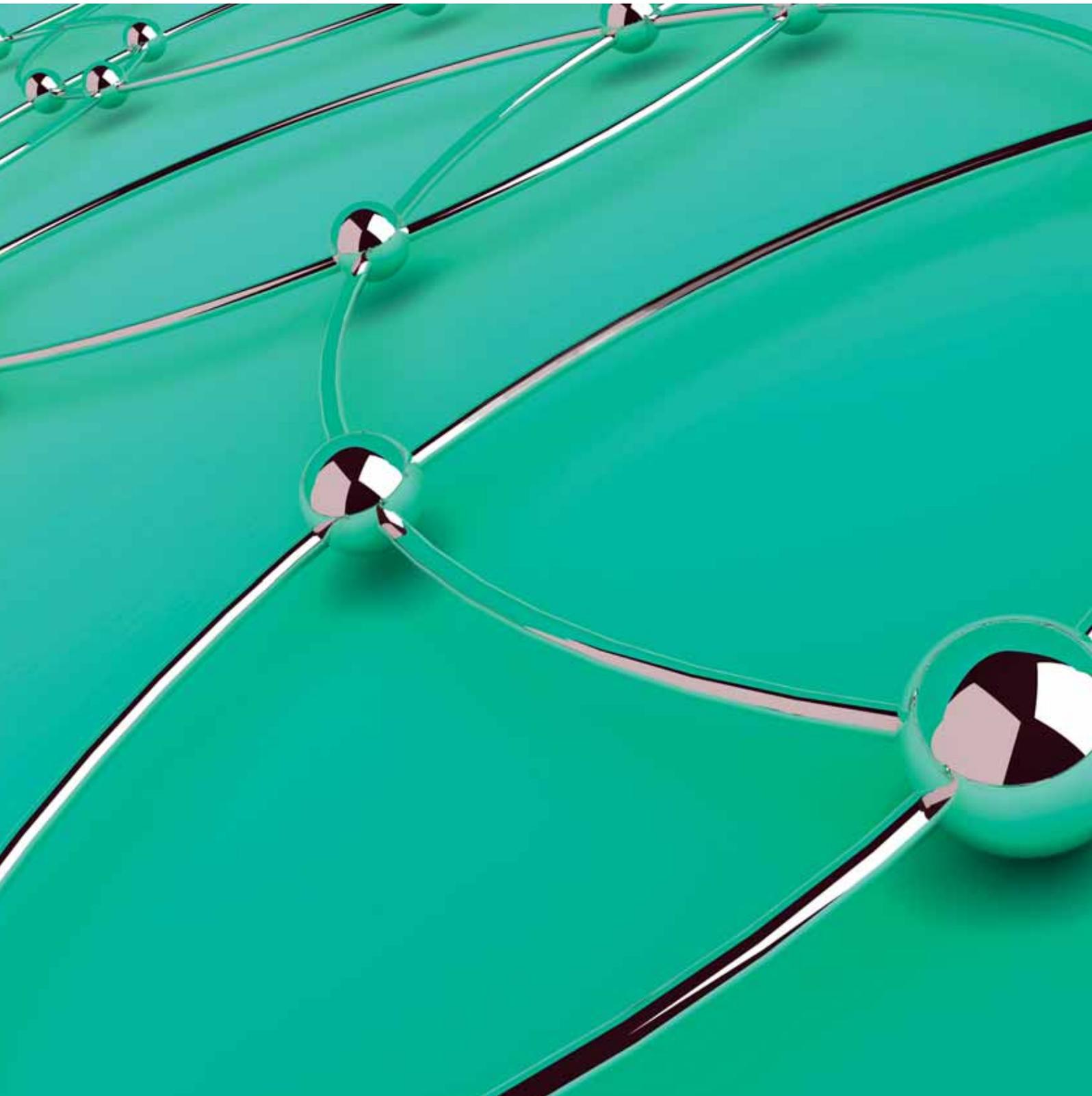
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*IMSTA is an independent representative body for  
med tech suppliers in Ireland*



## Appendix 4. MedTech Europe Code

# MedTech Europe Code of Ethical Business Practice



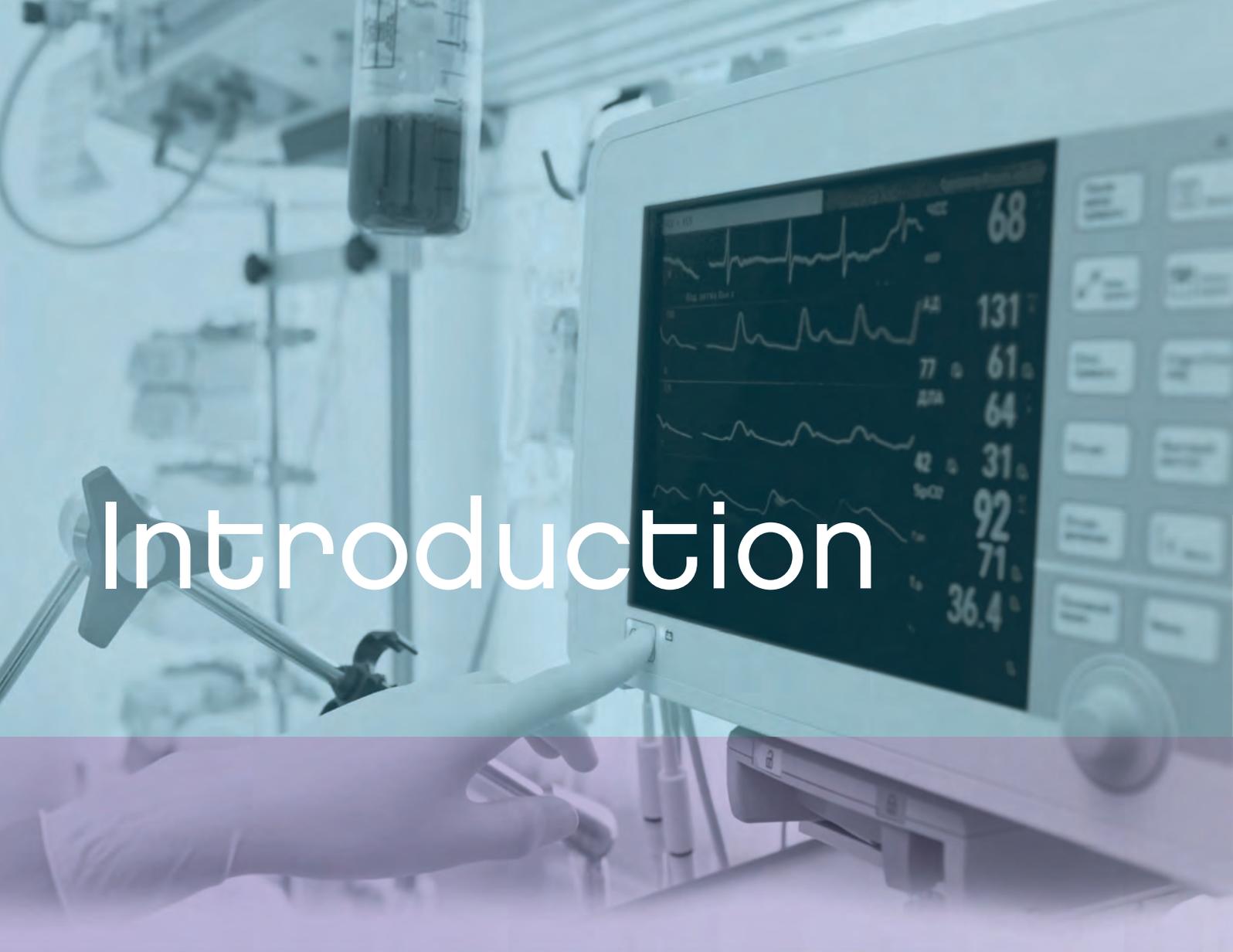
December 2016



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# Introduction

## CODE

### Promoting an Ethical Industry

MedTech Europe<sup>1</sup> 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

## QUESTIONS AND ANSWERS

<sup>1</sup>Please note that on 30 November 2016, Eucomed AISBL and EDMA AISBL members have decided to transfer the totality of their assets and liabilities to MedTech Europe and dissolve Eucomed and EDMA. Therefore any reference to EDMA and Eucomed have been deleted in the Code.

