

MedTech Europe Code of Ethical Business Practice

Disclosure Guidelines

Final version: 1st January 2022

Table of Contents

Table of Contents.....	1
Preamble.....	2
Chapter 1: Applicability of these Guidelines	2
1. Scope	2
2. Applicability of these Disclosure Guidelines.....	3
3. Applicability to Non-Member Companies	4
Chapter 2: Disclosure Obligation	4
1. General Obligation	4
Q&A 5.....	5
2 Aggregate Disclosure	5
3. Optional Object Specification	5
4. Methodology	5
Chapter 3: Form of Disclosure	6
1. Reporting Period.....	6
2. Time of Disclosure.....	6
3. Time of Publication.....	6
4. Template and Language of Disclosure	7
5. Platform of Disclosure	7
6. Retention and Modification of the Disclosures.....	7
7. Enquiries Regarding Reported Disclosures	7
Annex II: Calculating the value of in kind Educational Grants	8
Methodology Note Example.....	10
Structure.....	10

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.

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 Geographic Area¹.

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.

¹ The MedTech Europe Geographic Area currently includes: Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the countries where Mecomed is active, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom as countries with National Associations, and Croatia, Cyprus, Estonia, Iceland, Latvia, Liechtenstein Lithuania, Luxembourg and Malta as countries party to the European Economic Area agreement without a MedTech Europe National Association.

Countries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, are not currently under the scope of these Disclosure Guidelines.

Q&A 1

Q: Does the Disclosure Guideline’s definition of “Affiliate” include legal entities belonging to the same parent Member Company but registered outside Europe?

A: 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 Europe 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 non-European Affiliates.

Q&A 2

Q: 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?

A: 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.

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.

Q&A 3

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

A: Where a national professional 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 professional 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 professional 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.

Q&A 4

Q: How will it be decided if a national law, regulation or professional code imposes disclosure obligations regarding Educational Grants equivalent to the ones imposed by the Disclosure Guidelines?

A: The 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 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.

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 Logo².

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.

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

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.

Q&A 5

Q: Which Affiliate should disclose a particular Educational Grant?

A: 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.

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 Period³ which can be reasonably allocated to one of the categories set out below. Such amounts will be aggregated on a category-by-category basis, but itemised disclosure shall be made available upon request by the Member Company, as deemed necessary, to (i) the relevant recipient, and/or (ii) the relevant authorities.

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

- a. Educational Grants to support Third Party Organised Events (including Support for HCP Participation at Third Party Organised Educational Events) and,
- b. Other Educational Grants to Healthcare Organisations (including Scholarships, Fellowships and/or Grants for Public Awareness Campaigns).

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.

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

[Q&A 6](#)

Q: When should a Methodology Note be made available?

A: 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.

[Q&A 7](#)

Q: What is a “unique country local identifier”?

A: It refers to a specific, unique and sustainable reference to identify Healthcare Organisations. Reporting companies will use the Healthcare Organisation’s VAT as unique country local identifier by default. In those countries where Healthcare Organisations do not necessarily have a VAT number, another identifier, unique for this Healthcare Organisations and common for all reporting companies will be provided.

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.

[Q&A 8](#)

Q: When will the first Reporting Period start?

A: 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.

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

MedTech Europe shall make the disclosures public on the 31st August of the year of the relevant time of disclosure.

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.

[Q&A 9](#)

Q: In what currency should the amounts paid be disclosed?

A: 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.

5. Platform of Disclosure

Disclosures shall be made on the EthicalMedTech website⁴ 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, correcting, deleting the published data nor (ii) for the storage of data after the three years period of disclosure in the public domain.

6. Retention and Modification of the 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.

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 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 disclosed information remains in the public domain as stated in *Section 3.3 Time of Publication*.

⁴ www.ethicalmedtech.org

Annex II: Calculating the value of in kind Educational Grants

What is an in-kind Educational Grant?

