Disclaimer

The Compliance Handbook (the "Handbook") has been prepared by MedTech Europe based on information collected from both MedTech Europe members and public domain. While MedTech Europe considers the information herein to be reliable, it makes no warranty or representation as to its accuracy, completeness or correctness. The document is intended for informational purposes only and should not be construed as legal advice for any particular facts or circumstances. MedTech Europe is not responsible for any damage or loss incurred by any of its members or any third party acting based on the contents of this document.

MedTech Europe reserves the right to change or amend it at any time without notice.

This Handbook is intended for "internal use" by MedTech Europe members. Any "external use" of the contents of this Handbook is subject to prior written consent of MedTech Europe. Publication on a publicly accessible website is prohibited.

Introduction

MedTech Europe's Code of Ethical Business Practice provides an ethical framework to ensure appropriate interactions of their members with Healthcare Professionals ("HCPs") and Healthcare Organisations ("HCOs"). However, 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. The aim of this Compliance Handbook (hereafter referred to as "the Handbook") is to provide a general overview of national requirements, which might be more specific or more stringent than the MedTech Europe ones.

This Handbook summarises the national requirements for:

- Transparency (i.e. disclosure obligations if applicable)
- Educational Grants (e.g. employer notification requirements)
- Consultancy arrangements
- Hospitality (i.e. meals, accommodation and travel expenses)
- Gifts
- Promotion & advertisement
- Virtual Events
- Discounts
- Other national requirements that might be of interest (e.g. Fair Market Value ("FMV"), etc.)

In addition, on overview of National Associations' enforcement mechanisms as well as on overview of the different meal limits are available at the end of the Handbook.

How to use this Compliance Handbook

To allow a better overview of the content in the different chapters, a table has been included at the beginning of each chapter. The goal of this table is to bring to the attention of the reader specific information relating to the National Association (NA) and its code.

The first part of the table is about the **local Code of Conduct**: the table indicated when the NA transposed the MedTech Europe Code, when they phased-out-direct sponsorship, if they have any national "Conference Vetting System" (CVS) that reviews local events, if they have any rules regarding Transparency (i.e. disclosure obligations), and/or whether or not they have set up a national "Ethical Charter"[1].

The second part provides information on **additional rules,** included either in the local code (which would go beyond the MedTech Europe Code rules) or in local law. Further it provides any other relevant information about **the following categories:**

[1] For more information on what is meant by "Conference Vetting System", "Transparency" and "Ethical Charter", please consult the next chapter "MedTech Europe and the Code of Ethical Business Practice".

- Educational Grants,
- Company Organised Event,
- Consultancy arrangements,
- Meals, travel and accommodation expenses
- Gifts.

If there is a such an additional rule/ requirement, a "**yes**" will be included next to the relevant category. If there is a "**no**" it means there is none and you can refer to the rules included in MedTech Europe Code.

In the last part of the table, the reader can see if the National Association has developed any other guidance or if there is a local rule with regards to Fair Market Value (FMV), Promotion & advertisement, Competition law, Virtual Events, Discounts or on any other topic (see "others").

In summary, the table would look as follows:

Code	
MTE Code transposition	[date of Code transposition[2]]
Phase-out Direct Sponsorship	[date of entry into force of the ban of direct sponsorship]
National CVS	yes / no
Transparency	yes / no / law
National Ethical Charter	yes / no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes / no
Company Organised Events	yes / no
Consultancy arrangements	yes / no
Meals, travel and accommodation expenses	yes / no
Gifts	yes / no
Miscellaneous	
FMV	yes / no
Promotion & advertisement	yes / no
Competition law guidelines	yes / no
Virtual Events guidelines/rules	yes / no
Discounts guidelines/rules	yes / no
Others	yes / no

Information about the local code

Information about additional requirements other than those of the MTE Code (i.e. extra rule in NA Code, law, other info)

Other guidance on specific topics (either included in the local code or in a local law)

[2] Date of Code Transposition means the date of the Code approval by the Board of Directors or the General Assembly of the National Association, as applicable.

MedTech Europe and its Code of Ethical Business Practice

As per the MedTech Europe governance, there are mainly two types of Members: Full and Associate Corporate Members ("Member Companies") as well as Full and Associate National Association Members ("National/Member Associations")[3].

The Code adopted in December 2015, applies to all Members. They must comply with the Code as a minimum standard when interacting with HCPs and HCOs registered and practicing in MedTech Europe Geographic Area[4]. This includes Countries with National Associations[5] and Countries party to the European Economic Area agreement (EEA) without a MedTech Europe National Association[6].

For Companies, the Code entered into force on 1 January 2017, except for the phase out direct support of HCPs at Third Party Organised Educational Conferences, where a Transition Period of an additional year was granted to Member Companies to comply. From that point on, Educational Grants became the only way to provide financial support to Healthcare Professionals to attend Third Party Organised Educational Events.

For National Associations, the deadline to implement the Code was the 1 January 2020, to allow buy-in from Small and Medium Enterprises (SMEs) and in view of differing governance structures. As provided by the Code's Procedural Framework[7], National Associations can decide to transpose it in three possible ways:

- Transpose the Code in its entirety,
- Transpose the Code with some adjustments to the local situation,
- 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[8].

Given some country specific regulations, and after long discussion, the MedTech Europe Board of Directors granted an extension of the above-mentioned deadline to specificNational Associations. Nevertheless, the Code had to be transposed by all National Associations the latest on the 31 December 2021. For more information, please refer to the Overview of the National Associations.

On 25 March 2022, a new version of the Code was approved. The 2022 revised Code reflects evolving standards and best business practices and is designed as the core document for ethics and compliance across the European medical technology industry. The revisions will be effective as of 1 January 2023 for

[3] For more details, please see MedTech Europe's Statutes: https://www.medtecheurope.org/wp-content/uploads/2015/07/20161130_mte_statutes_EN_FINAL.pdf.
[4] Please refer to Annex III of the MedTech Europe Code.
[5] Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the countries where Mecomed is active, Latvia, Lithuania, The Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, UK.
[6] Iceland, Liechtenstein, Luxemburg and Malta.
[7] MTE Code, Part 3 Article 2.2. (Procedural Framework),
[8] MTE Code, Part 3, Article 2.

both member companies as well as National Associations. Some national associations may therefore amend parts of their national Codes in the coming months.

The Conference Vetting System

The Conference Vetting System (CVS) is a centralised and independent decision-making system which reviews the compliance of Third Party Organised Educational Events with the Code created in 2012. It aims at alleviating the administrative burden previously faced by MedTech Europe Members, of the compliance assessment of a Third Party Organised Educational Event, Members wished to support. As an integral part of the MedTech Europe Code, it became compulsory for MedTech Europe Members as of 1 January 2017 to submit a conference for assessment prior to any decision of sponsorship/participation ("mandatory submission").

The CVS evolved over time. End of 2018, MedTech Europe introduced a new section in the system, dedicated to Third Party Organised Procedure Trainings (TPPT)[9]. The most recent development and work in progress is the outsourcing of EFPIA's e4ethics assessments to the CVS team. The objective of such a collaboration is to ensure consistency and harmonisation across the healthcare industry, and for the benefit of all stakeholders involved.

Some National Associations have also created their own national vetting systems to assess national Events, either using MedTech Europe's platform[10] or creating their own platform, adapting it to the local reality. Other NAs are discussing to develop one[11].
So far, 5 National Associations (i.e. Confindustria Dispositivi Medici, Fenin, Mecomed, MedTech Poland/Polska and Polmed) have created their national CVS system.

Transparency

Transparency[12] is a one of the core principles of the Code. As such, Member Companies committed[13] to annually publish their Educational Grants on a central European platform.The first year of publication was 2018, where the data of 2017 was made public.

[9] Please see the Glossary of the Code.
[10] Please see: www.ethicalmedtech.eu
[11] In this context, the Compliance Panel developed a Guidance document for National Associations, available in the Members Area.
[12] To learn more about Transparency, please visit the Transparency section on the MedTech Europe website: https://www.medtecheurope.org/
[13] Please see the Code, Part 2, Disclosure Guidelines.

Educational Grants are further regulated in Chapter 4, Section 3 of the Code. In particular, the Code notes that Educational Grants can be provided for the following (non-exhaustive) purposes:

- Support for Third Party Organised Educational Events, including:
    - Support for HCP Participation at Third Party Organised Educational Events
    - Support for Third Party Organised Educational Events
- Scholarships and Fellowships
- Grants for Public Awareness Campaigns

The Transparency-sections in each of the chapters here below aim at providing additional information and guidance where National Associations and/or Member States have introduced specific rules or requirements regarding Transparency.

The Ethical Charter

An additional instrument developed to support Code buy-in from stakeholders as well (versus the Members) is MedTech Europe's Ethical Charter. The Ethical Charter[14] is a voluntary certification initiative for HCOs or PCOs, with the goal to allow these organisations to demonstrate to industry partners their commitment to comply with the ethical standards included in the Code. Launched in 2017, the number of certified Healthcare Organisations (HCOs) and Professional Conference Organisers (PCOs) has been growing over the years.

Some National Associations have adapted it for themselves and their local PCOs/HCOs (i.e. Mecomed, Apormed, Fenin, SNITEM).

Educational Grants

The Code defines Educational Grants[15] *as the provision by a Member Company of funding, products or other in-kind support to a Healthcare Organisation ("HCO") 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*[16]. According to The Code[17], these include Grants provided to support Healthcare Professional participation to Third Party Organised Educational Events. HCPs who benefit from this form of the Grant are selected by the recipient of the Grant. This means that Grants can only be provided to legal entities, and never to individuals. They also require a written contract, as well as other related documentation. Member Companies may define the type of

[14] More information is available at: https://www.ethicalmedtech.eu/ethical-charter/general-overview/
[15] MTE Code, Part 4,Glossary and Definitions and Part I, Chapter 4, Paragraph 3.
[16] MTE Code, Part I, Chapter 4, Paragraph 3.
[17] MTE Code, Part I, Chapter 4, Paragraph 3.a.

recipients eligible to benefit from the Grant but cannot select individual recipients. Furthermore, conferences benefitting from Educational Grants still need to comply with the specific requirements set out in the Code[18].

Consultancy Arrangements

According to the Code, *Member Companies may engage HCPs as consultants and advisors to provide bona fide consulting and other services (e.g. research, participation on advisory boards etc.). A reasonable remuneration based on fair-market-value may be paid for performing these services. However, consultancy arrangements must be permitted by laws and regulation in the country where the HCP is licensed to practice*.[19]

It is important to note that, under the MTE Code, Member Companies are required to implement an independent decision-making/review process when selecting consultants.[20]

In addition to these general criteria for consultancy agreements, the MTE Code lays down specific criteria that must be respected.[21]

Gifts

Generally, inexpensive gifts are allowed as long as they either relate to the HCP's practice, or benefit patients or serve a genuine educational function. In addition, provision of such gifts must comply with national laws, regulations and industry and professional codes of conduct of the country where the HCP is licensed. Please find an extensive list of requirements in the MedTech Europe Code of Ethical Business Practice.[22]

This section has been revised in the 2022 Code.

Virtual Events

The healthcare congress environment was significantly impacted by the Covid-19 pandemic, but the necessity for high-quality medical education and training remained. As a result, there was a significant shift towards Virtual Events. Virtual Events became the 'go to standard' and as such it is essential to shed some light on potential national rules and requirements applicable to such events. Additionally, please note that in relation to Virtual Events, MedTech Europe developed a Guidance on Virtual Events in 2020[23].

[18] MTE Code, Chapter 1, General Criteria for Events.
[19] MTE Code, Part 1, Chapter 5, Paragraph 1.
[20] MTE Code, Part 1, Chapter 5, Paragraph 1.
[21] A list can be found in the Code, Part 1, Chapter 5, Paragraph 2.
[22] MTE Code, Part 1, Chapter 8.
[23] MTE Guidance on Virtual Events, available at: https://www.medtecheurope.org/wp-content/uploads/2017/06/medtech-europe-code-of-ethical-business-practice-qa-dg.pdf#page=64

Virtual Events have been specifically addressed in the 2022 Code.

Discounts

This section outlines any specific rules relating to granting discounts to HCOs.

Table of Contents

Overview MedTech Europe's National Associations

At the time of writing, MedTech Europe has **50** National Associations. Please find below the full list[24]. In addition, the table provides an overview of the Code transposition and the phase-out of direct sponsorship by National Associations.

Country	National Association	Scope	MTE Code Transposition	Phased-out direct sponsorship
Austria	Austromed	MD & IVD	2017	2017
Belgium	BeMedTech	MD & IVD	2019	2020
Croatia	Cromed	MD & IVD	2017	2017
Cyprus	SAAIEK	MD & IVD	2018	2019
Czech Republic	CzechMed	MD	2017	2019
	CZEDMA	IVD	2017	2020
Denmark	Medicoindustrien	MD	2018	2019
	Dialab	IVD	2019	2020
Finland	Sai Lab - MedTech Finland	MD & IVD	2017	2019
France	SNITEM	MD	2019	2020/2022
	SIDIV	IVD	2019	2020
Germany	BV Med	MD	2020	2020
	Spectaris Medizintechnik	MD	2017	2020
	VDGH	IVD	2020	2021
Greece	SIEV	MD & IVD	2017	2018
Hungary	AMDM	MD	2018	2018
	ETOSZ	MD	2019	2019
	HIVDA	IVD	2017	2019
Ireland	HealthTech Ireland	MD & IVD	2016	2018
	Irish Medtech Association	MD & IVD	2016	2018
Israel	MedTech Israel	MD & IVD	*To be determined*	
Italy	Confindustria Dispositivi Medici	MD & IVD	2018	2019
Middle East - Africa	Mecomed	MD	2017	2019
Netherlands	NEFEMED	MD	2021	2021
	FHI	MD	2020	2020
	DIAGNED	IVD	2020	2021
Norway	Melanor	MD & IVD	2019	2011/2019
Poland	Polmed	MD	2017	2018

[24] Please note that the three European Associations Members of MedTech Europe, i.e. EDANA, EASSI and SBA as well as IPQ are, due to their nature, not included in this overview.

	Technomed	MD	2020	2020
	MedTech Polska/ Poland	IVD	2017	2018
Portugal	Apormed	MD	2017	2018
	Apifarma	IVD	2017	2018
Romania	AFPM	MD & IVD	2018	2018
Russia	IMEDA	MD	2019	2011
Slovakia	SK-MED	MD	2018	2018
	SEDMA	IVD	2019	2019
Slovenia	MedTech Slovenia	MD&IVD	2018	2018
Spain	FENIN	IVD & MD	2016	2018
Sweden	Swedish Medtech	MD	N/A	2015
	Swedish Labtech	IVD	N/A	2015
Switzerland	Swiss MedTech	MD	2017	2018
	SVDI/ ASID	IVD	2019	2019
Turkey	ARTED	MD & IVD	2019	2019
UK	ABHI	MD	2017	2019
	BIVDA	IVD	2018	2018

What's new in this edition

The structure of the Compliance Handbook has slightly changed. The table at the beginning of each Chapter contains two new sections: Virtual Events and Discounts. Furthermore, several minor corrections were included, and some references and footnotes were added or updated.