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, 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. 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<sup>2</sup>.

## 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.

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

## 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 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.

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.

**Q1:** Does the definition of Healthcare Professional include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket 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.*

## ■ 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' 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.

**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.

## 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

The Code operates within a Procedural Framework which includes procedures designed to provide an effective and efficient complaint-handling process, at national and European 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 the Procedural Framework 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 [Conference Vetting System](#) is an independently-managed system which reviews the compliance of Third Party Organised Educational Events with the Code.

The Code and the Procedural Framework shall be reviewed when required and at a minimum every five (5) years for the Code and every two (2) years for the Procedural Framework, in accordance with the governance rules of MedTech Europe.

## Implementation and Transposition Period

This edition of the Code comes into force as follows:

- [PART 3: The Dispute Resolution Principles](#) shall enter into force on 1 January 2016; and
- The balance of the Code [i.e. [Introduction](#), [PART 1](#) and [PART 4](#)] shall enter into force on 1 January 2017.

**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.*

For the avoidance of doubt, during the transposition period 1 January 2016 to 31 December 2016, no material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.

## Transition Period

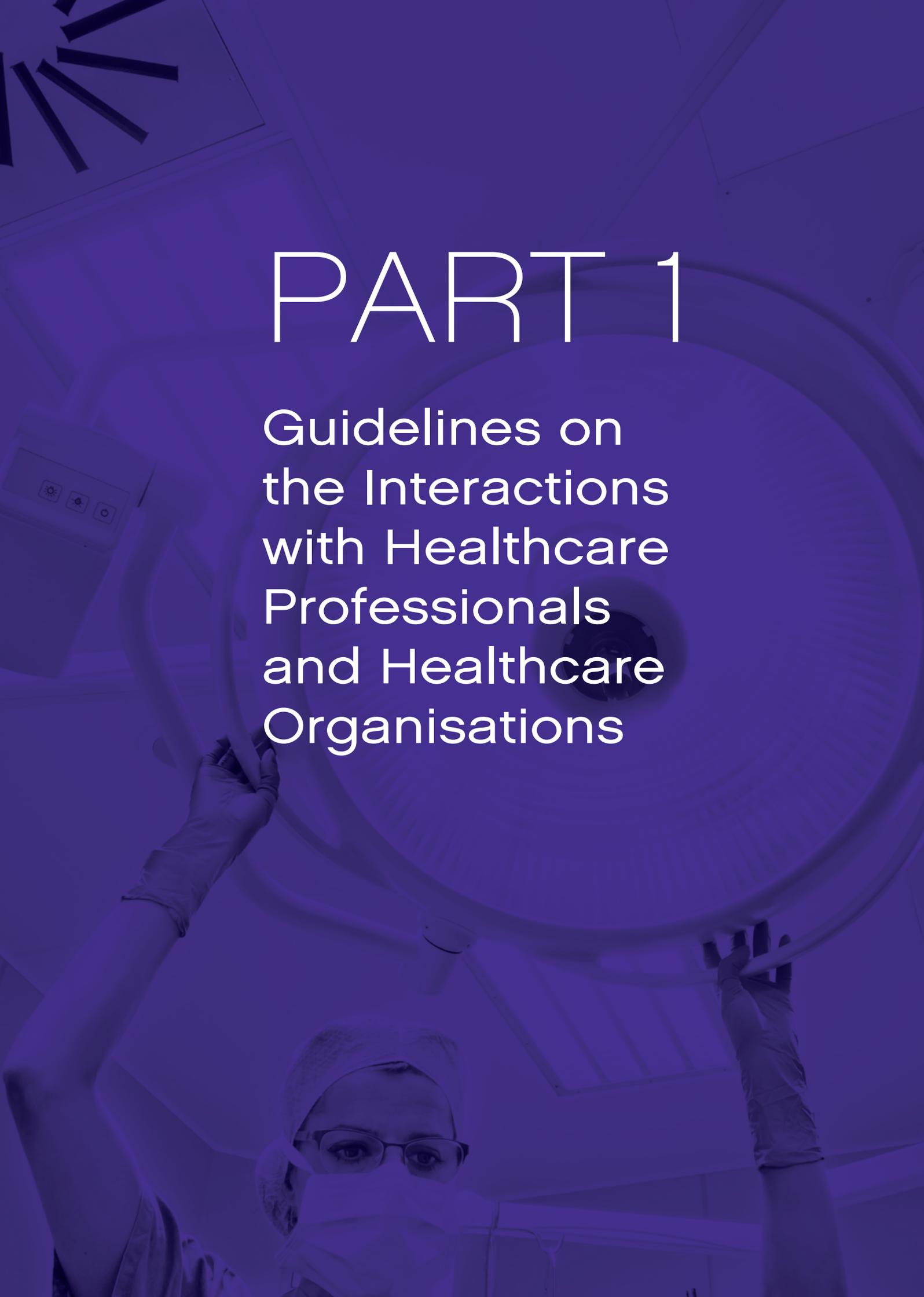
After the end of the Transition Period (see the [Glossary](#)) on 31 December 2017, Member Companies shall no longer provide financial or in kind support directly to individual Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium. This means that support of individual Healthcare Professionals to attend Third Party Organised Educational Events (as provided for at [Chapter 2, Section 3](#)) shall no longer be permitted under the Code.

After the Transition Period, Member Companies may provide financial or in kind support to Third Party Organised Educational Events only through Educational Grants or other types of funding in accordance with the rules of [Chapter 2: Third Party Organised Educational Events](#) and [Chapter 4: Grants and Charitable Donations](#).

**Q4:** What is the difference between the Transposition period and the Transition Period as defined in the [Glossary](#)? (added in September 2016)

**A4:** *Transposition means the process of incorporating the Code within the Member Company's own policy and procedures. This process must be completed by 1 January 2017.*

*Transition Period means the period between 1 January 2016 and 31 December 2017 by the end of which Member Companies must have ceased all financial or in kind direct support to Healthcare Professionals to attend Third Party Organised Educational Conferences. Any exceptions to this rule are outlined in the Code*

A person wearing a surgical cap, mask, and gloves is working on a circular ceiling light fixture in an operating room. The person is looking up at the fixture, and their hands are positioned to adjust or repair it. The background shows the ceiling with other light fixtures and a control panel with buttons and a dial.

# PART 1

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

# 1 | General Criteria For Events

## CODE

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

## QUESTIONS AND ANSWERS

**Q5:** What is meant by “legitimate” or “genuine” as used in the definitions of ‘Company Event’ and ‘Third Party Organised Educational Conferences’?