Please note that the Glossary includes a definition of Educational Grant, and Chapter 4 provides guidance as to how Member Companies can use them to support Third Party Organised Events or educational programs. The definition outlines two types of Educational Grants:

- **Monetary grants** which involve a transfer of funds to the organization
- **in-kind grants** which is a contribution that includes any other type of support

An in-kind Educational Grant is a non-monetary (i.e non-cash) contribution to an HCO to support an Event or educational program. Both Member Company and HCO should understand and clearly document what constitutes in-kind contributions, as well as how to value them.

Types of in-kind Educational Grant

An in-kind Educational Grant includes goods or services other than cash transfers, including when the in-kind support is provided by a third party and the payment is directly done by the Member Company to the third party (i.e, no funds are transferred to the final Educational Grant beneficiary). Any in-kind Educational Grant must always strictly comply with general requirements for Educational Grants and be aimed at the advancement of genuine medical education.

For example:

- **Goods** such as computers, furniture, electronic equipment, Xray protection clothing, masks, office equipment, etc.
- **Services** such as meeting space, transportation, copy services, administrative services, the supply of access to digital platforms (Zoom, Teams...) etc.
- **Expertise:** Members could also provide expertise to an HCO, such as providing technical support/analysis/work (hours of Members employee), all of which should be provided only for the purpose of supporting educational activities .
- **Member Company's products** including commercially available / saleable products, re-usable training products and equipment, which may be returned to the Member Company after use

Value of in-kind Contributions

The Member Company should, whenever possible and practical, determine the amount of the in-kind contribution and state the value under the Educational Grant agreement.

The basic principle for valuation of in-kind contributions should be the cost to the Member Company, which could, whenever possible and applicable include logistic, documentation and training costs.

For specific recommendations on how to value in kind Educational Grants please refer to the table below.

IN-KIND CATEGORY	EXAMPLES OF VALUES THAT CAN BE CONSIDERED, VAT EXCLUSIVE WHEN RELEVANT
Third Party Services	Contractual value or Fair Market Value
Services provided by Member Company Staff	The salary (incl. social contributions), or a portion of the salary, for technical support provided by personnel employed by the Member Company (based on time spent and salary)

Goods (whether TP or company-produced)	<ul style="list-style-type: none"> • Provision of used goods <ul style="list-style-type: none"> ○ Fair market value ○ Company book value • Provision of new goods <ul style="list-style-type: none"> ○ For third party goods, the listing price. ○ Contractual value or Fair market value ○ Internal costs, whether relating to cost of manufacture or transfer price • Loaned goods <ul style="list-style-type: none"> ○ Rental equivalent based on depreciation ○ Rental equivalent to highest-volume rate <p>NOTE: Rent cannot exceed accepted values if the equipment was donated or sold</p> <ul style="list-style-type: none"> • Exception: if single used products are bundled, they should be separated and valued as donation of equipment
Materials, technological infrastructure, components	<ul style="list-style-type: none"> • Fair market value
Licenses	<ul style="list-style-type: none"> • FMV for company-owned licenses • For licenses acquired from 3rd-Parties for HCO's use in the educational project, the cost.
Software	<ul style="list-style-type: none"> • Copying costs • Licensing costs • Software technical support costs
Use of Facilities	<ul style="list-style-type: none"> • Internal costs for use facilities with specialized equipment

In-kind Educational Grant do not include the following:

- Samples and demonstration products
- Products or services provided within a commercial deal (e.g. samples required under public procurement)
- Products and Services that could be used for clinical activities outside educational purposes
- Any Products or Services that are for research purposes (see Chapter 6: Research).

Methodology Note Example

Structure

- Introduction
- Executive summary of the methodologies used for disclosure purposes and countries specificities
- Definitions
 - o Recipients
 - o Types of Educational Grants
- Disclosure scope and timelines
- Disclosures in case of partial performance or cancellation
- Cross-border activities
- Specific considerations:
 - o Multi-year agreements
 - o Consent management (please note that some jurisdictions may require the legal entity's consent for publication of data)
 - Consent collection
 - Management of recipient consent withdrawal
 - Management of recipient's request
 - Partial consent
- Disclosure Form
 - o Date of submission
 - o Currency in case of aggregated payments made in different currencies
 - o VAT included or excluded and any other tax aspects
- Disclosure financial data and amount of Educational Grants provided
- Calculation rules

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