In addition, some of the key changes include:

- **Denmark:** MEDICOINDUSTRIEN's general assembly approved a new code, which will enter into force on 1 January 2023, as MEDICOINDUSTRIEN adopts the new MedTech Europe Code that will also enter into force as of 1 January 2023.
- **Italy:** On June 26, Law no. 62/2022 ("Sunshine Act") came into force.
- **Poland:** the new Polish Medical Devices Act of 7 April 2022 entered into force on 26 May 2022 and introduced new restrictions to advertising of medical devices.
- **Portugal (Apifarma):** As of 1 January 2022, Apifarma has a Code of Conduct for interactions between the pharmaceutical industry and patient organizations.
- **Spain:** FENIN finalised the Guidance on interactions between the medical device industry and patient organisations and it was adopted in April 2022 as an Annex to the FENIN Code, which is mandatory.

Please note that the following Chapters of the Compliance Handbook were not updated in 2022:

- CzechMed & CZEDMA (Czech Republic)
- Croatia
- VDGH (Germany)
- Greece
- HIVDA & ETOSZ (Hungary)
- Norway
- TECHNOMED (Poland)
- Romania
- SVDI/ASID (Switzerland)
- ABHI & BIVDA (UK)

The information contained in those Chapters is from previous years. The date of the update is mentioned at the beginning of each chapter.

AUSTRIA

Updated: 4 October August 2022

MEDICAL DEVICES & IN-VITRO DIAGNOSTICS: AUSTROMED

Code	
MTE Code transposition	29.3.2017
Phase-out Direct Sponsorship	29.3.2017
National CVS	no[25]
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MedTech Europe Code	
Educational Grants	yes
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	yes[26]
Virtual Events guidelines/rules	no[27]
Discounts guidelines/rules	no
Other information/ guidance	yes

About the AUSTROMED Code

AUSTROMED[28] has last revised its Code ("the AUSTROMED Code") (Verhaltenskodex der AUSTROMED) in 2017. The Code is also accompanied by a Questions and Answers (Q&A) document, which provides additional guidance on the application of the rules laid down in the AUSTROMED Code[29]. 2017 was also the

[25] However, AUSTROMED provides an event-assessment tool to its members, more information available at: https://extranet.medtecheurope.org/CT-ComplianceCommittee/Shared%20Documents/AUSTROMED_EventAssessment_final_170220.xlsx

[26] AUSTROMED Leitfaden zum Kartellrecht (Competition Law Guidelines)), accessible at: https://www.austromed.org/wp-content/uploads/2020/09/Austromed_Leitfaden_Kartellrecht.pdf

[27] Rules for on-site events are applicable for Virtual Events.

[28] The Austrian Medical Device and In-Vitro Diagnostic Association: https://www.austromed.org/

[29] Q&As 41-54, Questions and Answers (Q&A) Guidance Document on the AUSTROMED Code (Fragen & Antworten zum AUSTROMED-Kodex), 29 March 2017, accessible at: https://www.austromed.org/wp-content/uploads/2020/09/Kodex_Fragen_Antworten.pdf

year in which the former Austrian IVD association ODGH was dissolved and AUSTROMED created an IVD section becoming the sole industry association for medical devices and in-vitro diagnostics companies in Austria.

Educational Grants

Under the AUSTROMED Code, written invitations must be addressed to the HCP's employer (e.g. HCO) who will subsequently choose the attendees.[30] The Educational Grant should be limited to registration fees as well as reasonable travel, meals and accommodation costs, which need to be documented in writing.

Consultancy arrangements

The requirements regarding arrangements with consultants differ slightly depending on whether the arrangement concerns consultancy services in general[31] or consultancy services concerning research & development.[32]
Arrangements with consultants regarding consultancy services in general are permitted but subject to the following requirements[33]:

- Contracted HCP should be technically / scientifically qualified for consultancy services concerned;
- Company concerned should have a legitimate interest in the consultancy activities;
- Compensation should be reasonable and proportional to the consultancy services rendered;
- The agreements must be in writing and approval to be obtained by the consultant and not the company that is engaging the HCP.

The same requirements apply to arrangements regarding research & development, except the written contract must be approved by the HCPs employer.[34] Please refer to the AUSTROMED Q&A document for further guidance.[35]

Meals, travel, and accommodation expenses

The Austrian Act on Medical Devices (*Medizinproduktegesetz 2021* or *MPG 2021*)[36] does not set out specific rules applicable to the provision of meals and hospitality. According to the AUSTROMED Code, meals, travel and hospitality costs may only be covered if the member company did not invite HCPs directly, i.e. a written invitation was sent to the respective employer[37]

[30] AUSTROMED Code, Section 7(2)(c).
[31] AUSTROMED Code, Section 8.
[32] AUSTROMED Code, Section 5.
[33] Ibid.
[34] AUSTROMED Code, Section 5(1)(d).
[35] AUSTROMED Q&A Guidance Document, Q&As 7-14.
[36] The Austrian Act on Medical Devices (MPG-2021) (Bundesgesetz betreffend Medizinprodukte - Medizinproduktegesetz 2021- MPG-2021), BGBl I 122/2021.
[37] AUSTROMED Code, Section 7.

Similarly, to the MTE Code, the AUSTROMED Q&A guidance document explains that member companies should assess what is reasonable based on regional and country-specific practices. Generally, the following rules should apply:

- Accommodation should not normally be provided at a top category or luxury hotels, or venues known for their entertainment facilities;
- Air travel should be economy class unless the duration of the flight extends beyond 5 hours (in which case business class may be considered[38];
- Meals should be of a standard that HCPs would routinely expect if they were paying for them out of their own pockets.

Gifts

According to Section 75 of the MPG-2021, gifts to HCPs are prohibited unless they are of low value and related to the practice of medicine or to medical technology. The MPG-2021 does not give any information on what the minimal value/amount of a permissible gift is. However, the AUSTROMED Q&As provide a non-exhaustive[39] list of items that would qualify as permissible low-value gifts, including table or pocket calendars, computer accessories, and various clinical items.

Promotion & advertisement

The Austrian Medical Device Act contains specifics requirements for the promotion and advertisement of medical devices. For more information, please refer to §§ 70-76 of the Medical Device Act and Sections 9-10 of the AUSTROMED Code. Please note that the provisions on advertisement of the Medical Device Act will come into force with regard to in-vitro diagnostics as of May 26, 2022. For more information, please refer to § 91 of the same act.

Discounts

In Austria, there are no specific requirements in order to grant discounts to HCOs nor to customers in general on company products. However, members of AUSTROMED must take into consideration the principles laid down in the AUSTROMED Code when granting discounts. For more information on the principles, please refer to AUSTROMED's Code.[40]

Other

[38] AUSTROMED Q&A Guidance Document, Q&As 42 & 43.
[39] Q&A16, AUSTROMED Q&A Guidance Document.
[40] AUSTROMED Code, Section 2.

AUSTROMED has developed a position paper on the access to the operating room by company representatives.[41] In addition, they also offer workshops on this topic on a regular basis.[42]

Lastly, they have recently developed a compliance explainer video[43] and a compliance folder[44] related to AUSTROMED's Code of Ethics, which are available on their website.

[41] Positionspapier für die Anwesenheit und das Verhalten von Medizinprodukteberatern in Operationsräumen, Austromed, availible here.
[42] More information can be found on the AUSTROMED website, here.
[43] Compliance explainer video, accessible at: https://www.austromed.org/ueber-uns/kodex-und-statuten/
[44] Compliance folder, accessible at: https://www.austromed.org/ueber-uns/kodex-und-statuten/

BELGIUM

Last update: 4 October 2022

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: BEMEDTECH

Code	
MTE Code transposition	7.5.2019
Phase-out Direct Sponsorship	1.1.2020
National CVS	no*
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	beMedTech Code, ban of indirect sponsorship
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Others	no

About the beMedTech Code

The new beMedTech[45] Code of Ethics[46] ("beMedTech Code") (Code d'éthique / Deontologische Code), was adopted by their AGM on 7 May 2019, transposing the MedTech Europe Code.
In addition to a ban of direct sponsorship, the beMedTech Code also foresees a ban of indirect sponsorship as of 1 January 2022. This means that members of beMedTech should no longer provide Educational Grants for the support of HCPs to attend Third-Party Organised Educational Events. It is however still allowed to support financially Third-Party Organised Educational Events (e.g. sponsorship, satellite symposium), provided that other compliance considerations have been approved (e.g. Mdeon).

[45] beMedTech (formerly known as UNAMEC) is the Belgian Trade Association representing companies which manufacture, sell and distribute medical devices: https://www.bemedtech.be/fr/
[46] There is no English version available.

National CVS

In Belgium, Mdeon is responsible for overseen visa requirements. For more information, please visit Mdeon's website and see also below.

Transparency

The Belgian Sunshine Act - Chapter 1 of Title 3 of the Law of 18 December 2016 regarding various provisions on health (*Belgian official Journal*, 27 December 2016) - entered into force on 23 June 2017[47].
This legal transparency obligation imposes pharmaceutical and medical devices companies—both Belgian and foreign—to document and annually disclose on the platform www.betransparent.be the premiums and benefits that they granted directly or indirectly to HCPs —both Belgian and foreign—, active on the Belgian territory, healthcare organisations or patient associations as from 1 January 2017.

Betransparent.be is a centralised public platform which is the result of autoregulation put into place by the companies in close collaboration with several associations of healthcare professionals (physicians, pharmacists, veterinaries, dentists, nurses, physiotherapists, paramedics, and hospital technicians), that has grown into a legal obligation. Mdeon has been designated to manage the betransparent.be platform[48]. The companies need to notify their data to betransparent.be each year between 1 January and 31 May. Gifts and meals among others, on the other hand, are not subject to the disclosure obligations[49]. Fines for failure to comply with the Sunshine Act could run from 1.600 to 120.000 euros[50]. For further information on this transparency obligation see betransparent.be's FAQs[51].

Due to the above-described legal disclosure requirements, no reporting is needed for beMedTech's member companies on the MedTech Europe Transparency platform.

Educational Grants

In addition to what was mentioned under introductory section, for scientific Events in Belgium with Belgian or foreign HCPs active on the Belgian territory — that take place over more than one calendar day — prior approval by Mdeon[52] (i.e. visa) is legally required. Mdeon functions as Belgium's national conference vetting system and prior approval through this system is mandatory for all companies interacting with HCPs. It should

[47] Please see also the Royal Decree of June 14 2017 implementing the Sunshine Act.
[48] Please see news: "Mdeon is recognized to manage the transparency platform provided by the Sunshine Act," betransparent.be, 22 August 2017.
[49] Ibid. p. 6.
[50] Frequently Asked Questions Sunshine Act, p. 11, betransparent.be, July 2017.
[51] Ibid.
[52] Mdeon is a Belgian common ethical platform constituted of 28 associations of physicians, pharmacists, veterinarians, dentists, nurses, paramedical practitioners and of the pharmaceutical and medical devices industry. Mdeon was for the first timedesignated as a supervisor of the visa process by the Royal Decree of 25 February 2007 (M.B., 9 March 2007). For more information about Mdeon: https://www.mdeon.be/en/ethical-health-platform/ (last visited 4 September 2018). Please note that Mdeon has recently revised its Code of Ethics (published on August 31, 2018)

be emphasized that this visa application requirement applies to both direct and *indirect* sponsorship (e.g. Educational Grants)[53].

In the case of indirect sponsorship, with regards to the visa application, there are two options:

- the company can (continue to) submit the visa application itself, as the names of the invited HCPs do not have to be mentioned in the visa application. The healthcare organisation will, however, have to provide the company with the necessary information to introduce the file. In this particular case, the billing can also be handled directly by the company, on the condition that the selection of the beneficiaries is done by the HCO, independently of the company.
- or the visa application is submitted jointly by both the HCO and the company: the HCO completes the visa application, encloses the necessary annexes and sends it to the company who checks it, pays for it and introduces it. To find out how to apply for a visa jointly, consult the operating instructions on the Mdeon website (Visa procedure / Joined submission of a visa application).

The sponsor and/or organiser should make a request for approval no later than 15 working days before the start of the event. A decision is taken within 5 working days. However, the deadline to make a request for approval is reduced to 6 working days when:

1. the scientific event brings together a maximum of 15 persons (including participants and speakers),
2. companies have to introduce a new request for a visa (following a substantial modification after having received their visa or following a refusal), or
3. the invited HCP takes part in the meeting as a consultant.

The obligation is laid down in the Medicines Act of March 25, 1964[54]. It is also included in the Mdeon and beMedTech Codes of Ethics[55].
In December 2015 Mdeon published their updated guidelines regarding scientific events which do not require a visa[56].

Meals, travel and accommodation expenses

According to the Medicines Act[57], covering hospitality costs of HCPs attendance at scientific events is not allowed, unless the following conditions are met:

- The event is exclusively scientific;
- Hospitality is strictly limited to the scientific objective of the event;
- Location, date and duration of the event does not undermine its scientific character;

[53] Indirect sponsoring of the participation to scientific meetings: Joint Introduction of a Visa Application, 18 January 2017 (this communication lays out the steps to be taken for a joint introduction of a visa application) (last visited 22 September 2017).
[54] Article 10, par. 3, Medicines Act of March 25, 1964 (Medicines Act) (Loi du 25 mars 1964 sur les médicaments/ Wet van 25 maart 1964op de geneesmiddelen).
[55] Mdeon Code of Ethics, Part II, Chapter II, (Mdeon Code), (Code de déontologie/Code voor deontologie), August 2018; beMedTech Code May 2014 .
[56] Guidelines relating to Scientific Events not requiring Visa, 17 December 2015, please see Mdeon website: www.mdeon.be (Guidelines /Our guidelines/ Scientific Events not requiring visa).
[57] Medicines Act, Article 10, par. 2, p. 2.

- Hospitality is limited to the duration of the event;
- Hospitality cannot be extended to others than HCPs.

Mdeon adopted the following rules for hospitality costs[58]:

- Overnight stay: up to 250 EUR (breakfast included);
- Meals: up to 80 EUR for dinner and 40 EUR for lunch[59] (drinks included).

In 2012 Mdeon also adopted rules for travel costs. If the HCP takes part in a scientific event as a participant, the following rules apply[60]:

- Travel by train: Economy or Business Class;
  Travel by plane: Always Standard Economy Class (with an exception for consultants, for flights longer than 6 hours).

Gifts

Inexpensive gifts which are related to an HCP's practice are allowed.[61] Mdeon published its most recent guidelines relating to gifts in 2016. According to these guidelines[62], the following amounts for gifts should be considered as acceptable:

- Maximum 50 EUR per gift (market value, VAT included);
- Maximum 125 EUR per annum per HCP per company (VAT included).