**A5:** 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.

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.
- 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.

**Q6:** Can a Member Company organise or support an Event at a hotel that offers leisure facilities such as golf, casinos or water sports?

**A6:** *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.*

**Q7:** Under the Code, what is meant by “ease of access” in relation to Event location and venue?

**A7:** *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.*

**Q8:** Under the Code, how does the “season” impact evaluation of Event location and venue?

**A8:** *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.*

### 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.

### 4. 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.

**Q9:** What does the term "facilitate" mean where used in connection with the Guest expenses?

**A9:** *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.*

**Q10:** 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?

**A10:** *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.*

**Q11:** 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 Professionals' travel or accommodation expenses for attendance at the Event?

**A11:** *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.*

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.

## 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.

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 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.

**Q12:** 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?

**A12:** 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.

**Q13:** 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 Professional a gift, which is otherwise in line with the requirements of the Code?

**A13:** *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.*

**Q14:** 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?

**A14:** *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.*

**Q15:** 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?

**A15:** *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.*

# 2 Third Party Organised Educational Events

## CODE

### 1. 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](#))<sup>2</sup>.

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:

<sup>2</sup> For scope of application of CVS please refer to: [www.ethicalmedtech.eu](http://www.ethicalmedtech.eu)

## QUESTIONS AND ANSWERS

**Q16:** 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)

**A16:** “In kind support” must be provided to the Healthcare Organisation (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, after the Transition Period, 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.

## 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.

**Q17:** Please provide examples of appropriate booth activities which will be perceived as professional?

**A17:** *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.*

**Q18:** Can a Member Company 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 (CVS)? (modified in October 2016)

**A18:** *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.*

**Q19:** 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?

**A19:** *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.*

## 2. 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](#))<sup>3</sup>.
- 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.

**Q20:** What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings? (added in September 2016)

**A20:** 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.

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 organised 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.

<sup>3</sup> For scope of application of CVS please refer to:

### 3. Transition Period: Support of Individual Healthcare Professionals to Third Party Organised Educational Events

Member Companies may provide financial support directly to individual Healthcare Professionals to cover the costs of attendance at Third Party Organised Educational Events where this is permitted under national laws, regulations and professional codes of conduct. Such support shall be in accordance with the following rules:

- Financial support must comply with the criteria provided in [Chapter 1: General Criteria for Events](#). In addition Member Companies may pay the registration fee.
- Where applicable, the Third Party Organised Educational Event has approval via the Conference Vetting System (see the [Glossary](#)).
- For financial support to Third Party Organised Educational Events Member Companies must apply the requirements governing conduct and attendance at such Third Party Organised Educational Event 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.

**Q21:** In the definition of Third Party Organised Procedure Training, what is meant by “Proctorship” and “Preceptorship”? Further, do Proctorships and Preceptorships require CVS approval before they can be provided and/or supported by a Member Company? *(added in November 2016)*

**A21:** *For the purpose of the Code both Proctorship and Preceptorship are types of clinician-to-clinician trainings funded by a Member Company.*

*Proctorship is 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.*

*Preceptorship is 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.*

*Such Proctorships and Preceptorships normally take place on Healthcare Organisation 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.*



# 3 | Company Events

## CODE

### 1. 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.

## QUESTIONS AND ANSWERS

**Q22:** 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?

**A22:** 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.

## 2. 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.

**Q23:** Under the Code, Chapter 3, Point 2, what is meant by “Company Organised Education Events”? (added in September 2016)

**A23:** A “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.
- 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.

**Q24:** Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Education Events?

**A24:** 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.

### 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.

**Q25:** What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Education Events?

**A25:** *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.*

**Q26:** Can a Member Company use a meeting venue outside Europe?

**A26:** *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.*



# 4 | Grants and Charitable Donations

## CODE

### 1. 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.

## QUESTIONS AND ANSWERS

- 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 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.
- 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.
- 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.

**Q27:** Under the General Principles in Chapter 4. Grants and Charitable Donations, what is meant by an “independent decision-making/review process”?

**A27:** 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.

**Q28:** 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?

**A28:** 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.

**Q29:** What does “sufficient information” mean where used in connection with documentation of Grants and Charitable Donations?

**A29:** 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.

## 2. 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.

**Q30:** Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?

**A30:** *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.*

**Q31:** 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*)

**A31:** *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.*

**Q32:** 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?

**A32:** *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.*

**Q33:** 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?

**A33:** *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.*

**Q34:** Can a small sized Healthcare Organisation receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events? (added in September 2016)

**A34:** *A: 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.*

<sup>4</sup> For scope of application of CVS please refer to:

[www.ethicalmedtech.eu](http://www.ethicalmedtech.eu)

## 3. 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 the end of the Transition Period.

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](#))<sup>4</sup>

#### 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.

#### 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 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.

**Q35:** 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?

**A35:** *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.*

**Q36:** 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?

**A36:** *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.*

**Q37:** 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)

**A37:** *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 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.*

## 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.

**Q38:** Can a Member Company pay for or reimburse travel costs to a Third Party Organised Educational Event for a Scholar or Fellow?

**A38:** *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.*

**Q39:** 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?

**A39:** *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 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, 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.*

## 4. Research Grants

Where permitted by national laws, 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.

# 5

# Arrangements with Consultants

## CODE

## 1. 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.

## QUESTIONS AND ANSWERS

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.

## 2. 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.

- h.** 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. 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.

### 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, 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.

**Q40:** What is meant by Fair-Market-Value (FMV) in the context of consulting arrangements?

**A40:** *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.*

**Q41:** How should Member Companies determine Fair-Market-Value (FMV) for a service?

**A41:** *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.*



# 6 | Research

## 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 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.

## QUESTIONS AND ANSWERS

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.