[58] Mdeon Visa Office of 10 October 2014, please see Mdeon website: www.mdeon.be (Publications / Case law).
[59] Please note that discussions are held between Mdeon and the Federal Agency for Medicines and Health Products (FAMHP) regarding indexation of amounts for meals (lunch – 40 to 45 EUR and dinner from 80 to 90 EUR). These changes are expected to enter into force by the end of 2022 or beginning of 2023.
[60] Mdeon Visa Office, please see Mdeon website: www.mdeon.be (Communications: maximum amount meals)
[61] Medicines Act, Art. 10, par. 2, p. 1.
[62] Premiums and Benefits of Negligible Value: Guidelines, 1 July 2016, please see Mdeon website: www.mdeon.be (Publications / Premiums and Benefits of Negligible Value).

CROATIA

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Last update: 31 August 2021

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: CROMED

Code	
MTE Code transposition	28.11.2017
Phase-out Direct Sponsorship	28.11.2017
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About CROMED

CROMED[63] was founded on 27 July 2017 and has joined MedTech Europe shortly after. The Croatian association adopted the MedTech Europe Code without any changes the 28 November 2017. The association is composed of only seven members, which are all MedTech Europe members.

[63] The Croatian Medical Devices & In-Vitro Diagnostics Industry Association: https://cromed.hr/

CYPRUS

Last update: 4 October 2022

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: SAIEEK

Code	
MTE Code transposition	2018
Phase-out Direct Sponsorship	1.1.2019
National CVS	no
Transparency	yes
National Ethical Charter	yes
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	yes[64]
Virtual Events guidelines/rules	yes*
Discounts guidelines/rules	no
Others	no

About the SAIEEK Code

The Cyprus National Association of Importers of Medical and Scientific Instruments Device, SAIEEK[65], joined MedTech Europe in 2018 and their AGM approved their Code of Conduct in May 2018 [66](Κώδικα Ηθικής Επιχειρηματικής Πρακτικής ΣΑΙΕΕΚ) ("SAIEEK Code"). The Code entered into force end of 2018. The sole

[64] Please see here.
[65] The Cyprus Association of Importers of Medical and Scientific Instruments (Σωματείο Αντιπροσώπων Ιατρικού και Επιστημονικού Εξοπλισμού Κύπρου) is the Association of Medical Device and In vitro Diagnostic, accessible at: https://www.saieek.com/
[66] The SAIEEK Code is an identical translation of the MedTech Europe Code into Greek.

difference between the MedTech Europe Code and the SAIEEK Code is that the CVS assessments were required only as of 1 January 2019.
SAIEEK is composed of forty-two members and all of them are IVDR and MDR distributors.

Transparency

Please note that the Cyprian Ministry of Health requires to follow certain accounting obligations with regards to Educational Grants as well as expenses related to promotional events for Companies based in Cyprus[67].

Hospitality & Gifts

In February 2019, the Audit Office of the Republic of Cyprus has adopted a Code of Ethics to encourage and ensure a professional work environment. The Code applies to government officials (i.e. all public employees in Cyprus) and it contains provisions on hospitality and gifts. More information can be found on the website of the Audit Office of the Republic of Cyprus[68].

Virtual Events

Providing meals during Virtual Events is not allowed in Cyprus[69].

[67] For more information, please see: https://www.cysec.gov.cy/en-GB/legislation/issuers/TRANSPARENCY/
[68] Please see: http://www.audit.gov.cy/audit/audit.nsf/ethics_en/ethics_en?opendocument (last visited: 04.10.2022).
[69] For more information on Virtual Events (in Greek), please see here.

CZECH REPUBLIC

MEDICAL DEVICES: CZECHMED

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years**.

Updated: 21 September 2020

Code	
MTE Code transposition	1.3.2017
Phase-out Direct Sponsorship	1.1.2019
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Others	no

About the CzechMed Code

CzechMed's[70] General Assembly approved their new Code of Ethics ("CzechMed Code") (ETICKÝ KODEX CZECHMED) in March 2017.

Transparency

Even before the MedTech Europe Code included Transparency provisions and the Transparent MedTech platform was created, the Czech legislation partly regulated this area.

[70] CzechMed is the Czech Association of Medical Device: http://www.czechmed.cz/

In January 2013, the third version of an Order of the Czech Ministry of Health came into force[71]. One part of the Order is dedicated to transparency rules for interactions between HCPs and the healthcare industry (e.g. reporting of all sponsorship donations above CZK 100.000 (~4000 Euros) to the relevant ministerial department). There is also a ban on the cooperation of HCPs (who are directly or indirectly involved in preparing of the tender documentation) with companies participating in public tenders. However, the Order is only binding on the directly controlled organizations of the Ministry of Health, which are the hospitals expressively listed in the document (e.g. university hospitals). Therefore, for the moment the rules are not (directly) binding on the medical technology industry. CzechMed has been negotiating on softening the regulation.

Consultancy arrangements

Arrangements with consultants are permitted. The consulting contract must be signed specifying the services that are to be provided. In addition, the contract may only be signed upon the establishment of a legitimate purpose for the services. The contract must conform to applicable legal regulations. Compensation for services rendered must be based on the nature of the services being provided and reasonable for such services. It may not be tied into the sale of medical devices. The payment must be made for services that have in fact been provided and conform to the applicable tax laws and other legal requirements[72].

Meals, travel and accommodation expenses

There are no specific legislative rules applicable to the provision of meals and hospitality. The CzechMed Code allows the compensation of reasonable travel, meals and accommodation costs:

- Travel: Any travel expenses must be related to the timing of the event plus or minus 1 day. In addition, for plane travel where flight duration is less than 5 hours the Economy Class may only be reimbursed, while for those which exceed 5 hours Business Class might be considered.
- Accommodation: In case the educational conference is held at a five star or luxury hotel, member companies may only cover registration and travel fees but not the accommodation at such a hotel. Sponsorship of HCPs' accommodation at five star or luxury hotels is not permitted under the CzechMed Code.

Financial assistance must be always in compliance with Czech law and its terms and conditions must be clearly called out prior to the event[73].

[71] Order on the Anti-Corruption Strategy of the Ministry of Health of the Czech Republic for Directly Controlled Organizations, No. 3/2013 (Příkaz ministra č. 3/2013 Protikorupční strategie Ministerstva zdravotnictví České republiky pro přímo řízené organizace). The first version of the Order was adopted in March 2011.
[72] CzechMed Directive, Section V.
[73] CzechMed Directive, Section III.

Gifts

There are no specific legislative rules applicable to the provision of gifts. However, there is a specification of the maximum annual amount for gifts to HCPs who can prescribe drugs (applicable for pharma companies)[74]. In addition, according to the CzechMed Code, gifts which are modest in nature and in conformity with the legal requirements applicable in the Czech Republic are permitted. Such gifts must contribute positively to the patient care or the working conditions of the respective HCP or be purely educational. Monetary gifts are not allowed[75].

[74] ÚST 16, version 1, please see here (available in the Czech language only); last visited 31 July 2020). Maximum amount for gifts per one HCP per calendar year is CZK 1500 / € 60.
[75] CzechMed Directive, Section VI.

IN VITRO DIAGNOSTICS: CZEDMA

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 08 October 2021

Code	
MTE Code transposition	11.4.2017
Phase-out Direct Sponsorship	1.1.2020
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	no
Others	no

About the CZEDMA Code

CZEDMA[76] has revised its Code of Ethics[77] ("CZEDMA Code") (Etický kodex CZEDMA) in line with the new MTE Code. It was approved by the General Assembly on the 11th April 2017 and entered into force on 1 January 2020. Their Code is the same as the MedTech Europe Code.

Promotion & advertisement

Act No. 90/2021 on IVDs came into force in 2021 and amended the Advertising Regulation. The law defines what is advertising of MDs and IVDs, what is not advertising, mandatory information for advertising to the

[76] CZEDMA is the Czech Association of Manufacturers and Suppliers of In Vitro Diagnostics: http://www.czedma.cz/
The new CZEDMA Code is a translation of the MedTech Europe Code.

general public, what can be advertised to HCPs and prohibits gifts or other benefits for HCPs, except those of insignificant values[78].

[78] For more information, please refer to Act No. 90/2021 on IVDs, Part 3: Amendment to the Act of Advertisement Regulation, available at: https://www.niszp.cz/sites/default/files/dokumenty/90_20212_IVD_AJ.pdf

DENMARK

MEDICAL DEVICES: MEDICOINDUSTRIEN

Updated: 17 October 2022

Code	
MTE Code transposition	22.3.2018
Phase-out Direct Sponsorship	1.1.2019
National CVS	no
Transparency	law
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	no
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	yes
Virtual Events guidelines/rules	yes
Discounts guidelines/rules	yes
Others	no

About MEDICOINDUSTRIEN

In March 2018, MEDICOINDUSTRIEN's[79] General Assembly approved the adoption of its new Code (the "MEDICOINDUSTRIEN Code"), in line with the MedTech Europe Code[80].

MEDICOINDUSTRIEN adopted "PART 1 – Guidelines on the interactions with Healthcare Professionals and Healthcare Organisations" of the MedTech Europe Code (English version[81]), adding a Preamble in Danish,

[79] MEDICOINDUSTRIEN is the Danish Association of Medical Devices: https://medicoindustrien.dk/
[80] MEDICOINDUSTRIEN adopted the English version of the MedTech Europe Code, verbatim, but added a Danish Preamble which adapts certain rules for Danish companies.
[81] MEDICOINDUSTRIEN adopted the July 2017 version of the MTE Code.

which adapts the Transparency obligations for MEDICOINDUSTRIEN'S member companies[82]. There is also an English translation available. The preamble also includes an exception on the applicability of the Code to pharmaceutical companies. As a result, drug companies which are members of the medical industry, and who are also manufacturers of medical devices, may choose to follow the "EFPIA code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals". However, if these companies do not comply with the EFPIA Code, they will need to apply the MedTech Europe one.

The revision of the Danish transparency ordinance and the advertisement regulation has been completed and both have been in effect since May 2021.

On 4 May 2022, MEDICOINDUSTRIEN's general assemply approved a new Code. The new Code will enter into force as of 1st of January 2023, since MEDICOINDUSTRIEN will adopt the new MedTech Europe Code (English version) that will also enter into force as of 1 January 2023. MEDICOINDUSTRIEN's Code retains the existing Preamble in Danish of the old version of the Code, which adapts the Transparency obligations for MEDICOINDUSTRIEN's member companies and still includes the existing the exception on the applicability of the Code to pharmaceutical companies as mentioned above.

Transparency

In 2014, the Danish Ministry of Health revised the legislative framework for interactions between pharmaceutical companies and HCPs and extended it to the medical device industry[83], which included the adoption of a new transparency regime.

The first reporting requirements were submitted in 2016. Medical device companies must report to the Danish Medicines Agency, on an annual basis, their collaborations with Danish HCPs (e.g. services between industry and HCPs, such as, for example, research cooperation, speaker arrangements, training services, consultancies). However, it is important to note that interactions with relation to class I products are exempt from these transparency rules.

The reporting obligation of the company does not include the actual fees paid to the HCP, however, the Danish Medicines Agency may require at a later stage further information from the company about the size of the payment that the HCP has received and also, the individual affiliation, including the nature and extent of the affiliation as well. Medical device companies are required to disclose the following information to the Danish Medicines Agency[84]:

- Name of the company and CVR-number (equivalent to VAT-number)
- The HCP's full name, email address, workplace, authorization ID or civil registration number
- The period of time the HCP has been affiliated with the company

[82] See below the paragraph on Transparency.
[83] Order 1154 amending the Medicines Act, the Medical Devices Act, Pharmacies Act, Health Act and the Act for promotion of healthcare of 26 May 2014 (Lov om ændring af lægemiddelloven, lov om medicinsk udstyr, apotekerloven, sundhedsloven og lov om markedsføring af sundhedsydelser).
[84] For more information, please refer to Danish executive order no. 716 of 24 May 2022, paragraph 18, available in Danish at: https://www.retsinformation.dk/eli/lta/2022/716

This information has to be reported digitally once a year no later than 31 January using the form which is available at the Danish Medicines Agency's website. This information must be entered in a specific Excel template before completing the form.[85] The company has the obligation to inform the HCP of the content of this report.[86] A fine will be imposed on companies which have failed to fulfil this reporting obligation.[87]

The HCPs included in this obligation are doctors, nurses, dentists, and pharmacists who have had an affiliation with a company during the past calendar year.

Furthermore, these categories of HCPs have a notification duty or the obligation to apply for permission to establish a relationship with a medical device company. Not all types of relationships require permission from the Danish Medicines Agency. In some cases, a notification to the Danish Medicines Agency is sufficient.[88] Also, the form to notify or apply for permission to establish a relationship is available on the website of the Danish Medicines Agency.[89]Further, all relevant information on the notification duty and the obligation to apply for permission, including which HCPs are covered by the notification duty and the obligation to apply for permission can be found in the Guidelines on doctors having a relationship with pharmaceutical and medical device companies as well as stores specialised in the sale of medical devices.[90] . The HCPs have the obligation to report the actual fees received[91]. Furthermore, medical device companies have the obligation to inform the Danish HCPs of their obligation to report/apply for permission.

Third Party Organised Educational Conferences and Company Events[92] that take place outside Denmark fall within the scope of the new transparency obligations[93]. The scope of covered HCPs under this reporting obligation is even wider: doctors, dentists, pharmacists, nurses, pharmacy assistants, midwives, bioanalysis, clinical dietitians, radiographers, social and healthcare assistants or students in these disciplines as well as owners and senior executives in stores selling medical devices as well as medical technicians must report sponsorships to the National Health Board, where it will be public information. There is no reporting obligation for the company in these cases.

Lastly, the company will have an obligation to inform HCPs of the reporting requirements at the time of granting the sponsorship.

---

[85] The template and form are available at: https://laegemiddelstyrelsen.dk/da/godkendelse/sundhedspersoners-tilknytning-til-virksomheder/indberet-tilknyttede-sundhedspersoner/
[86] For more information, please refer to Danish executive order no. 716 of 24 May 2022, paragraph 18, available in Danish at: https://www.retsinformation.dk/eli/lta/2022/716
[87] For more information, please refer to Danish executive order no. 716 of 24 May 2022, paragraph 20, available in Danish at: https://www.retsinformation.dk/eli/lta/2022/716
[88] More information regarding when a permission or a notification is required, available in English at: https://laegemiddelstyrelsen.dk/en/licensing/relationships/doctors/
[89] Form to notify or apply for permission to establish a relationship with a medical device company, available in English at: https://laegemiddelstyrelsen.dk/en/licensing/relationships/doctors/
[90] Guidelines on doctors having a relationship with pharmaceutical and medical device companies as well as stores specialised in the sale of medical devices, available in Danish at: https://laegemiddelstyrelsen.dk/en/licensing/relationships/doctors/
[91] For more information, please refer to Danish executive order no. 716 of 24 May 2022, paragraph 10, section 2, number 2 available in Danish at: https://www.retsinformation.dk/eli/lta/2022/716
[92] After the revision of the current law, it may be the case that Company Events will fall out of the above-described scope.
[93] The Drugs Act, in the Consolidation Act no. 506 of 20 April 2013, Article 43c of (lovbekendtgørelse nr. 506 af 20. april 2013).