## 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 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.

**Q42:** What is an example of an external public registry for clinical trial transparency?

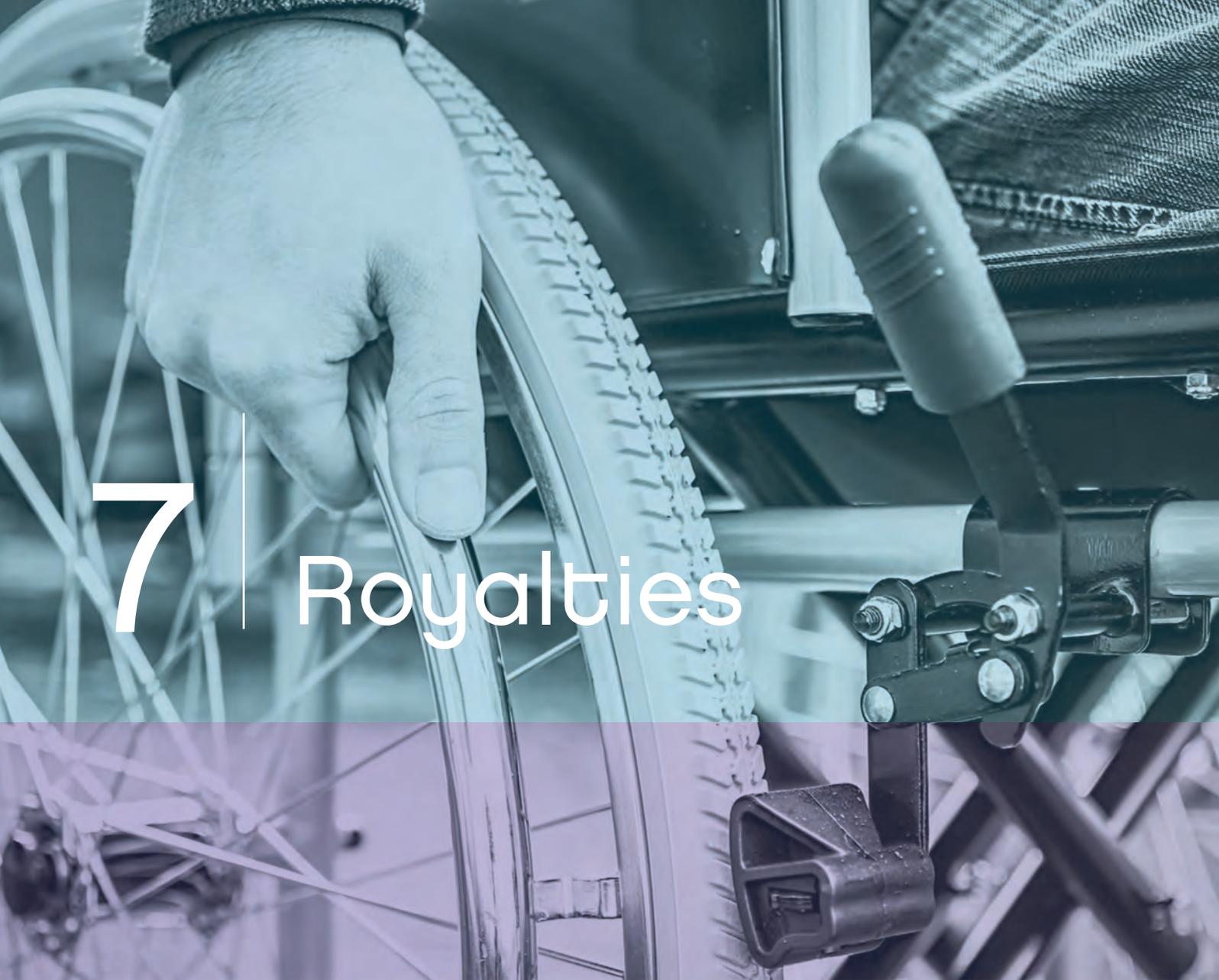
**A42:** *Examples of an external public register for clinical trial transparency are [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or [www.who.org](http://www.who.org)*

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 conduct.

### 3. Third Party-Initiated Research

Please refer to [Chapter 4: Grants and Charitable Donations: Research Grants](#).



# 7 | Royalties

## CODE

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'

## QUESTIONS AND ANSWERS

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.



# 8 | Educational Items and Gifts

## CODE

Member Companies exceptionally may provide inexpensive educational items and/or gifts, 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 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.

## QUESTIONS AND ANSWERS

**Q43:** 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".

**A43:** 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.

- 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.

**Q44:** 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?

**A44:** *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.*

**Q45:** 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?

**A45:** *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 Gifts as they neither relate to a Healthcare Professional's practice nor serve an educational function.*

**Q46:** Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?

**A46:** *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.*



# 9 | Demonstration Products and Samples

## CODE

### 1. 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

## QUESTIONS AND ANSWERS

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.

## 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.

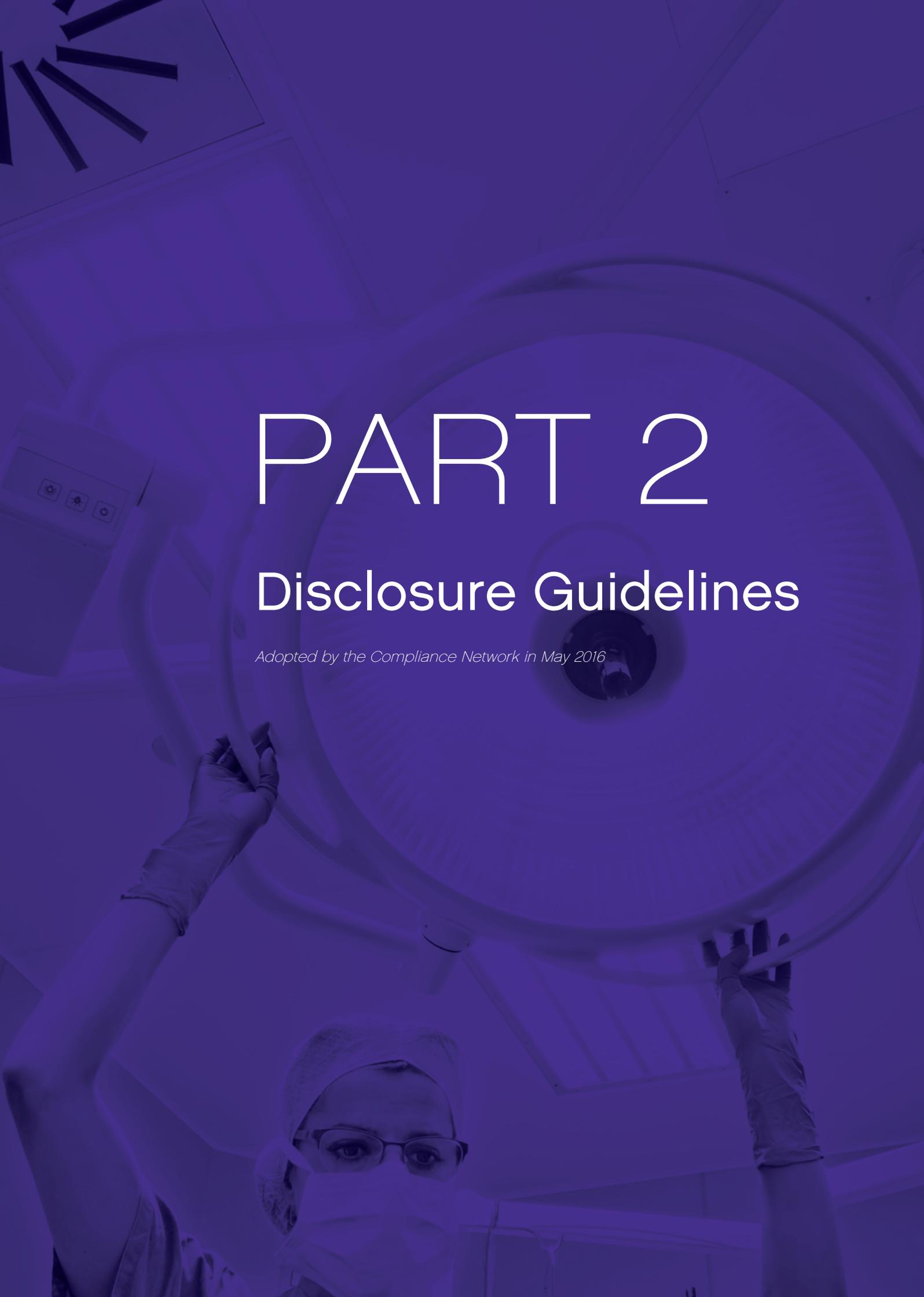
Demonstration Products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge 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 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

*Adopted by the Compliance Network in May 2016*

## Preamble

Under the MedTech Europe 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 1<sup>st</sup> 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

### 1. Scope

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

**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. 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.

## QUESTIONS AND ANSWERS

**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 Note.

### 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<sup>2</sup>.

## Chapter 2: Disclosure Obligation

### 1. 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 the MedTech Europe Geographic Area.

### 2. 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 Period<sup>3</sup> 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 Scholarships, Fellowships and/or Grants for Public Awareness Campaigns).