Please note that the latest revision of the above-mentioned framework has been completed and became effective as of the 26th of May 2021. The changes have the following implications for MedTech-companies:

- With the revision it is now obligatory for companies to report to the Danish Medicines Agency when they provide financial support to HCPs and governmental purchasing agents' participation in activities with relevance to their profession, which are held in Denmark. Before, companies only had to report financial support for activities held in foreign countries. It is important to note that these activities refer to international congresses, conferences, and not corporate events.
- The scope of the law is extended to also include companies that make products without a medical purpose.
- Furthermore, the requirements for the process of reporting interactions between HCP's and companies to the Danish Medicines Agency have been revised. With the revision, the notification system includes providing information of professional nature. This could be an HCP giving a company brief information that cannot be characterized as consultancy work. Another example could be an HCP giving a small input to a press release. The purpose of this modification is a relaxation of the rules. Now it is sufficient to give notice of teaching, providing professional information and doing research work, whereas before the scheme only included teaching and research.

Consultancy arrangements

In accordance the above-mentioned Danish legislation, HCPs will have to comply with the notification or authorisation requirements when engaging in certain arrangements with the industry (see under "Transparency").

Gifts

In accordance with the newly revised legislation, gifts must be of insignificant value and for professional use only. The Ministry of Health noted that, as a general rule, the amount for gifts per HCP per year should not exceed ~DKK 300 (~EUR 40)[94]. It is also prohibited to organise competitions (e.g. lottery etc.) in any location.

Promotion & advertisement

In Denmark, the ordinance on advertisement[95] sets guidelines for the advertisement of medical devices. The basic requirements for advertisement of company products are the following:

- Information in advertisements must be adequate and scientific;
- Information in advertisements must be in line with what the producer has proclaimed to be the purpose and scope of application of the product;

[94] Rapport on the Proposal for the Regulation on Cooperation between Healthcare Professionals and Drug and Medical Devices Companies, June 2013, point 4.1.2.2 (Forslag Til Regulering af Sundhedspersoners Samarbejde Med Lægemiddel Og Medicovirksomheder, Rapport Juni 2013) This is a comment on the meaning of "limited value" regarding gifts to HCPs by the Danish Ministry of Health in an official rapport.
[95] For more information, please refer to Danish executive order no. 715 of 24 May 2022 available in Danish at: https://www.retsinformation.dk/eli/lta/2022/715

- Advertisements must not present incorrect, misleading, exaggerated, or incomplete information;
- If the advertisement for a specific product compares it with other medical devices, it has to be clearly stated to which devices the comparison refers to. The comparison must only involve products with a similar scope of application.

Additionally, Medicoindustrien does not have specific promotion and advertisement guidelines for its members. Medicoindustrien refers to MedTech Europe's Code and the Danish ordinance on advertisement when providing guidance to its members for questions related to advertisement.

Also, there is Ordinance no. 957 of 29 April 2021 on advertisement for products without a medical purpose[96]. These products share the same characteristics and levels of risk as medical devices but so far there has been no rules regarding their safety and function. More specifically, products without a medical purpose include for example fillers, implants, contact lenses without strength – generally products with a cosmetic purpose. These are now regulated by rules that are similar to the ones regarding medical devices (Annex XVI).

Virtual Events

Until recently, The Danish Medicines Agency has not regarded Virtual Events as being "held abroad". However, as of 26 May 2021 Virtual Events have been regulated by the ordinance on advertisement (see above) and therefore the same rules apply as for other Events.

Discounts

Companies are not allowed to provide financial benefits in the form of a marketing contribution or a sales bonus to HCPs[97]. However, this ban against offering HCPs financial benefits does not include discounts.[98] Companies are allowed to offer HCPs a reduction on the price of their medical devices, and HCPs working in stores selling medical devices are also allowed to make a discount on the product.

[96] For more information, please refer to Danish executive order no. 714 of 24 May 2022 available in Danish at: https://www.retsinformation.dk/eli/lta/2022/714
[97] For more information, please refer to Danish executive order no. 715 of 24 May 2022, paragraph 9, section 1, available in Danish at: https://www.retsinformation.dk/eli/lta/2022/715
[98] For more information, please refer to Danish executive order no. 715 of 24 May 2022, paragraph 9, section 2, available in Danish at: https://www.retsinformation.dk/eli/lta/2022/715

IN VITRO DIAGNOSTICS: DIALAB

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 27 September 2021

Code	
MTE Code transposition	5.12.2019
Phase-out Direct Sponsorship	1.1.2020
National CVS	no
Transparency	law
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	no
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	yes[99]
Discounts guidelines/rules	no
Others	no

About the DiaLab Code

DiaLab[100] adopted the MedTech Europe Code of Ethics in December 2020.

Transparency

Please also note that Order 1154, which introduces certain reporting and transparency obligations regarding sponsorship of HCPs and arrangements with consultants in Denmark, is also applicable in the IVD industry. Please refer to the medical devices section for more information.

[99] In Denmark, the same rules apply for Virtual Events as for in-person events.
[100] DiaLab is the Danish diagnostics and laboratories industry association. http://www.dialab.dk/

Consultancy arrangements

Please refer to the Medical Device section above.

Gifts

Please refer to the Medical Device section above.

FINLAND

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: SAILAB - MEDTECH FINLAND

Updated: 4 September 2022

Code	
MTE Code transposition	14.12.2017
Phase-out Direct Sponsorship	1.1.2019
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	yes
Others	no

About the Sailab – MedTech Finland Code

The General Assembly of the Finish National Association Sailab – MedTech Finland[101] approved its new Code of Ethics (" Sailab – MedTech Finland's Code") on 14 December 2017.

The Sailab - MedTech Code is fully aligned with the MedTech Europe's Code but they foresee two exceptions with regards to Events: firstly, it is not accepted to serve alcohol in booths during working hours and secondly, the winter season ends on 30 April in Finland (instead of 30 March).

[101] The Finish association of laboratory and healthcare product suppliers: http://www.sailab.fi/

Educational Grants

Invitations to Third Party Organised Educational Events must be addressed to the Healthcare Organisation the Healthcare Professional (HCP) works for[102].

Arrangements with consultants

Prior written notification should be made to the hospital's administration, the HCP's superior or other locally designed competent authority, disclosing the purpose and scope of the consultancy arrangement[103].

Meals, travel, and accommodation expenses

Meals, travels, and lodging should be reasonable in value and in connection with the event as well as in compliance with the regulations of the country where the HCP is licensed to practice[104].

Gifts

Members may occasionally provide inexpensive, branded or non-branded items as gifts to HCPs 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 HCP is licensed to practice. Gifts must relate to the HCP's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents[105].

[102] Sailab informed MedTech Europe Secretariat that this requirement is provided in several internal regulations of Finish healthcare regions. Finland is divided into 20 regions for healthcare-related matters.
[103] MTE Code, Part 1 Chapter 5 – Arrangements with Consultants.
[104] MTE Code, Part 1 Chapter 1 – General Criteria for Events.
[105] MTE Code, Part 1 Chapter 8 – Educational Items & Gifts.

FRANCE

Updated: 4 October 2022

Please note that given the specificities of the French legislative framework, we structured this chapter slightly different than the others.

MEDICAL DEVICES: SNITEM

Code	
MTE Code transposition	18.09.2019
Phase-out Direct Sponsorship	2022
National CVS	no
Transparency	law
National Ethical Charter	yes
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	yes
Promotion & advertisement	no[106]
Competition law guidelines	no
Others	no

About the SNITEM Code

SNITEM[107] Board agreed on 18 September 2019 to transpose the MedTech Europe Code by 1 January 2020. The MTE Code is applicable in its entirety to all member companies of SNITEM as of 1 January 2022. SNITEM has also modified its ethics charter in compliance with the provisions of the Code.

[106] There is no additional requirement regarding promotion and advertisement in the SNITEM code but please note there is a French law on promotion on MedTech products.
[107] SNITEM is the French MD association: https://www.snitem.fr/

IN VITRO DIAGNOSTICS: SIDIV

Code	
MTE Code transposition	24.6.2019
Phase-out Direct Sponsorship	1.1.2020
National CVS	no
Transparency	law
National Ethical Charter	yes
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	yes
Promotion & advertisement	yes[108]
Competition law guidelines	yes
Others	no

About the SIDIV Code

The SIDIV[109] General Assembly approved the transposition of the MedTech Europe Code on 24 June 2019, which came into force on 1 January 2020. The SIDIV Code is available here.

SIDIV has a Deontology Commission to ensure compliance with its Code. This Commission is composed of at least five members, not involved in the dispute, and it then appoints a Chairman from among its members.

[108] In France promotion/advertising is subject to an authorization/declaration to ANSM depending on the product.
[109] SIDIV is the French IVD association: https://sidiv.fr/

Updated: October 19, 2022

The new French anti-gift legislation

The French anti-gift legislation ("AG Law")[110] exists since 1993 but has been completely modified. The new law on entered into force on 1 October 2020.

1. Which companies are bound by the AG Law?

The AG Law applies to entities (whether located in France or not), hereafter "Companies", which:

- manufacture or sell products:
  - reimbursed by the French social security
  - or falling under the scope of ANSM (notably medical devices and in-vitro medical devices)
- or/and provide health services (healthcare institutions, home healthcare providers, labs…).

Such entities must comply with AG Law each time they interact with HCPs practicing in France or HCOs located in France (as defined below).

2. Which HCPs and HCOs are concerned?

The AG Law applies to interactions between Companies and the following persons and entities:

- All healthcare professionals ("HCPs");
- Students intending to practice any healthcare profession;
- Persons undertaking medical training or following programs of "continuing professional development" (in French *développement professionnel continu* - "DPC"); these persons are actually generally HCPs;
- Associations of HCPs and Associations of students (intending to practice any healthcare profession);
- «*société savantes*» (societies);
- « *Conseils nationaux professionnels* » (national professional boards)[111];
- Public servants and officials of administrations, local and regional authorities (such as the "ARS"[112]) and of public establishments (such as public hospitals)[113];
- Public servants and officials of any other authority, who elaborates or participates for public health or social security policies, or who are entrusted with sanitary administrative powers.

We shall refer to these persons and entities, collectively, as the "Health Actors".

3. What are the principles of the AG Law?

[110] Articles L. 1453-3 *et seq.* and R. 1453-13 *et seq.* of the public health code.
[111] The official list of "CNP" may be found here: arrêté 20 may 2020
[112] Agence régionale de santé
[113] This category includes public servant of public healthcare institutions, such as notably directors of hospitals.

In principle, it is prohibited for Health Actors to receive from Companies "advantages", whether in cash or in kind, in whatever manner, whether directly or indirectly, and it is prohibited to Companies to promise or offer "advantages" to Health Actors.

The AG Law provides for some exclusions and some derogations to this general ban.

However, the exclusions and derogations do not apply to CNP and public servants listed above, so that Companies cannot provide any kind of advantages to these two categories of Health Actors.

The exclusions and derogations applicable to the other categories of Health Actors are as follow:

3.1 The exclusions [114]

The AG Law provides that some "advantages"' and some agreements are excluded from its scope of application. Those advantages and agreements may, therefore, be procured and entered into, without any prior formalities as per the AG Law[115].

The excluded agreements are:

- Agreement relating to the direct and exclusive practice of a healthcare profession[116].
- Royalties' agreements relating to the exploitation or the assignments of intellectual property rights on health products.

The excluded advantages are:

- Commercial advantages granted under commercial agreements (discounts, rebates…);
- Unplanned meals and breaks, "having a link with the healthcare profession"[117] under €30 incl. VAT (per meal, per HCP and per Company), within the limit of two (2) per year;
- Books, publication or magazines, including subscription to magazines, relating to the practice of the beneficiary's profession, which shall not exceed €30 incl. VAT. per book, publication or magazine, and within a total limit of €150 incl. VAT, per year;
- Office supplies, which shall not exceed €20 incl. VAT, in total per year;
- Other product or service relating to the practice of the beneficiary's profession, which shall not exceed €20 incl. VAT, in total per year;
- Samples of health products or demo products, which shall not exceed €20 incl. VAT, within the limit of three (3) per year.

[114] The exclusions do not concern CNP and public servants.
[115] Transparency lax would still apply though.
[116] This does not concern services agreements such as speaker, proctoring, study agreements… since these services are not part of the HCPs' practice.
[117] The wording of the legal text implies that the meal/break must take place at or near the working place of the HCPs, or during a professional event.

By exception, are authorized (with no value limit):

- Samples of medicines whose supply is governed by Articles L.5122-10 and R.5122-17 of the French Public Health Code;
- Samples and demo products for educational or training purposes of HCPs and which are not used as part of the patient's care pathway;
- Samples and demo products used by HCPs for educational purposes of the patient, or which are given to the patient exclusively for the purpose of testing the product and for a limited time.

Above the limits hereto mentioned (whether in terms of value and/or of quantity) it is simply forbidden to procure the advantage.

3.2 The derogations

The AG Law provides that the following advantages may be procured to Health Actors[118] under certain conditions:

- Compensation, fees, reimbursement of costs relating to activities of research, development of research, scientific evaluation, consulting, services, commercial promotion;
- Hospitality offered during professional or scientific events, or during promotional events of products or services;
- Financing or financial participation of professional training actions or continuing professional development;
- Grants for research activities;
- Grants to associations of HCPs or students.

The main conditions established by the AG Law are (for each type of advantages):

- An agreement must be entered into between the Company and the Health Actor[119];
- Depending on the value of the agreement (fees, hospitality costs, reimbursement costs, grants…), the agreement must be:
  - Either declared in advance, by the Company, if none of the advantages mentioned under such agreement exceeds[120] the regulatory thresholds (defined below),
  - Or authorized, if one or several of the advantages mentioned under such agreement exceed(s) the regulatory thresholds.

[118] Except CNP and public servants.
[119] The agreement must contain some mandatory clauses (Articles R. 1453-14 of the public health code and *arrêté* dated September 24, 2020).
[120] The declaration process must be followed when the value of the advantages equals the thresholds.

4. What are the thresholds which determine the process to follow?

The thresholds vary depending on the nature of the agreement, and on the quality of the party to the agreement:

4.1 For services agreements

- With HCPs:
  - €200 per hour[121]
  - €800 per half-day
  - €2,000 for the whole agreement

- With Students
  - €80 per hour
  - €320 per half-day
  - €800 for the whole agreement

- With Students' and HCPs' associations and societies[122]
  - €200 per hour
  - €800 per half-day
  - €2,000 for the whole agreement

4.2 For Hospitality procured to HCPs

- Meal: €50 incl. VAT[123]
- Break: €15 incl. VAT
- Accommodation: €150 incl. VAT
- Total amount: €2,000 incl. VAT including the travel costs and fees related to the services of the HCP.
- Registration fees: €1,000 incl. VAT

It is strictly forbidden to procure hospitality, whether directly or indirectly, to students intending to practice a healthcare profession[124].

4.3 Financing or financial participation to professional training actions or programs of DPC procured to HCPs:

The threshold is of €1,000.