<sup>2</sup> 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.

**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.

<sup>3</sup> Reporting Period means a full calendar year (starting on the 1st of January and ending in the 31st of December).

### 3. 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*.

### 4. 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.

## Chapter 3: Form of Disclosure

### 1. Reporting Period

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

### 2. Time of Disclosure

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

### 3. 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 of disclosure

#### **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](#)

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

**A7:** *Chapter 4, Section 3 of the MedTech Europe Code of Ethical Business Practice establishes that the first disclosure shall occur no later than the end of the Transition Period. The Transition Period ends on the 31st December 2017. As a consequence, the first Reporting Period is the calendar year 2017, starting on the 1st January 2017, and ending on 31st December 2017.*

## 4. 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.

## 5. Disclosure Platform

Disclosures shall be made on the [EthicalMedTech website](#)<sup>4</sup> 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, MedTech Europe shall not be held liable for (i) maintaining, correct-ing, deleting the published data nor (ii) for the storage of data after the three years period of disclosure in the public domain.

## 6. 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.

## 7. 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 Organizations 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.

<sup>4</sup> [www.ethicalmedtech.org](http://www.ethicalmedtech.org)

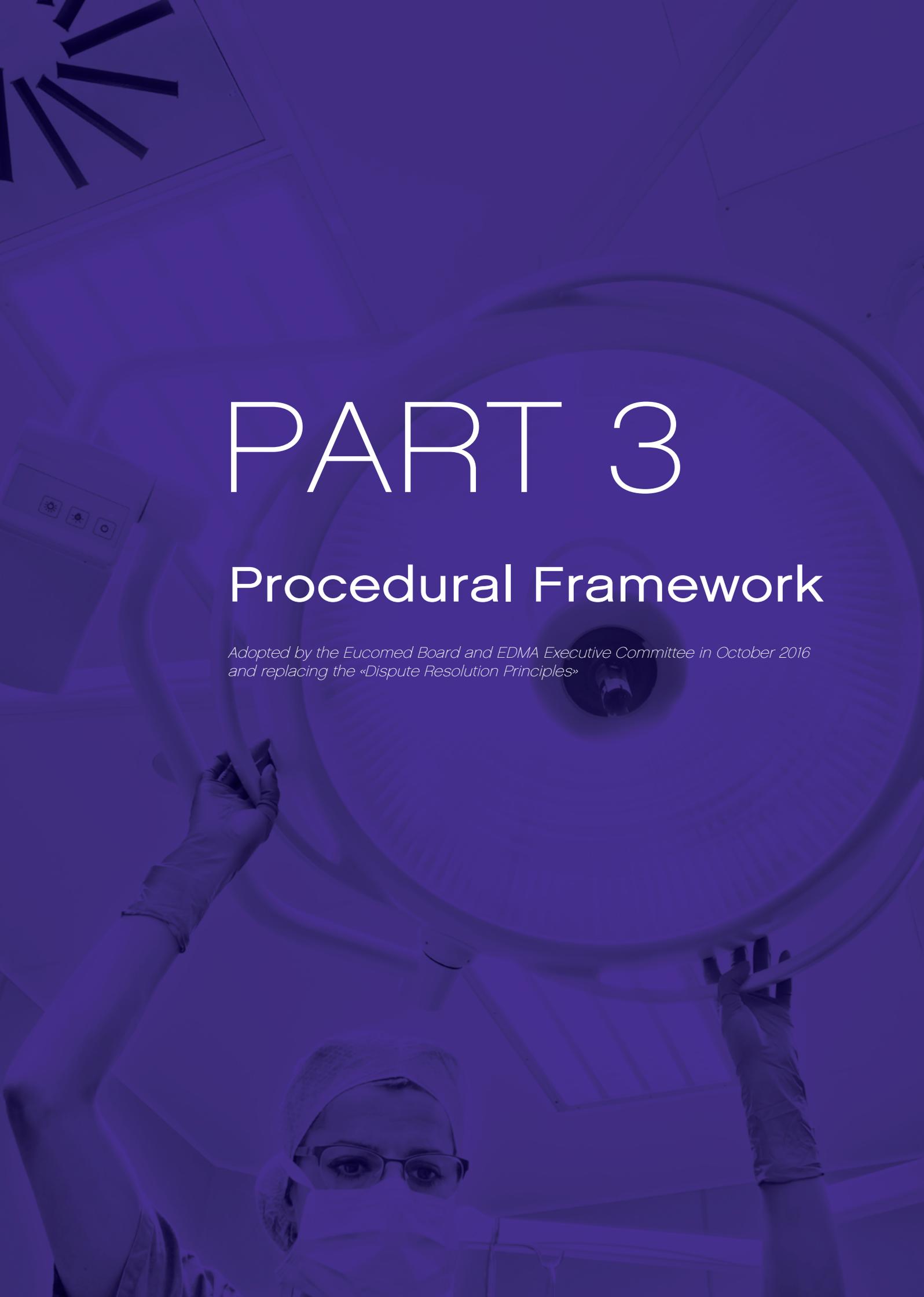
**Q8:** In what currency should the amounts payed be disclosed?

**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

## Procedural Framework

*Adopted by the Eucomed Board and EDMA Executive Committee in October 2016  
and replacing the «Dispute Resolution Principles»*



## 1. Preamble

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. This Procedural Framework shall be reviewed when required and at a minimum every 2 years. This Procedural Framework shall be amended in accordance with the MedTech Europe Statutes.

## 2. Transposition Obligations

**2.1. Member Companies** shall transpose the provisions of this Code internally between 1 January 2016 and 31 December 2016 at the latest. No later than 1 January 2018, Member Companies shall cease direct financial and in kind support to individual HCPs to cover the costs of their attendance at Third Party Organised Educational Events. New Members of MedTech Europe will be subject to the same obligations as current Members.

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.

**2.2. Member Associations** shall transpose the Code at the national level by 1 January 2020. This means that Member Associations shall either:

- a) Transpose the Code in its entirety,
- b) Transpose the Code with some adjustments to the local situation,
- c) If transposition of the Code is not feasible for objective reasons, the Member Association shall promote the Code as a best practice and actively engage national, and if applicable local government/authorities and/or other stakeholders, to change practice in their country through legal or self-regulatory measures.

In particular on 1 January 2017 at the latest each Member Association shall submit, in a timely manner, to the MedTech Europe Board its strategy and action plan on how the Member Association plans to transpose the Code in its country, timelines, and main milestones as well as how enforcement of the Code will be addressed during the transition period as well as after 2020. After 1 January 2018, Member Associations shall provide annual progress updates to the MedTech Europe Board.

The MedTech Europe Secretariat shall support the Member Associations in their transposition of the Code at the national level. Upon the request of the MedTech Secretariat, Member Associations shall provide, in a timely manner, a copy of its national code of conduct including its dispute resolution process.

## 3. Code Applicability

**3.1.** This Code only applies to the Member Companies of MedTech Europe, who are manufacturers of medical technologies, in particular Medical Devices and In Vitro Diagnostics.

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 practicing.

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

– The Code shall be directly applicable to all activities of Member Companies and their affiliated companies in the MedTech Europe Geographic Area within the scope applicability defined in Section 3.1. 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 3.1. 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.

– 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.

– For complaints and other matters that are handled by the MedTech Europe Compliance Panel, the latter 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.

## 4. Dispute Resolution Principles

**4.1.** Each Member Association shall adopt a national dispute resolution framework which complies with the principles of this Procedural Framework. To that effect, each Member Association is also required to establish a panel (i.e. a national body) that is designated to handle complaints relating to their code. MedTech Europe strongly recommends that this panel is headed by a non-active industry chairman and for obvious reasons of independence, transparency and expertise, is composed not only of persons having industry experience. MedTech Europe recommends that at least one of the members of a national panel should have a professional legal background. In the composition of the panel, Member Associations should balance the need for independence, legal background, expertise and knowledge of the industry and industry practices.

**4.2.** The dispute resolution principles set out in this Procedural Framework do not preclude complainants from having recourse to the regular courts or other tribunals to seek resolution of complaints based upon applicable laws and regulations. The Code, including this Procedural Framework, shall not be interpreted so as to provide a legal basis for such recourse to regular courts or other tribunals.

**4.3.** In all territories where there is no dispute resolution process which complies with these MedTech Europe dispute resolution principles or in cases provided under sections 3.4 and 6.1.5, the MedTech Europe Compliance Panel (as defined below) shall handle complaints as a first and last instance decision-maker.

**4.4.** Member Associations shall take due account of the interpretation issued by the MedTech Europe Compliance Panel in accordance with sections 7.4.6 (iv) & (v).

## 5. MedTech Europe Code Committee

**5.1.** 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 this Procedural Framework.

**5.2.** 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 the dispute resolution principles set out in this Procedural Framework.

**5.3.** The MedTech Europe Code Committee will be composed of five (5) representatives of the MedTech Europe Legal Affairs Committee and five (5) representatives of the MedTech Europe Compliance Network, at least one representative from Member Associations, and a chair appointed by the Legal Affairs Committee. In addition, the Code Committee may co-opt up to five (5) other members, where Code Committee is satisfied that, the concerned Members will positively enhance the representativeness, operation and objectives of the Code Committee.

## 6. MedTech Europe Compliance Panel

**6.1.** The MedTech Europe Compliance Panel shall have the following tasks:

- a)** Supervise the MedTech Europe Conference Vetting System.
- b)** Review consistency with the Code of interpretations of national panels of nationally applicable codes of conduct, upon request of the MedTech Europe Code Committee;
- c)** Provide guidance to Member Associations on the dispute resolution principles set out in this Procedural Framework;
- d)** Interact, upon request of the Secretariat, with relevant MedTech Europe groups to further develop the Code and guidance documents;
- e)** Render decisions directly on complaints or procedural matters, as a first and last instance in the following cases:
  - 1.** there is no dispute resolution process which complies with the dispute resolution principles set out in this Procedural Framework in the territory concerned; or
  - 2.** a Member Company is not a direct member of a Member Association; or
  - 3.** a dispute concerns an alleged abuse or violation of the MedTech Europe Ethical Business Logo System; or
  - 4.** more than one national compliance panel has or may have jurisdiction, but the parties to the dispute cannot agree on which one does. In such case, the matter shall be referred to the MedTech Europe Compliance Panel for a determination. The referral may be made either by one of the parties or by a Member Association Secretariat or by the MedTech Europe Secretariat. Following such referral, the MedTech Europe Compliance Panel may decide that a specific panel has jurisdiction and refer the complaint to that panel or that more than one national panel has jurisdiction, in which case the matter shall be resolved by the MedTech Europe Compliance Panel in the first and last instance; or
  - 5.** the national panel having jurisdiction refuses to hear a complaint for any reason or cannot take the case based on provisions of its national code; or
  - 6.** 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
  - 7.** 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 sections 7.1.(a) and 7.3.b).4 of this Procedural Framework; or
  - 8.** a dispute concerns an alleged abuse or 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.

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

**6.2.** 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.

**6.3.** 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 conflict of interest situations, in particular as regards complaint handling process. The chair of the MedTech Europe Compliance Panel must have a legal background. Neither the chair nor any member of the Com-

pliance 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 position in the Board of Directors of a Member Association without any consulting or employment relationship with a Member Company will not be considered as 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 gave his/her consent.

## 7. Procedural principles

**7.1.** The general principles underlying the dispute resolution principles set out in this Procedural Framework, 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 sections 3.4. and 6.1.5.

**7.2.** 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 article 7 of this Procedural Framework.

**7.3.** Reception of Complaints

**a)** 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 sections 3.4. and 6.1.5.

**b)** Complaints received by the MedTech Europe Secretariat shall be processed as follows:

- 1.** 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 sections 3.4. and 6.1.5.
- 2.** 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.
- 3.** 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.
- 4.** For complaints for which the MedTech Europe Compliance Panel has jurisdiction, within a reasonably short timeframe of receipt of a written complaint by MedTech Europe Secretariat, a genuine mediation should be attempted, if considered appropriate by the Secretariat, involving an independent third-party or mediator or depending on the nature of the complainant an attempt to reach an amicable solution.
- 5.** Complaints shall be handled confidentially by all parties involved in the procedure.

**c)** Notwithstanding any provisions of this Procedural Framework 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 cases set out in sections 3.4. and 6.1.5.

**d)** When deciding on such matters, the MedTech Europe Compliance Panel will act in conformity with the dispute resolution principles set out below and the Internal Procedural Rules, if any, and will have the right to impose sanctions in line with the ones enumerated below in article 8.

**7.4.** Processing of complaints and sanctions by Member Associations as well as the MedTech Europe Compliance Panel shall follow the following principles:

**a)** 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. As a minimum, the national panel and the MedTech Europe Compliance Panel should know the identity of the complainant.

**b)** Member Associations may request any company which is not a member of the Association and making a complaint under their code to undertake to abide by the provisions of the national code of conduct and of its complaint handling principles in force in its country, and/or the MedTech Europe Code, as a pre-condition before processing the complaint.

**c)** Each Member Association's national panel and the MedTech Europe Compliance Panel shall respect fair procedure rules allowing all parties to be heard fairly.

**d)** Each Member Association's national panel and the MedTech Europe Compliance Panel shall take decisions and pronounce any sanctions to be applied on the basis of the national code of conduct in force in its country.

**e)** 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.

**f)** The procedural steps for dispute resolution should be as follows:

**1.** The first stage of any dispute resolution procedure shall be the filing of a written complaint with the Member Association or the referral of such a complaint to a Member Association by the MedTech Europe Secretariat. Where a national panel or where applicable the MedTech Europe Panel consider a complaint fails to establish a prima facie case of violation of its national code, such complaint shall be dismissed with respect to that code. A national panel or, where applicable, the MedTech Europe Panel may also provide that any complaint, which a national panel considers to be in pursuit of an entirely or predominantly commercial interest, shall be dismissed.

**2.** The second stage of the complaints handling procedure shall be based on the principle provided in section 7.1. 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 the MedTech Europe Secretariat, if considered appropriate, a genuine 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. For complaints between companies, mediation should be considered seriously before further pursuit of the matter directly via any complaints handling process based on the dispute resolution principles set out in this Procedural Framework.