[121] With regard to remuneration, the decree is clear on the fact that the amounts to be taken into account regarding the thresholds are 'net' amounts. The Ministry of Health has indicated that the 'net' remuneration is:
- For salaried HCPs the fees paid less social security charges
- For self-employed HCPs the fees paid less VAT (20%) and the URSSAF contributions (if known URSSAF rate must be indicated in the contract, if unknown a 19% rate is used).

[122] This applies to booth rental for instance.
[123] Please see also table at the end of the Handbook and the difference between planned and unplanned meals.
[124] French « *internes* » are students as per the AG Law.

4.4 Research grants[125]

- For HCPs: €5,000
- For students: €1,000

4.5 Grants to students' or HCPs' associations and societies

- € 8,000 for research
- € 1,000 for any other purpose related to the health – this would apply to educational grants
- € 10,000 if the association is an « association reconnue d'utilité publique »

It is forbidden to procure a grant to an association the purpose of which has no link with the practice of a healthcare profession (such as for instance sports association of HCPs).

5. What is the process?

5.1 Where to file the declaration and authorization requests?

For physicians and students intending to practice medicine, the relevant authority is the CNOM. The declarations and authorization requests must be made online, on the "IDAHE" intranet of the CNOM.

For HCPs having a professional board and students intending to practice a profession having such a professional board, the authority is the relevant national board. The declarations and authorization requests must be made on line, on a new website "*éthique des professionnels de santé*" (EPS) : https://eps.sante.gouv.fr.

For all other HCPs, all other students, all students' and HCPs' associations and societies, the relevant authority is the "ARS" of the place of signature of the agreement. The declarations and authorization requests must be made online, on the "EPS" website.

5.2 What are the timeframes?

(a) The declaration must be made 8 business days before the agreement enters into force, or before the advantage is procured.
Recommendations may be issued by the relevant authority. Those are not binding but should be taken into account by the Companies.

(b) The authorization is delivered (implicitly) 2 months after the (complete) authorization request is filed.

[125] This may apply to fellowship and research prize.

In case of refusal, Companies may submit a modified agreement within fifteen (15) days after the refusal. The modified file is then re-examined within fifteen (15) days.
For legitimate reasons (to be duly justified) Companies may request that their file be examined under an emergency process of three (3) weeks.
Refusal may be appealed in front of administrative courts.
The fact of entering into an agreement which has not been authorized and the fact of procuring (and receiving) an advantage which has not been authorized, constitute a criminal offence.

5.3 What must contain the declaration file?

The declaration file must contain:

- The signed agreement;
- The program of the event (if applicable);
- The copy of the authorisation for carrying out secondary activities from the institution (and, as the case maybe, the university) to which the public HCPs belong (if applicable).[126]
- The summary, drafted in French, of the research protocol (if applicable)
- The draft of the case report for research activities (if applicable)
- A copy of the by-laws of the association or society (if applicable)

5.4 What must contain the authorization request file?

The authorization request file must contain:

- The draft agreement;
- The program of the event (if applicable);
- The copy of the authorization for carrying out secondary activities from the institution (and, as the case maybe, the university) to which the public HCPs belong (if applicable).[127]
- The summary, drafted in French, of the research protocol (if applicable)
- The draft of the case report for research activities (if applicable)
- A copy of the by-laws of the association or society (if applicable)

5.5 Simplified processes for Healthcare Professionals

Simplified processes have been put into place for recurrent events at which hospitality is procured to physicians only[128].

[126] Such authorization (in French *autorisation de cumul d'activités*) must be requested and obtained by the public HCPs. Companies may not interfere into this process, and should, therefore, request such authorization far in advance (it may take at least one month – and sometimes more – for the public practitioner to obtain such authorization from his/her employer(s).
[127] Ibid 16.
[128] Such recurrent events are:

Provided that the organization of the events strictly complies with the conditions detailed under the relevant process, and provided that the Company has undertaken to comply with such simplified processes, the Company is exempted from making a prior declaration as per AG Law.

6. What are the sanctions?

Both the Companies and the Health Actors may be criminally sanctioned.

The penalties incurred by Companies may be as high as 750,000 euros per violation, up to 50% of the costs incurred for committing the offense.

Companies may also be banned from participating to public tenders.

Also, the sanctions are notified to the health authorities in charge of reimbursement of health products (in French CEPS).

The legal representatives of the Company may also be personally sanctioned by a fine of up to 150,000 euros per violation and 2 years of imprisonment.

The French Transparency legislation

The Bertrand Law (article L.1453-1 of the French Public Health Code) requires the publication of the following information on the public transparency website by Companies:

- Information relating to the agreements concluded with the following health operators: the identity of the parties, the specific purpose, the date, the potential final beneficiaries, as well as the amount of each agreement;
    - Healthcare professionals (doctor, dentist, midwife, pharmacist, pharmacy technician and hospital pharmacy technician, nurse, physiotherapist, podiatrist, occupational therapist, psycho-motor therapist, speech-therapist, orthoptist, technician specialized in electroradiology, medical laboratory technologist, hearing care professional, optician, orthesist/prosthetist for medical devices of disabled persons, dietitian, healthcare assistant, childcare assistant, dental assistant, medical physicist or veterinary);
    - Associations of healthcare professionals;

- Professional meetings in the evening or during the day
- Professional and scientific events, weekend seminars
- Professional meetings organised at an industrial site during one day or between one and a half to two days
- On-site practical training sessions lasting between half a day to a day or two days
- Events at healthcare institutions

  - Students intending to become healthcare professionals and associations and groups representing them;
  - Associations of users of the healthcare system (e.g., patient associations);
  - Healthcare institutions;
  - Academies, foundations, learned societies and advisory companies or bodies operating in the health products and/or services sector;
  - Legal persons who are press, radio, or television services publishers and publishers of online communication services to the public;
  - Any person who, either in the media or on social networks, presents one or several health products in a way to influence the public;
  - Publishers of software for prescribing and dispensing health products;
  - Legal entities providing the initial training or the "continuous training" of healthcare professionals or participating in such trainings (i.e., universities, professional schools).

- Compensations of a value equal to or greater than € 10 incl. VAT, paid to health operators under the agreement;
- Other advantages procured to health operators, whether in cash or in kind, having a value equal or more than € 10 incl. VAT.

Companies must upload on the transparency website:

- No later than 1st September: Information regarding agreements concluded, compensations paid, and advantages granted during the first semester of the same year; and
- No later than 1st March: Information regarding agreements concluded, compensations paid, advantages granted during the second semester of the previous year.

It is worth mentioning that Companies must also comply with data protection requirements regarding transparency. Notably, Companies must inform the health operators that their personal data will be published on the transparency website by Companies and that they have a right to access and rectify information concerning them. Health operators can also exercise their rights by contacting the authority of the transparency public website and also find information regarding formalities to the French data protection authority (in French "CNIL") in case of data transfer to a non-European country. Companies must also indicate to health operators who are individuals, for example HCPs, that they cannot object to the processing of their personal data.

GERMANY

Germany has two medical device and one in-vitro diagnostic associations.

MEDICAL DEVICES: BVMED

Updated: 4 October 2022

Code	
MTE Code transposition	20.6.2020
Phase-out Direct Sponsorship	20.6.2020
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	yes
Others	yes

About the BVMed Code

Following a decision of BVMeds[129] Board of Directors of November 2019, BVMed adopted a new version of their Code (the "BVMed Code")[130] (Kodex Medizinprodukte) after Corona-Lockdown on 19 June 2020. The Code is also aligned with the German legislation that entered into force in June 2016 that introduced some additional rules around corruption in the healthcare sector, modifying the former anti-bribery legislation.
As of 19 June 2020, BVMed recommends to all its members to abstain from the direct sponsorship model and to support Third Party Organised Events through Educational Grants[131].

[129] The German Medical Device association BVMed: https://www.bvmed.de/
[130] Kodex Medizinprodukte (BVMed Code), BVMed, June 2020. An English version will be published soon.
[131] BVMed Code, Article 8.

In addition, BVMed has a specific committee, Healthcare Compliance Committee (HCCC), that supports the association as well as their Management regarding all the questions affecting the interaction of the medical device industry with medical institutions as well as their employees and other healthcare partners ("Healthcare Compliance"). There is also foreseen in the Medical Device Code of BVMed a conflict resolution mechanism between BVMed-Members (mediation).

Consultancy arrangements

According to the BVMed Code, such agreements are permissible, but for reasons of transparency, a written agreement must be concluded between a physician and a company. Physicians must obtain the consent of their employer prior to this agreement[132].

Meals, travel and accommodation expenses

The invitation of HCPs to meals is limited. The invitation to business lunches/dinners is not allowed in connection with the sales of products or the creation of business opportunities.
In particular, the invitation is only permissible in course of internal Continued Medical Education or around a scientific background, for example in preparation of a lecture.
Moreover, the hospitality must be in an appropriate and socially acceptable manner and the occasion for a work lunch/dinner must be documented. Hospitality for accompanying guests is not allowed. Socially acceptable hospitality means any hospitality which complies with the generally accepted principles of politeness.

BVMed recommends that the maximum amount for meals should not exceed 60 € per person. In exceptional situations (meals in expensive cities in foreign countries), higher costs might be appropriate if duly justified. Booth catering at congresses in a single-digit euro range is permitted.
Registration fees, meals, travel and lodging expenses should be reasonable in value and directly related to the event. It is only allowed to cover meal costs for internal education events of companies and working lunches/dinner.

Gifts

The MedTech Europe Code imposes minimum standards in areas where National Associations might be regulating it differently. They may adopt a higher standard, however, a lower is not allowed. According to the MTE Code, Educational items and gifts are generally not allowed[133]. Therefore, even if National Associations' Codes allow this practise under certain circumstances, MTE Member Companies may not provide those educational items or gifts[134].

[132] BVMed Code, Article 8.
[133] Please see MedTech Europe Code, Chapter 8, Part 1: Educational Items and Promotional Items.
[134] Allowed only in exceptional cases and in accordance with the principles of the MTE Code, Part 1, Chapter 8,p. 32.

Having said that, under the BVMed Code, although gifts are generally not allowed, there are some exceptions to the rule[135]:

- Advertising gifts or promotional giveaways of minor value,
- Gifts on occasions of special events (employment anniversaries, retirement etc.) as long as their value remains within the "socially acceptable" limits. Christmas and similar holidays are not considered special occasions[136]. These gifts are allowed, if they are use and are intended for healthcare professional practice, benefit patients or serve further education.

Others

BVMed has developed guidelines on the access to the operating room by company representatives[137].

Furthermore, in 2022, BVMed developed a Compliance Standard for MedTech Companies. The BVMed Compliance Standard offers practical suggestions and advice for setting up a suitable compliance organisation. This practical guide is the first compliance standard of a European medical device association. Alongside the applicable law and the Medical Devices Code, it is an essential third pillar based on which a medical device company can structure its cooperation with medical facilities in a legally secure manner.

.

[135] BVMed Code, Article 11.
[136] BVMed Code, Article 11, The interpretation of BVMed´s Healthcare Compliance Committee. However, please note that this is not allowed under the MedTech Europe Code.
[137] BVMed-Empfehlung zur Erstellung einer Unternehmensrichtlinie für die Anwesenheit und das Verhalten von Medizinprodukteberatern in Operationsräumen, 2013, available here: https://www.bvmed.de/download/medizinprodukteberater-im-op (last visited: 29.09.2021).

MEDICAL DEVICES: SPECTARIS MEDIZINTECHNIK

Updated: 4 October 2022

Code	
MTE Code transposition	16.10.2017
Phase-out Direct Sponsorship	1.1.2020
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	yes[138]
Virtual Events guidelines/rules	yes
Discounts guidelines/rules	no
Others	no

About the Spectaris Code

The German National Association "Medizintechnik im Deutschen Industrieverband SPECTARIS" (herefafter "Spectaris Medizintechnik[139]") approved the latest version of their Code of Conduct in 2017 (Empfehlungen zur Zusammenarbeit in der Gesundheitswirtschaft)[140], coming into effect as of 1 January 2018. This new Code transposes the MTE Code, with the exception of part 3 - Procedural Framework and the Q&As. Additionally, it is important to note that SPECTARIS' new Code is meant to provide guidance and recommended best-practices to its members. Therefore, it recommends that its members abstain from the direct sponsorship model, at the latest by 1 January 2020.

[138] SPECTARIS has its own Competition Law Code which was updated in July 2018.
[139] The German Medical Device association Spectaris Medizintechnik: https://www.spectaris.de/medizintechnik/
[140] Code of Conduct, Recommendation on relations with Healthcare Professionals (Empfehlungen zur Zusammenarbeit in der Gesundheitswirtschaft), 2017. A leaflet of the SPECTARIS Code is available here (in German). There is an English version available, please see here.

Transparency

Spectaris recommends to its members to disclose as of 1 January 2020 Educational Grants on the MedTech Europe Transparency platform[141].

Meals, travel and accommodation expenses

Please refer to the BVMed chapter above.

Meals, travel and accommodation expenses

Like BVMed, Spectaris also recommends that the maximum amount for meals should not exceed 60 €.

Promotion & advertisement

In Germany, with regards to marketing/advertising for medical devices, apart from the Medical Device Regulation ("MDR"), the following must be observed in particular: the German Drug Advertising Act ("HWG"), the German Unfair Competition Act ("UWG") and the professional codes of conduct for physicians from the respective federal states, or, generally, the Model Professional Code of Conduct for Physicians ("MBO-Ä").

The MDR in Article 7 regulates a product-related prohibition of misleading statements. According to this, it is prohibited, among other things, to use texts, names, trademarks, pictures and figurative other signs in the advertising of products that may mislead the user or patient with regard to the intended purpose, safety and performance of the product, for example by ascribing functions and properties to the device which it does not possess (lit. a) or suggesting other uses for the product than those for which it is stated that they are part of the intended purpose for which the conformity assessment was carried out (a kind of off-label advertising ban, lit. d).

The HWG[142] regulates advertising for medical devices in a stricter way than other commercial goods. In particular, the prohibition of misleading statements in Section 3 HWG and the prohibition of donations in Section 7 HWG must be observed. Also, there are specific advertising bans outside of specialist circles („Fachkreise“), according to Section 11 (1) sentence 2 in conjunction with sentence 1 nos. 7-9, 11, 12 and sentence 3 HWG. Reference to specific diseases, such as Covid-19, is also not permitted in advertising outside of specialist circles according to Section 12 (1) HWG.

According to Section 3 of the UWG[143], advertising for medical devices must not be unfair. In addition, the advertising or marketing action must not be misleading (Sections 5, 5a UWG) and must not be comparative (Section 6 UWG). With regard to the form of the advertising, no unreasonable impairment may be chosen

[141] SPECTARIS Code of Conduct, paragraph 5, p. 31.
[142] Please refer to the German Drug Advertising Act ("HWG") (Heilmittelwerbegesetz), available at: https://www.gesetze-im-internet.de/heilmwerbg/
[143] For more information on the German Unfair Competition Act (UWG), please refer to: https://www.gesetze-im-internet.de/englisch_uwg/englisch_uwg.html

(Section 7 UWG). According to Section 7 (2) No. 2 UWG, an unreasonable impairment exists, for example, in the case of a telephone call to a market participant without their presumed consent.
Sections 27 (3) is particularly relevant for the cooperation between physicians and the medical device industry.