– In cases of a serious or repeated breach, the Member Association Secretariat, the MedTech Europe Secretariat or the mediator may decide to direct complainant(s) to further pursue the matter directly via the relevant complaints handling process.

– 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.

– When it appears to a Member Association or to the MedTech Europe Secretariat that a company may have breached the code, it may direct matter as a complaint to the relevant panel.

**3.** Member Associations may establish a national appeal procedure, pursuant to which either party may appeal in writing against a decision of the national panel.

**4.** During a national dispute resolution process,

– The national panel may, at any time, or

– Any of the parties (with the permission of the national panel) may, at any time, or

– Any of the parties may within 15 days following a decision by the national panel (without permission of the national panel) 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 determines that no question of principle is at issue, or

– Accept the interpretation referral, review and provide guidance on the interpretation of the MedTech Europe Code (i.e. but not rule on merits/facts) with a view to ensuring harmonised interpretation and enforcement of the principles of the Code and these dispute resolution principles.

The MedTech Europe Compliance Panel shall promptly issue guidance on the interpretation and no later than 90 days from receipt of a request for interpretation.

**5.** Where an interpretation referral is made to the MedTech Europe Compliance Panel during a national dispute resolution process, in accordance with the procedure described above, the national panel shall suspend the proceedings pending the issuance of guidance by the MedTech Europe Compliance Panel and shall take such guidance into consideration when making its final decision. In the event that one of the parties to a national dispute resolution process refers a question of interpretation to the MedTech Europe Compliance Panel within 15 days following a decision by a national panel, that decision shall be suspended pending the issuance of guidance by the MedTech Europe Compliance Panel and the national panel shall take such guidance into consideration prior to rendering its final decision.

**6.** 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. The 15 day period referred to above shall commence for each party upon the date of receipt of the decision by that party. If a party makes an interpretation referral to the MedTech Europe Compliance Panel, it shall copy the other party or parties and such other party or parties shall have an additional 15 days after such referral to submit written observations to the MedTech Europe Compliance Panel. All national panel notices of decisions shall inform the parties to a national proceeding of their right to make an interpretation referral to the MedTech Europe Compliance Panel within 15 days of the decision and to submit written observations on the other parties' referral in accordance with the procedures described above.

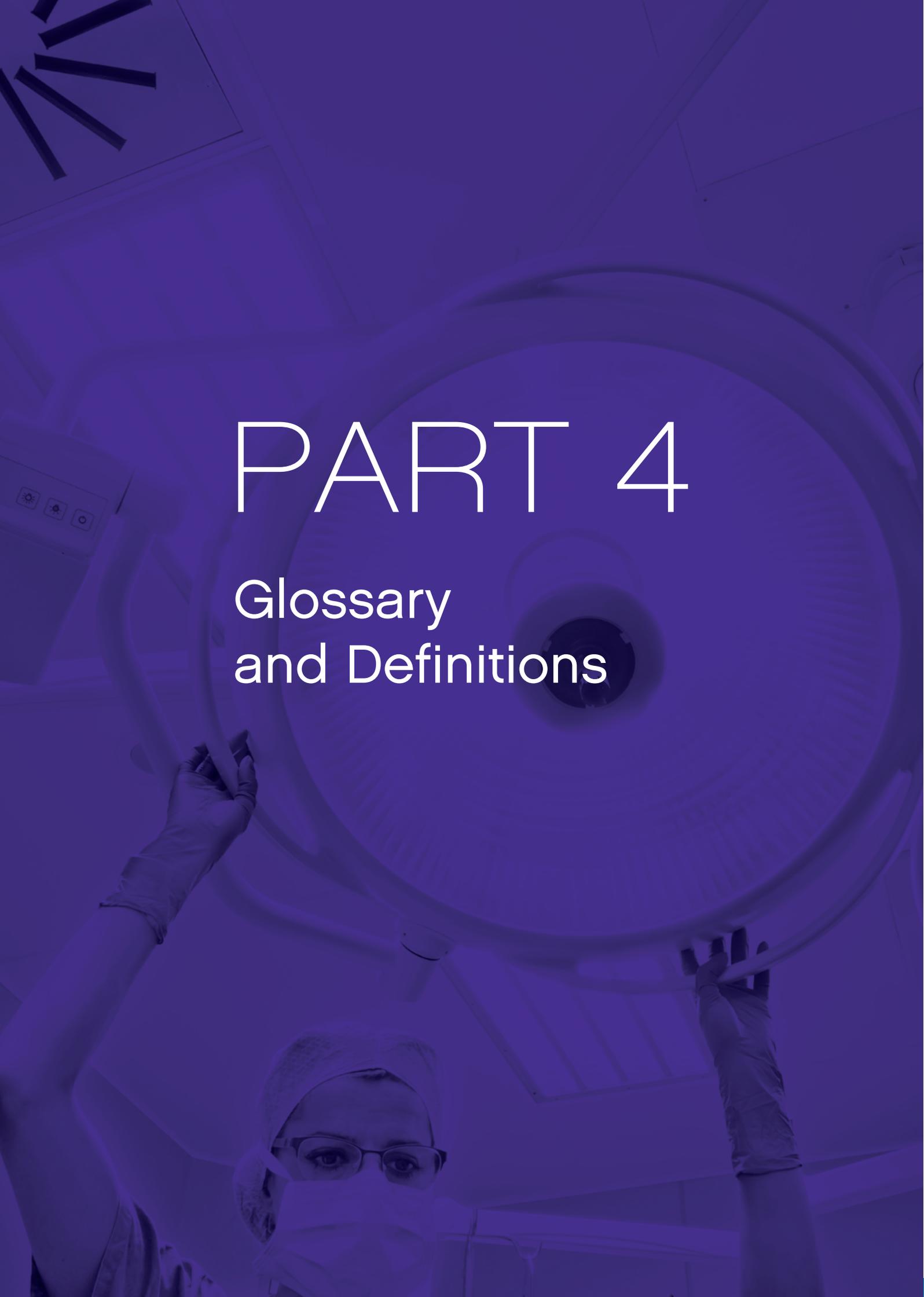
## 8. Sanctions

**8.1.** The potential sanctions available to the MedTech Europe Compliance Panel and Member Associations' national panels must be proportionate to the infringement, predictable and act as a deterrent. Commensurate with the seriousness and/or persistence of the breach, such sanctions may range from:

- a) A written reprimand;
- b) 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);
- c) The inspection and audit by a third party (at the offender's cost and expense) of the offender's relevant compliance systems ;
- d) 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;
- e) The requirement that the offender publishes or otherwise disseminates corrective or clarificatory information or statements;
- f) 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;
- g) Expulsion from membership of the Member Association and/or MedTech Europe;
- h) Up to publication of any decisions or sanctions imposed upon the offender.

**8.2.** 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.

**8.3.** 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.

A person wearing a hairnet, glasses, and a face mask is working on a large circular ceiling fixture in a cleanroom environment. The person is wearing gloves and is holding a tool to adjust the fixture. The background shows a grid of ceiling panels and a control panel with buttons.

# 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.

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**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.

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**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>.

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**Code:** means this MedTech Europe Code of Ethical Business Practice (including the incorporated Questions and Answers), the Disclosure Guidelines, the Procedural Framework and the Dispute Resolution Principles. For the avoidance of doubt the Dispute Resolution Principles shall be replaced by the Procedural Framework and shall cease to have effect once the MedTech Europe Board approves the Procedural Framework.

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

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**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 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.

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**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.

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**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.

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

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**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.

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**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.

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

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**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.

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**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.

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**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.

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**Members:** means all full and associate corporate members ("**Member Companies**") of Eucomed and/or EDMA (or as applicable MedTech Europe) as well as full and associate national association members of Eucomed and/or EDMA (or as applicable MedTech Europe) ("**Member Associations**"), as defined in the respective Eucomed, EDMA or MedTech Europe statutes, as applicable and as amended from time to time.

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

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**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.

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**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 medical, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve patient outcomes.

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**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 Member Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use and/or commercial terms of supply.

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**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.

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**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.

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**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 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.

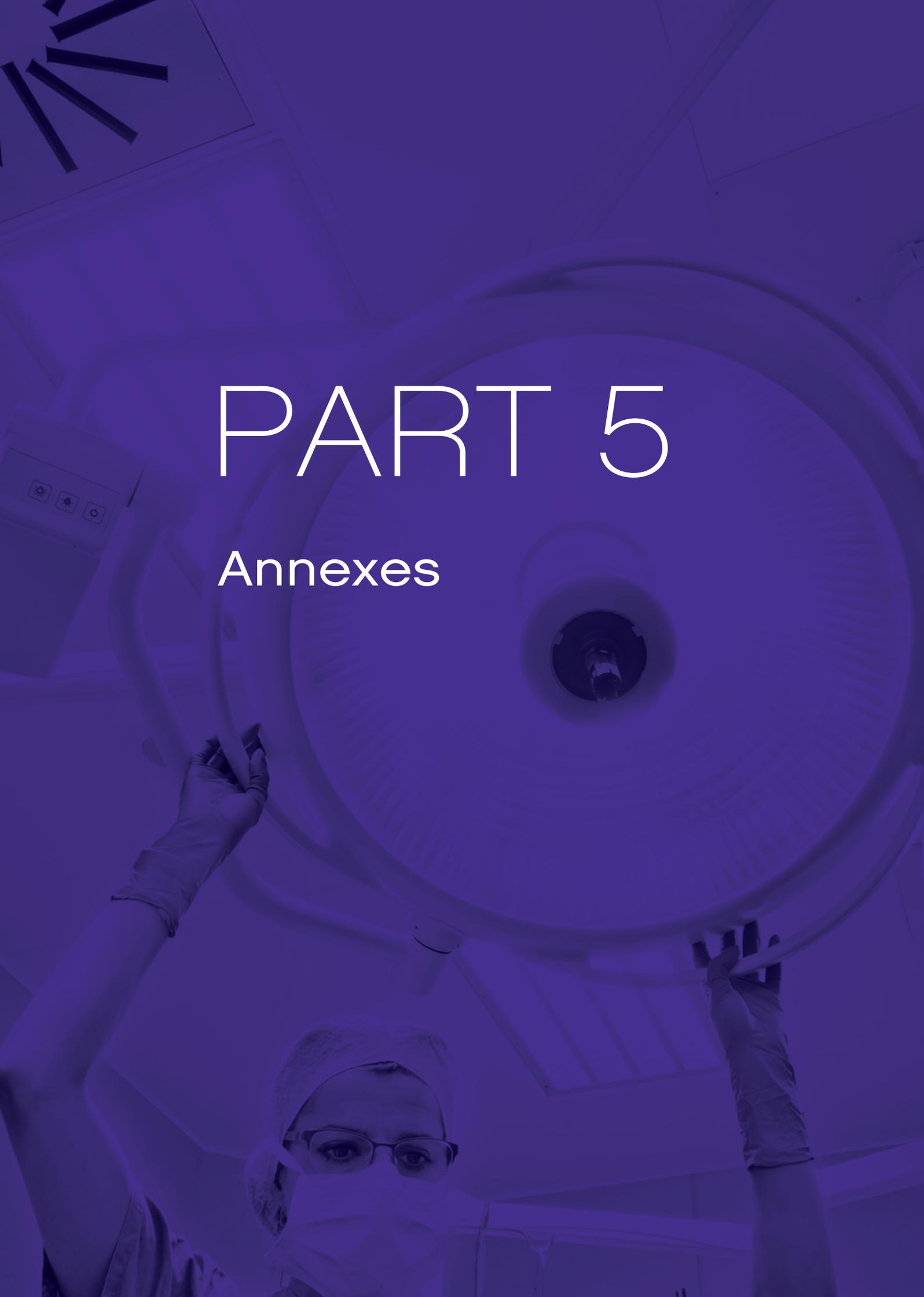
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**Transition Period:** means the period from 1 January 2016 up to and including 31 December 2017, following which Member Companies shall no longer provide financial or in kind support direct to Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training -meetings or pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium.

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# PART 5

Annexes



# ANNEX I (added in October 2016)

## 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?		<b>NATIONAL</b> Third Party Organised Educational Events attended by delegates which are local HCPs only)	<b>INTERNATIONAL</b> (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area <sup>1, 2</sup> )	<b>INTERNATIONAL</b> (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area <sup>3</sup> )	<b>INTERNATIONAL</b> (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 <sup>4</sup> PROVIDED TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE	Educational Grant to support the general running of a conference	2017 – Allowed <sup>5</sup> . 2018 – Allowed.	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Allowed. Not subject to CVS decision	Out of scope of the application of the Code <sup>6</sup>
	Educational Grants that includes funds to support HCP attendance to the conference	2017 – Allowed. 2018 – Allowed.	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	N/A
	Educational Grants that includes funds to support Faculty	2017 – Allowed. 2018 – Allowed.	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Allowed. Not subject to CVS decision	N/A
COMMERCIAL ACTIVITIES	Consultancy agreement for speakers in satellite symposia	2017 – Allowed. 2018 – Allowed.	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Allowed. Not subject to CVS decision	N/A
	Booths/advertising	2017 – Allowed. 2018 – Allowed.	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – 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)	2017 – Allowed. 2018 – Not allowed.	2017 – Subject to CVS decision 2018 – Not allowed	2017 – Subject to CVS decision 2018 – Not allowed	N/A
	Direct sponsorship of HCPs as Faculty (active participation)	2017 – Allowed. 2018 – Not allowed.	2017 – Allowed. Not subject to CVS decision <sup>7</sup> 2018 – Not allowed	2017 – Allowed. Not subject to CVS decision 2018 – Not allowed	N/A

<sup>1</sup> MedTech Europe Geographic Area includes the countries in the European Economic Area (EEA), as well as those other countries where Member Associations are located.

<sup>2</sup> Formerly referred to as “Cross-border Events”.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> 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.

<sup>7</sup> 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\*

TEMPLATE								
Full HCO Name	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)	Object (Optional)	B. Other Educational Grants to HCOs (including Scholarships, Fellowships and Grants for Public Awareness Campaigns).	Object (Optional)
HCO/PCO 1					Yearly amount	Optional	Yearly amount	Optional
HCO/PCO 2					Yearly amount	Optional	Yearly amount	Optional
etc.					Yearly amount	Optional	Yearly amount	Optional

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

## 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
- 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*.

## MedTech Europe Geographical Area



The MedTech Europe Geographic Area currently includes:

a) countries with National Associations:

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

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

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

Please note that countries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, are not currently under the scope of the Disclosure Guidelines.





[www.medtecheurope.org](http://www.medtecheurope.org)