According to Section 27 (3) MBO-Ä[144], physicians are prohibited from advertisements that are contrary to their profession. Advertising contrary to professional standards is laudatory, misleading, or comparative advertising. In addition, it is prohibited to advertise own or third-party commercial activities or products in connection with the medical activity.

Virtual Events

There are no explicit compliance regulations for Virtual Events for medical device companies. However, in principle, the term "events" or "training events" should be understood broadly, so that the current Dos & Don'ts should also apply to Virtual Events. In addition, it should be ensured that only the registered physician and no other person attends the Virtual Event through entrance checks or similar measures. Otherwise, problems could arise with the granting of educational points or the requirement to present an employer's certificate (“Dienstherrengenehmigung”).

In this regard, it should also be noted that according to Section 13 (6) of the Telemedia Act (TMG)[145], the provider must actually enable the use of telemedia and their payment anonymously or under a pseudonym, provided this is technically possible and reasonable. When examining whether this is reasonable, a consideration of proportionality must be carried out on a case-by-case basis, taking into account not only the right to informational self-determination, but also the interests of the provider. In the present case, the company must be in a position to identify the physician in order to comply with the required documentation for the sponsorship and to comply with the transparency requirement. Therefore, there might be sufficient reasons to justify an identification obligation.

[144] Model Professional Code of Conduct for Physicians (MBO-Ä), Section 27, available at: https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/MBO/MBO-AE.pdf
[145] Telemedia Act, Section 13 (6), available at: https://www.gesetze-im-internet.de/tmg/__6.html

IN VITRO DIAGNOSTICS: VDGH

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 29 September 2021

Code	
MTE Code transposition	7.5.2020
Phase-out Direct Sponsorship	1.1.2021
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	no
Virtual Events guidelines/rules	no[146]
Discounts guidelines/rules	no
Others	no

About the VDGH Code

The new "VDGH-Kodex für In-vitro-Diagnostika und Medizinprodukte"[147] (the "VDGH Code") represents the implementation of the MTE Code and it has been approved by the Members of the Board in December 2019 and by the AGM in June 2021.

[146] There are no explicit compliance regulations for Virtual Events for medical device companies. For additional information on this topic, please refer to the SPECTARIS Chapter.
[147] No English version available. The VDGH Code only applies to its self-testing IVD members (e.g. manufacturers of blood glucose strips).

VDGH[148] is also a party to the “Common Position” (Gemeinsamer Standpunkt) which was signed by different stakeholders in the healthcare field in 2000.

Meals, travel and accommodation expenses

According to the VDGH Code, hospitality and accommodation must not exceed reasonable limits. Travel costs may also be covered provided the training activity or the event of medical relevance remains the main attraction[149].

Regarding "Support of Individual Healthcare Professionals to Third Party Organised Educational Events", the VDGH Kodex recommends not to directly support individual healthcare professionals to Third Party Organised Educational Events.

Promotion & advertisement

Please refer to the Spectaris chapter.

The „VDGH Kodex Eigenanwendungs IVD“, which is not mandatory for the VDGH members, includes rules also concerning advertisement. Some of the members voluntarily obligated themselves to follow that Kodex.

The VDGH has no general guidelines on promotion and advertisement for its members.

[148] VDGH is the German IVD association: https://www.vdgh.de/
[149] VDGH Code, Part II, 1.

GREECE

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: SEIV

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 9 August 2021

Code	
MTE Code transposition	22.07.2017
Phase-out Direct Sponsorship	1.1.2018
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	yes[150]
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

General update on the national code

The "SEIV[151] Code for Ethical Business Practice" ("SEIV Code") (ΚΩΔΙΚΑΣ ΗΘΙΚΗΣ ΕΠΑΓΓΕΛΜΑΤΙΚΗΣ ΠΡΑΚΤΙΚΗΣ ΣΕΙΒ) was approved on 22 June 2017 and came into force on 1 January 2018. The Code is in line with the MedTech Europe Code[152].

[150] SEIV's website, available at: http://www.seiv.gr/?section=2716&language=el_GR (09.09.2021).
[151] SEIV is the Greek Medical Devices Association, previously known as HELLASMES: http://www.seiv.gr/
[152] The Code is a direct translation of the MedTech Europe Code into Greek.

Company Events

It is important to note that publicly employed HCPs are not allowed to attend company promotional meetings[153]. Further, the Greek National Association for Medicines (Ο Εθνικός Οργανισμός Φαρμάκων, "EOF") has issued several rather detailed circulars applicable to sponsorship and organisation of scientific events. For more information refer to the EOF website[154]. The SEIV Code is in line with the EOF circulars.

Meals, travel and accommodation expenses

In addition to the criteria of the MedTech Europe Code, the Greek National Association for Medicines - so called EOF, also imposes some limits with regards scientific events in Greece: according to the latest Circulars, lodging expenses for local events cannot exceed EUR 150 per day per HCP (including VAT), while for events in Europe and the rest of the world these expenses are limited to 400 EUR per day per HCP (including VAT)[155]. Expenses for meals in Greece cannot go beyond EUR 70[156] per day per HCP while for meals outside Greece these expenses are limited to 150 EUR per day per HCP including breakfast (excluding VAT)[157][158].

Gifts

The Greek legislation does not permit gifts unless they are of negligible value and related to the HCPs' practice[159].

[153] This is explicitly forbidden by EOF and, as a result, by the SEIV Code. Please refer to SEIV Code, p. 3, par. 1, line 2, "*Ο Κώδικας …. Απαιτήσεις*", which means: ""The SEIV Code is not intended to take precedence over the national laws or regulations or business codes (including corporate ones) that may impose stricter requirements".
[154] EOF's website, available at: http://www.eof.gr
[155] Stricter rules may apply under the laws of different countries and/or each company's compliance guidelines
[156] For local events amounts include VAT, while for Europe and the rest of the world, VAT is excluded.
[157] Stricter rules may apply under the laws of different countries and/or each company's compliance guidelines.
[158] EOF circular for scientific events No. 37201 of 23.03.2020.
[159] Joint Ministerial Decision DYG3(a)/83657, Article 114, p. 1 (ΚοινήΥπουργικήΑπόφασηΔΥΓ3(α)/83657), published on 24 January 2006. The Joint Ministerial Decision transposed into national legislation the EU 2001/1983/EC Directive on the Community Code for Medicinal Products for Human Use.

HUNGARY

MEDICAL DEVICES: AMDM

Updated: 4 October 2022

Code	
MTE Code transposition	18.4.2018
Phase-out Direct Sponsorship	1.6.2018
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes (by the law for medical aid suppliers only)
Gifts	yes (by the law for medical aid suppliers only)
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	no[160]
Virtual Events guidelines/rules	no
Discount guidelines/rules	no
Others	no

About AMDM

In April 2018 AMDM[161] adopted the MedTech Europe Code, available also in Hungarian[162]. Direct sponsorship of individual HCPs to attend Third O]Party Organised Educational Events is prohibited under the AMDM Code as of 1 June 2018[163].

[160] No, but there is a reference to Competition law in their Code (See Article 2 and 3 AMDM Code).
[161] The Hungarian Medical Devise Association: http://www.osz.hu
[162] Please see: https://osz.hu/hu/medtech-etika/medtech-kodex
[163] Please note that direct support to HCPs attendance at Third Party Organised events is also regulated by a Hungarian Law. According to the Act XCVIII of 2006, "(…) support may be provided in-kind to persons engaged in healthcare and scientific activities for participating in trade events and training courses. This type of in-kind support may be provided to cover only the expenses (such as, in particular, travel expenses, accommodation, entry fees).arising directly out of or in connection with attending [such] events". Additionally, companies may also provide support for events and programs for

Transparency

The transparency obligations laid down in Act XCVIII of 2006 apply not only to the pharmaceutical industry, but also to companies manufacturing medical aids[164]. All promotional activities, e.g. the sponsoring of events and training courses related to medical aids, must be notified to the National Institute of Pharmacy and Nutrition which publishes them on an aggregate basis.

Also please see Section 5.6 of AMDM Code.

Educational Grants

The AMDM Code of Ethics states that "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[165]".

Also see Section 5.6 of AMDM Code.

Meals, travel and accommodation expenses

For the promotion of medical devices hospitality may be arranged only for professional, scientific and educational reasons. The daily amount spent on hospitality functions by promoters of medical device representatives may not exceed 5% of the official minimum wage and shall remain subordinate to the main objective of the meeting[166].

Also please see Section 5.4 and 5.5 of AMDM Code.

Gifts

Please note that according to Act XCVIII of 2006, gifts are not allowed unless they are inexpensive and related to the professional activity of the HCP[167]. Inexpensive means that the value of the gift does not exceed

purely professional and scientific purposes. Such support must be reasonable in scope as well as subordinate to the main scientific objective of the meeting. Please refer to Article 14, p. 4, Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products.

[164] The Act XCVII of 2006 defines *medical aid* as follows: 'medical aid' shall mean any medical device made available for personal use to patients suffering in a temporary or persistent health impairment or disability (including in vitro diagnostic medical devices for self-testing purposes), and other technical devices for nursing and caring purposes, which are not treated as medical devices, designed for use without the continued presence of a healthcare professional. Personal use shall mean where the medical aid is worn, applied or administered in body cavities with exterior opening, whether natural or artificial, or on the body, including the use of in vitro diagnostic medical devices for self-testing purposes on specimens derived from the human body, and the use of equipment for supporting or moving the body for diagnostics purposes or for the purpose of therapy, rehabilitation or nursing.

[165] AMDM Code, Article 5.1.

[166] Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products, Article 14, p. 2,

[167] Act XCVIII of 2006, Article 14, p. 1.

5% of the official minimum wage[168]. Additionally, the total value of the gifts on an annual basis cannot exceed 60% of the official minimum wage[169]. Furthermore, gifts in the form of cash or cash equivalents are prohibited[170]. Please also see Section 5.7 and 5.8 of AMDM Code.

Promotion & advertisement

Act XCVIII of 2006 distinguishes between the concepts of promotion and information in relation to medicinal products and medical devices. The advertising of prescription-only devices is prohibited. On promotional activities involving product information for healthcare professionals there are additional rules. For detailed information on promotion and advertisement, please refer to Act XCVIII of 2006.[171]

[168] Act XCVIII of 2006, Article 3, p. 8. Minimum wage for 2022: HUF 200,000 (approx. EUR 500).
[169] Act XCVIII of 2006, Article 14.
[170] Act XCVIII of 2006, Article 14, p. 1.
[171] Act XCVIII of 2006, Available at: https://net.jogtar.hu/getpdf?docid=a0600098.tv&targetdate=&printTitle=Act+XCVIII+of+2006&dbnum=62&getdoc=1

MEDICAL DEVICES: ETOSZ

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 21 September 2021

Code	
MTE Code transposition	1.1.2019
Phase-out Direct Sponsorship	1.1.2019
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Others	no

About ETOSZ

ETOSZ is the voice of the innovation-driven market players of the Hungarian medtech sector[172]. ETOSZ joined MedTech Europe end of 2018 and transposed the MedTech Europe Code as early as of 01.01.2019. The ETOSZ Code is available both in English[173] and in Hungarian[174].

[172] The Association of Health Technology Suppliers and Medical Device Manufacturers (ETOSZ) website: **Error! Hyperlink reference not valid.**http://www.etosz.org/index_en.html

[173] The English version of the ETOSZ Code is available here: https://www.ethicalmedtech.eu/wp-content/uploads/2017/06/ETOSZ_Code-of-Conduct_20190101.pdf

[174] The Hungarian version of the ETOSZ Code is available here: https://etosz.org/assets/doc/kodex/etikai_kodex_20190101.pdf

Transparency

The Transparency provisions of the ETOSZ Code are harmonised with the MTE Code without additional requirements. See Section 2.4 of ETOSZ Code.

Consultancy Agreements

The Healthcare Employment Act of 2020 requires the prior authorization by a state body for HCPs employed by state-owned healthcare institutions to engage in any further employment relationship or remunerated activity. There are certain exceptions (scientific, educational, editorial work etc.). It should be considered on a case-by-case basis whether consultancy agreements fall under the exception or not.

Meals, travel and accommodation expenses

The ETOSZ Code provisions are harmonised with the MTE Code. See Section 2.2.1 and 3.9 of ETOSZ Code.

Gifts

The ETOSZ Code provisions are harmonised with the MTE Code. Please refer to Sections 3.3-3.5 and 3.10 of the ETOSZ Code.

Please note that in addition to the aforesaid, there are further legal provisions on medical aids. These special rules are related to promotion and advertising activities, transparency, hospitality, and gifts. For more information, please refer to the AMDM chapter.

Also, please note, that it is prohibited for HCPs working in state-owned healthcare to accept any informal payment. The exception would be a minor gift (worth less than 5% of the minimum wage) that may be accepted from patients after treatment.

IN VITRO DIAGNOSTICS: HIVDA

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years**.

Updated: 1 September 2020

Code	
MTE Code transposition	1.9.2017
Phase-out Direct Sponsorship	1.1.2019
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Others	no

About HIVDA

HIVDA's[175] Code of Ethics ("HIVDA Code") (HIVDA Etikai Kodex) was adopted in September 2017 and came into effect on 1 January 2019. The Code is an exact translation into Hungarian of the MedTech Europe Code[176].

For more general information on Transparency, Hospitality and Gifts in Hungary, please refer to the AMDM chapter.

[175] The Hungarian Diagnostics Association: http://www.hivda.hu/english
[176] MedTech Europe Az üzleti gyakorlat etikai kódex (MedTech Europe Code of Ethical Business Practice).

IRELAND

Updated: 4 October 2022

MedTech Europe has two Irish national Association members.

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: HealthTech Ireland

Code	
MTE Code transposition	2016
Phase-out Direct Sponsorship	1.1.2018
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About HealthTech Ireland

HealthTech Ireland[177], previously known as IMSTA (Irish Medical & Surgical Trade association), approved the MedTech Europe Code in 2016. The Code entered into force on 1 January 2018, and it is the same as the MedTech Europe Code.

[177] The independent trade association for manufacturers, developers and distributors of health technology products and solutions to the health system in Ireland: https://www.healthtechireland.ie/

Transparency

HealthTech Ireland has decided to use the MedTech Europe platform for grant disclosures.

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: IRISH MEDTECH

Updated: 4 October 2022

Code	
MTE Code transposition	2016
Phase-out Direct Sponsorship	1.1.2018
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	no
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	yes

About the Irish MedTech Code

The Irish MedTech Association ("Irish Medtech")[178], previously known as IMDA, transposed and adopted the MedTech Europe Code as its new Code ("The Irish MedTech Code"), which entered into force on 1 January 2018.

Transparency

Irish MedTech has decided to use the MedTech Europe platform for grant disclosures.[179]

[178] The Irish Medtech Association: http://www.irishmedtechassoc.ie/
[179] Transparent MedTech, available at: https://www.ethicalmedtech.eu/transparent-medtech/

Promotion and advertisement

The Advertising Standards Authority for Ireland (ASAI) has issued a Code in order to regulate marketing communications in the interest of consumers. In Section 11 of ASAI's Code, information related to marketing communications for medicines, medical devices, treatments, health-related products, and beauty related products is available.[180] For more information, please refer to Section 11 of the ASAI Code.

Others

Irish Medtech does not publish its own Competition Law guidelines but does provide the Irish Competition Authority's Notice 09/002 on Activities of Trade Associations and Compliance with Competition Law.

[180] ASAI Code, Section 11, available at: https://www.asai.ie/asaicode/section-11-health-and-beauty/

ISRAEL

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: MEDTECH ISRAEL

Updated: 1 September 2020

MedTech Israel, an association representing advanced medical technology companies with R&D[181], was founded about a year ago and their initial activities have been devoted to setting up the new operation with the help of the founding members of our association. In spring 2020, they filed their membership application at MedTech Europe, which was preliminarily accepted by the MedTech Board of Directors in May 2020. The General Assembly will be asked to ratify its membership application on 11 December 2020.

From that day on, Members will have one year to apply the Code also in Israel and the association will also have one year to transpose the Code there as well.

[181] Please note that there is another organisation that represents medtech companies in Israel, which is Federation of Israeli Chambers of Commerce. However, to date, they did not request to join MedTech Europe.

ITALY

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: CONFINDUSTRIA DISPOSITIVI MEDICI

Updated: 4 October 2022

Code	
MTE Code transposition	20.2.2018
Phase-out Direct Sponsorship	1.1.2019
National CVS	yes
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	*Work in progress*[182]
Promotion & advertisement	yes
Competition law guidelines	yes[183]
Virtual Events guidelines/rules	no
Discounts guidelines/rules	yes
Others	yes

About the Confindustria Dispositivi Medici Code

Confindustria Dispositivi Medici[184], previously called Assobiomedica, has recently revised its Code of Ethics ("Confindustria Dispositivi Medici Code") (Codice Etico), in December 2021. The Code is in line with the MedTech Europe Code and in some instances even goes beyond the MTE Code requirements. There is also an English version available. In addition, Confindustria Dispositivi Medici enters into yearly agreements with several hotel associations, as specified in the Code of Ethics[185]. The latest one was signed in September 2021.

[182] Confindustria Dispositivi Medici Conflict of interest guidelines, Annex 1.
[183] They are currently updating their competition law guidelines.
[184] Confindustria Dispositivi Medici is the Italian association representing companies manufacturing medical technology: https://www.confindustriadm.it/
[185] Confindustria Dispositivi Medici Code of Ethics, Annex 3.

National CVS

Confindustria Dispositivi Medici has its own national "conference vetting system', the so called "Sistema di Valutazione delle Conferenze"(SVC)[186].
The system started operating on 1 July 2018 and it started to review events taking place as of 1 January 2019[187]. It follows the logic of MedTech Europe's Conference Vetting System. As such, there is the possibility of a pre-clearance submission (up to six months before the event takes place), a standard submission (up to 60 days before the event takes place) or an appeals procedure in front of the Control Commission (within five days after the first decision has been taken)[188]. The submission of the information dealing with the Third Party Organised Educational National events will be provided to Confindustria Dispositivi Medici SVC only by the same Organiser.

Note that according to the Confindustria Dispositivi Medici Code[189], it is forbidden to sponsor HCPs to attend events in seaside locations, from June 1 to September 30 and in mountain locations, from 15 June to 15 September and from 15 December to 31 March.

Due to the current COVID-19 crisis, Confindustria Dispositivi Medici has approved an exemption to the above-mentioned restriction periods: until 31 December 2022, it is allowed to support events organised in Italian Regional and Provincial Capitals and/or places seat of prominent hospitals without the seasonality limitation.

Transparency

Transparency requirements imposed by law

There are transparency legal requirements applicable to the public service employees in Italy. In this framework, medical technology companies are required to report aggregate amounts paid to HCPs employed by the Italian National Health Service (NHS). The aggregate amounts have to be reported to the relevant NHS's local health unit (*Aziende Sanitarie Locali* – ASL)[190]. These transparency provisions were amended by the new Anti-Corruption Law. Specifically, the reporting periods were changed: instead of once per year, companies now have to report no later than 15 days after the payment[191].

The services *excluded*[192] from the transparency obligations are:

- Collaborations with journals, encyclopaedias or similar publications
- Economic use of the HCP's intellectual property
- Participation in seminars or conferences

[186] For more information, please refer to the SVC website: http://svc.confindustriadm.it/ (20.07.2021).
[187] Sistema di Valutazione delle Conferenze: http://svc.confindustriadm.it/ (20.07.2021).
[188] For more information, please visit the SVC website (in Italian): http://svc.confindustriadm.it/ (20.07.2021).
[189] Code of Ethics, Art. 2.7.1
[190] Legislative Decree 165/2001 of 30th March, Article 53.
[191] Law no 190/2012 of 6th November, Article 1, paragraph 42.
[192] Legislative Decree 156/2001 Article 53, paragraph 6.

- Whenever only the costs are reimbursed to the HCP
- When the performance of the services puts the HCP in "leave" from his/her position
- Assignments pursuant to a role or position in trade unions
- Training activities and training directed to employees of the public administration as well as scientific research

Transparency requirements imposed by the Confindustria Dispositivi Medici Code

In order to adapt its revised Code also in the light of the new Anti-Corruption Laws, Confindustria Dispositivi Medici decided to introduce with the new Code a full transparency system. Thus, Confindustria Dispositivi Medici's Member Companies are required, as of 2021, to disclose all direct and indirect transfers of value to HCPs, HCOs and Third Parties by means of a specific Transparency Template[193]. More precisely:

- Data related to transfers of value shall be published annually starting from 1 January 2021, with reference to data regarding the 2020 calendar year;
- The Members shall publish the transfers of value made each year within the first six months of the following year[194];
- The Members associated throughout the year have to fulfil transparent obligations by December 31, if associated by June 30. If associated between July 1 and December 31, the fulfilment of transparent obligations is postponed to the following year.
- The information shall remain in the public domain for a period of at least 3 years from the time of publication.
- The related transfers of value to be published shall include: financial support to events (e.g. sponsorship of conventions, congresses and scientific meetings, etc), fees for consultancy activities and professional services, including speaking services, as of a specific contract between the Member and the Healthcare Organisation, indicating the type of service rendered, including the related travel and accommodation costs (excluding meals and beverages), donations in cash or cash equivalents provided to the Healthcare Organisation etc[195].

Please note that the MedTech Europe Code Committee granted Confindustria Dispositivi Medici an exception from the obligation to disclose Educational Grants on TransparentMedTech starting in 2021.

This means that members of MedTech Europe that are members of Confindustria Dispositivi Medici will still need to report the 2019 data during 2020 in TransparentMedTech. As of 2021, members of both MedTech Europe and Confindustria Dispositivi Medici are exempted from reporting in TransparentMedTech. Member Companies that are only members of MedTech Europe will not be affected by this exception.

[193] The template is part of Confindustria Dispositivi Medici's Code itself (Annex II).
[194] Members shall publish the data either on its own website.
[195] For the detailed information please refer to Confindustria Dispositivi Medici Code, Chapter 4, 2020.

Law no. 62/2022 (so called "Sunshine Act")

In addition to the transparency requirements set by Confindustria Dispositivi Medici Code, the Law no. 62/2022 (so-called "Sunshine Act"[196]) came into force on June 26, 2022, in order to fight corruption in the health system and maximise transparency in the relationships between companies and healthcare providers. The Sunshine Act establishes the disclosure of transfers of value within specific threshold ranges, agreements consisting in participation to events, scientific committees, and financial reports, etc., according to the deadlines provided for by the Law on an online public register of the Ministry of Health (the so-called "Sanità Trasparente" register). Data should be published on an individual basis.
According to the Law, the register should be set up within six months as of June 26, 2022.

Educational Grants

In June 2020, Confindustria Dispositivi Medici approved an exception to the ban of direct sponsorship of training and educational activities for HCPs who do not prescribe medical technology and provided that they are not bound by professional collaboration of any kind with public, private or private health care facilities that have an agreement with the public healthcare sector (i.e. Healthcare Professionals who operate exclusively on a self-employed basis)[197]. This exception reflects the Italian reality: there are HCPs (mostly providers or technicians of medtech) who sell medtech products that are not subject to reimbursement and have therefore, a commercial relationship with the companies.

In Italy, a general obligation of public service employees requires a prior authorisation by the relevant public administration. Please note that the definition of "public service employees" also covers private practitioners who are eligible for reimbursement[198]. In particular,[199] when sponsoring HCPs to passively attend Third Party Organised Educational Events: it is expressly forbidden any direct financial support to individual Healthcare Professionals in order to cover costs of their attendance. Member company may provide a financial support directly to the Third Party Organiser and the suggestion of names of potential attendees is not allowed. In this case, the Third Party Organiser must send a communication to the relevant public administration (i.e. HCPs' employer).

- when sponsoring HCPs to passively attend procedure courses or training: the suggestion of names of potential attendees is allowed and the Third Party Organiser must send a communication to the relevant public administration (i.e. HCPs' employer).
- when sponsoring HCPs who receive remuneration (e.g. speakers at the conference): Member company must obtain an explicit authorisation by the public administration to provide financial support. The same authorization is required supporting participation to Educational and promotional activities organized by Members on Company's products, for both public and private HCPs.

[196] To consult the text of the law please click here.
[197] Confindustria Dispositivi Medici Code, See Art. 2.7.2 last paragraph.
[198] Legislative Decree 165/2001 laying down the general rules applicable to employment in public administration, Art. 53 (Legislative Decree 165/2011) (Decreto Legislativo 165/2011 "Norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche").
[199] Confindustria Dispositivi Medici Code, Art. 2.7.

- when sponsoring non-prescribing HCPs: direct financial support is allowed provided that they are not bound by any kind of professional collaboration with public or private structures or part of the state run healthcare organisations.

Arrangements with consultants

The Confindustria Dispositivi Medici Code allows agreements with consultants. Consultants may receive reasonable compensation for services rendered. Moreover, the consultancy agreement between member companies and HCPs should adhere to the rules laid down in the Code[200]:

- A written agreement must be signed. Such agreement must specify the service to be provided and must be in compliance with the rules of the country where the HCP is professionally active
- Any compensation paid must be reasonable and based on the nature of and in proportion to the service actually rendered
- A legitimate purpose for services is identified in advance
- A consultant is chosen based on his/her qualifications and experience
- The venue and circumstances for the meetings between the member companies and consultants must be appropriate to the subject matter of the consultation
- All required authorizations and approvals from HCP's employer must be obtained.

In June 2013, Confindustria Dispositivi Medici amended its Code to include the prohibition to engage individuals as consultants who in the past three years have exercised authoritative or negotiation powers on behalf of public administration. This requirement originates from the Italian Anti-Corruption Law adopted in November 2012[201].
In August 2014, the Italian government published "General Requirements for Engagements Prohibited to Public Service Employees". The document explains the principle of conflict of interest and provides examples of what type of interactions might fall under this principle and would therefore be forbidden[202]. Consultancy services provided by HCPs to MedTech companies are not expressively listed among the prohibited activities. However, it is important to note that in practice several cases were reported where certain hospitals and healthcare organisations had interpreted this principle quite broadly and, as a result, did not allow their employees to engage in consulting services with the medical technology companies.

Meals, travel and accommodation expenses

Hospitality and travel expenses must be limited to the duration of the scientific event and cannot exceed 24 hours before or after the event[203]. In addition, any hospitality must be related to the scientific objective of the

[200] Confindustria Dispositivi Medici Code, Art. 2.10 (see the article for all requirements).
[201] Law no 190/2012, containing provisions for the prevention and prosecution of corruption and misconducts in the public administration (Law no 190/2012) (Legge 6 novembre 2012, n. 190, Disposizioni per la prevenzione e la repressione della corruzione e dell'illegalita' nella pubblica amministrazione), November 6, 2012.
[202] General Requirements for Engagements Prohibited to Public Service Employees (Criteri generali in materia di incarichi vietati ai dipendenti delle amministrazioni pubbliche), August 2014.
[203] Confindustria Dispositivi Medici Code, Art. 2.7.

event. In this sense, the Code attempts to stress that Member Companies may offer low-cost meals to the participants in the events and, for those requiring a night stay, additional hotel services may be appropriate. However, hotel ratings cannot be higher than four-stars, except for hotels and conference venues that have adhered to the agreements signed between Confindustria Dispositivi Medici and several Italian Associations of Hotels[204]. In these cases, the use of the structures is independent of the hotel's category. All flights should be economy class except for intercontinental flights: for those flights business is allowed. For the avoidance of doubt, first class is never allowed [205].

Gifts

Although gifts are generally not allowed, there are some exceptions[206]:

- Members may occasionally provide gifts of modest value;
- They must serve a promotional function and relate to the HCP's practice or be of benefit to the patients;
- No cash or equivalent are allowed (e.g. book or fuel vouchers, prepaid cards, etc.).

Promotion & advertisement

Confindustria Dispositivi Medici has guidelines on promotion and advertisement for members.[207]

Discounts

In Italy, purchases in the healthcare sector are generally managed through public tenders and therefore, further discounts than the awarding price are not allowed.

Other

In January 2019, a new anti-corruption law (No. 3/2019, the so-called "Spazza corrotti") entered into force, containing measures to fight crimes against the public administration. This law introduces important measures affecting Italian criminal law and significantly amends Legislative Decree No. 231/2001 with respect to corporate liability. In particular, the most relevant changes are:

- Increasing in the penalties for corruption;

[204] Assobiomedica has signed agreements with several Italian Associations of Hotels which introduce some flexibility around the five-star hotel rule for the members of both associations. In accordance with the agreement, it is possible to consider five-star hotels in certain cases when hotels adhere to the restraints specified in the Annexes of the Confindustria Dispositivi Medici Code.
[205] Confindustria Dispositivi Medici Code, Art. 2.7.1.
[206] Confindustria Dispositivi Medici Code, Art. 2.7.
[207] Promotion and advertisement guidelines of Confindustria Dispositivi Medici, available at: https://extranet.medtecheurope.org/CT-ComplianceCommittee/Shared%20Documents/Advertising%20of%20medical%20devices.pdf

- Introducing a life-long prohibition on dealing with public administrations and a life-long disqualification from holding public office for individuals sentenced for a corruption-related crimes, except for sentences of imprisonment not exceeding two years or where an attenuating circumstance is provided;
- Extending the prohibition on dealing with public administrations to the crimes of embezzlement, corruption in judicial proceedings, and trafficking in illegal influence (i.e. influence peddling);
- Amending the Italian Civil Code by introducing the possibility of prosecuting ex officio private-to-private corruption and incitement of private-to-private corruption;
- Among the various legislative changes introduced by Law No. 3/2019, the most relevant for companies doing business in Italy are those increasing the duration of restraining measures (e.g. suspension of the company's business, prohibition from dealing with the public administration, suspension of licenses, permits and authorizations which have been instrumental in committing the crime, etc.) applicable to certain crimes against the public administration and those introducing a leniency program for companies attempting to effectively reduce the negative consequences resulting from the commission of these crimes.
- Finally, given the inclusion of the new crimes among those which may trigger corporate liability, companies should update their organizational, management and control models in order to ensure conformity with the amendments made to Legislative Decree No. 231/2001.

MIDDLE EAST – AFRICA

MEDICAL DEVICES: MECOMED

Updated: 19 October 2022

Code	
MTE Code transposition	18.06.2017
Phase-out Direct Sponsorship	1.1.2019
National CVS	yes
Transparency	yes
National Ethical Charter	yes
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	yes
Discounts guidelines/rules	no
Others	yes

About the Mecomed Code

The Mecomed[208] Code of Business Practice ("Mecomed Code") was approved in 2017. It applies to all Mecomed member companies as well as to all Third-Party Intermediaries[209]. Mecomed revised their Code in January 2021.

[208] Mecomed is the association of Medical Device and Equipment companies operating in the Middle East and Africa: http://www.mecomed.com
[209] Mecomed Code, Part 3: Procedural Framework, p 29, January 2021.

National CVS

Since February 2015, the Medtech Europe Conference Vetting System (CVS) has been extended to cross border Third Party Organised Educational Events taking place in all countries covered in the scope of Mecomed. For more information on this extension and on CVS itself, please visit ABOUT CVS – Ethical MedTech EU . And Conference Vetting System – Mecomed for more information

Mecomed's CVS scope is extended to include national events in addition to international and regional events. In addition, Mecomed added a seventh criteria of assessment for their CVS, i.e. the assessment of sponsorship packages.

The following events are excluded from Mecomed's CVS assessment:

a.) National in-institution activities:

National events organised by Healthcare Organisations (HCOs) in a medical facility (e.g. clinic, hospital, laboratory etc) are exempted from the CVS assessment process.

For the avoidance of doubt, member companies must ensure compliance to the Chapter 1: General Criteria for events in all cases.

b.) Public Awareness Campaigns:

Events organised by HCO intended to provide information, promoting awareness and/or educating patients and the public about relevant healthcare topics or medical conditions or diseases in therapeutic areas are exempted from a CVS submission.
In case a part of the agenda includes a session addressed to HCPs, the event cannot fall into this qualification and will be subject to CVS.

Transparency

Under Mecomed's new Code, member companies must document and disclose all Educational Grants that occurred in the Mecomed's region according to its Disclosure Guidelines published on the Mecomed Disclosure Platform[210]. The Disclosure Guidelines came into force only on 1 January 2020 and the first publication of Educational Grants began at the end of the transition period: 31 August 2020[211].

Mecomed Certified Partners

To allow Healthcare Organizations (HCOs), including Medical Associations (MAs) and Professional Congress Organizers (PCOs) to demonstrate their commitment to the ethical standards included in the

[210] Mecomed Code, Part 1: Guidelines on Interactions with HCPs and HCOs, p. 17, January 2021.
[211] Mecomed Code, Disclosure Guidelines, p. 26, January 2021.

Mecomed Code, they set up a voluntary certification process similar to MedTech Europe's "Ethical Charter"[212].

Mecomed TPI Certification

To allow Third-Party Intermediaries and Distributors of the MedTech Industries to demonstrate their commitment to the ethical standards included in the Mecomed Code, they set up a voluntary certification process.

Educational Grants

The Mecomed Code mandates that member companies must cease direct financial and in kind support to individual HCPs to cover the costs of their attendance at Third Party Organised Educational Events.[213] From that point on member companies may provide financial support for HCPs to attend Third Party Organized Educational Events through Educational Grants[214]. The Mecomed Code contains the same definition of Educational Grant as that in the MTE Code[215]. The procedure for and situations where an Educational Grant can be provided mirror those in the MTE Code.
In addition, the Mecomed Code states that Member Companies shall ensure full compliance with local laws regarding the disclosure or approval requirements associated with such financial support. Where no such national requirements are prescribed, Member Companies shall nevertheless maintain appropriate transparency by requiring Employer Notification.
Employer Notification is required whenever a Member Company sponsors/engages Healthcare Professional in Company Event, Third Party Organised Educational Event, or as a Consultant. Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of promotional or educational items related to the Healthcare Professional's practice, do not require Employer Notification.

Consultancy arrangements

The Mecomed Code states that where no national requirement is prescribed, prior written notification must be made to the hospital administration, the HCP's superior or other locally-designed competent authority, disclosing the purpose and scope of the consultancy arrangement[216]. Furthermore, consulting agreement should comply with the criteria laid down in Section V of the Mecomed Code[217]:

- Legitimate purpose for the services is identified in advance;
- Consultant is selected on the basis of his/her qualifications and expertise;

[212] For more information, please see: https://www.mecomed.com/certified-partners/#partners
[213] Mecomed Code, Part 3: Procedural Framework, p. 29, January 2021.
[214] Mecomed Code, Part 4: Grants and Charitable Donations, p. 17, January 2021.
[215] Mecomed Code, Part 5: Glossary and Definitions, p. 34, January 2021.
[216] Mecomed Code, Part 1: Guidelines on Interactions with HCPs and HCOs, p 10, January 2021.
[217] For the rest of the requirements, please see Mecomed Code, Part 5.2: Section 5, p. 20, January 2021.

- Consulting agreement is made in writing, in accordance with local and national law and specifies the services to be provided;
- Compensation should be fair market value for the services provided and should not be tied in any way to the value of medical devices which the consultant may use for his/her own practice, etc.
- 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.
- 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.
- 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 Part 1, Chapter 1. Events.

Meals, travel and accommodation expenses

Mecomed members are permitted, through Educational Grants, to cover reasonably priced travel, meals and accommodation costs in connection with the event and in compliance with applicable national and local laws[218].
In addition, the Mecomed Code also provides for specific rules regarding acceptable limits for such expenses:

- Hotels: Business city hotels are acceptable provided the hotel is not a resort or beach hotel nor has leisure elements such as casinos, golf courses, etc.
- Travel: Generally, only Economy Class is permissible. Business Class may be considered as acceptable only when flight is equal or greater than 5 hours airtime unless special health conditions make traveling in business class necessary, in which case an exception may be granted. First class is never appropriate.

Promotional & Educational Items

All promotional & educational items should comply with the General Principles outlined in the Mecomed Code.

Virtual Events

For more information on Virtual Events, please refer to the Mecomed Guidance on Virtual and Hybrid Events.[219]

Other

[218] Mecomed Code, Part 1: Guidelines on Interactions with HCPs and HCOs, p. 9, January 2021.
[219] Mecomed Guidance on Virtual and Hybrid Events, available at: https://www.ethicalmedtech.eu/wp-content/uploads/2021/02/Mecomed-Guidance_VirtualHybridEvents.Final_.2021.pdf

One of the most notable differences between Mecomed' s Code and the MTE Code is its scope, which unlike the MTE Code also includes Third Party Intermediaries[220]. Mecomed's Code requires that member companies have in place an effective compliance program that covers its business partners (e.g. intermediaries, distributors, suppliers, etc.). This should be done via a risk-based due diligence process, the steps of which are laid out in Part 4 of the new Mecomed Code.

[220] Mecomed Code, Part 4: Third Party Intermediaries Compliance & Due Diligence, p. 32, January 2021.

THE NETHERLANDS

MEDICAL DEVICES: NEFEMED

Updated: 18 October 2022

Code	
MTE Code transposition	1.1.2021
Phase-out Direct Sponsorship	1.1.2021/1.7.2021
National CVS	no
Transparency	yes[221]
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	yes
Promotion & advertisement	yes
Competition law guidelines	no
Others	no

About NEFEMED

Nefemed is part of the GMH (Gedragscode Medische Hulpmiddelen) foundation and has subscribed to its Code of Conduct, the GMH Code[222], which is an industry and healthcare professional wide Code.
The following industry associations have subscribed to the GMH Code: Diagned, FHI, Firevaned, GAIN, FME Zorg, Nefemed. The GMH Code also applies to the members of the following associations of HCPs: KNMG (doctors), NVZ (hospitals), NFU (academic centres) and V&VN (nurses). There is an English version available.

[221] Please refer to GMH Code, Articles 22-26, available at: chrome- chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/http://www.gmh.nu/images/Gedragscode_GMH_-_May_2022_English.pdf

[222] The GMH Code is available here: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/http://www.gmh.nu/images/Gedragscode_GMH_-_May_2022_English.pdf

On 1 January 2018, legislation on inducements in the context of medical devices entered into force (article 6 of the Medical Device Act[223] and Policy Rules on Inducements Medical Device Act[224]).
The Dutch Health and Youth Care Inspectorate supervises compliance with this new legislation and can impose administrative fines to companies and HCPs who violate the legislation. GMH agreed working agreements with the Inspectorate, which includes specifying tasks under its supervision.[225]
As a result of this new legislation, the GMH Code had to be reviewed[226] before 1 January 2018. Consequently, this review and the fact that not only medtech associations are part of the GMH foundation, delayed the implementation of the MedTech Europe Code and, in particular, the phase-out of direct sponsorship.
Nevertheless, since it was not possible to implement the MedTech Europe Code within the GMH industry wide code, Nefemed[227] decided to transpose the MedTech Europe Code at association level.
Direct sponsorship will be banned as of 1 January 2021 with an additional implementation period until 1 July 2021 for sponsorships for which companies have already engaged.

Transparency

In 2015, sunshine requirements were introduced the in the GMH by self-regulation, first as a pilot and for certain physicians (cardiologists and orthopedics) and suppliers of certain implantable medical devices and after only for healthcare providers listed in the BIG register under the category 'doctor' which includes any collaboration involving these healthcare professionals or, in the event that the interactions take place via the institutions at which these healthcare professionals are employed or participating (please see article 22.1.i of the GMH).
Consequently, the Dutch medical technology industry introduced a self-regulatory disclosure system similar to the one pharmaceutical companies have used in the Netherlands since 2013[228]. The register and the published data can be found on a web site called the "Transparency register care" (*Transparantieregister Zorg)*.[229]
On 1 January 2017 the pilot phase ended, and the system was extended healthcare providers listed in the BIG register under the category 'doctor' which includes any collaboration involving these healthcare professionals. The scope of the transparency system has been broadened to include all medical device industry specialists (including GPs) entered in the BIG Register[230] and data was published for the first time in July 2018.

In particular, the scope of the Dutch transparency system covers the following:

[223] Official Gazette of the Kingdom of the Netherlands (Staatscourant 2022, 9777 van het Koninkrijk der Nederlanden ,).
[224] Policy Rules by the Minster of Health Care of 22 August 2017, Staatscourant 49208 van 31 August 2017.
[225] Werkafspraken tussen Inspectie Gezondheidszorg en Jeugd en de stichting Gedragscode Medische Hulpmiddelen over samenwerking op het gebied van gunstbetoon medische hulpmiddelen, 26 February 2018.
[226] GMH Code, Article. 10.
[227] Please note that also the other two Dutch associations members of MedTech Europe – FHI and Diagned – have decided to transpose the Code at association level.
[228] Articles 22 to 27 of the Code. Please see also the Explanatory notes regarding these Articles.
[229] Please follow this link: https://www.transparantieregister.nl/home?lang=en-us
[230] The BIG (Beroepen in de Individuele Gezondheidszorg) register is the official HCP register in the Netherlands.

- Remuneration for consultancy services, general sponsorship agreements, hospitality and agreements on fees for services between suppliers of medical devices and medical specialists other than Educational Events and clinical studies.
- Only if the total annual amount per HCP is higher than EUR 500.

Educational Grants & Company Organised Events

According to the GMH Code, direct sponsorship of HCPs to attend Third Party Organised Educational Conferences is allowed, if it is in accordance with the requirements laid down in article 9.2 of the GMH Code. Companies may cover reasonable expenses incurred by individual HCPs (e.g. registration fees, meals, necessary overnight stays, and travel expenses). However, reimbursement of the costs is subject to the following rules: max € 500/meeting/HCP and max € 1.500/year; or HCP pays at least 50% of the costs personally[231]. In addition, conditions with regard to the programme and location have to be met. HCPs must notify arrangements concerning the reimbursement of expenses to the board of the institution or his/her employer[232].
Those conditions also apply in case of indirect sponsoring of Third Party Organised Educational Conferences.

The requirements in the Policy Rules on Inducements Medical Device Act (paragraph 3.2.1) are identical. The Dutch Code and the Policy Rules on Inducements Medical Device Act also set specific (and identical) conditions on financial support of HCPs for attendance at:
- Product related meetings organised by companies (article 10 Code);
- Accredited meetings organised by companies (article 11 Code);
- Other meetings organised by companies (article 12 Code).

It is therefore **important** to highlight that even if a company is not a member of any of the GMH signatory associations, these rules will still be of application to them.

With the phase out of direct sponsorship by the Dutch associations members of MedTech Europe (Nefemed, Diagned and FHI), companies are no longer allowed to sponsor HCPs directly; however, they still need, even if they sponsor indirectly, to comply with the legal limits mentioned above.

Consultancy arrangements

Arrangements with consultants are allowed if in compliance with the criteria specified in Articles 13 and 14[233] of the GMH Code:

- Legitimate objective of the service
- Choice of service provider is based on his/her qualifications and expertise

[231] GMH Code, Article 9.
[232] GMH Code, Article 9.
[233] Please refer to Articles 13 and 14 for all criteria.

- Written agreement of a limited duration[234]
- Remuneration is in line with the market and is not linked to the HCP's past or future use of the medical devices
- Prior approval received, etc.

The 2015 update of the GMH Code introduced a definition of what "in line with the market" means regarding consultancy hourly fees to be paid to different types of HCPs[235]. These amounts are:

- Professor 200€
- Medical specialist 140€
- General practitioner 100€
- Pharmacist 100€
- Dentist 85€
- Nurse 70€

The Policy Rules on Inducements Medical Device Act refer to these maximum hourly tariffs in the GMH Code[236], and therefore are of application to all companies operating in the Netherlands.

Meals, travel and accommodation expenses

The GMH Code does not provide for specific amounts for meals, travel and lodging expenses. However, such expenses have to be *reasonable*[237]. It is important to note that for some categories of meetings it is clarified what *reasonable* means[238]. For example, see above the rules applying to the Third Party Organised Educational Conferences.
The 2015 revision of the Code introduced some specific standards for the reimbursement of travel expenses in the context of consultancy services:

- Car: 0.37€ per km;
- Train: cost of first class travel (regardless of whether a train subscription is held);
- Taxi: full reimbursement, in addition to public transport;
- Airplane: first class not permitted,only economy class allowed[239]..

[234] Article 14 lays down the essential elements of the written agreement.
[235] GMH Code, Explanatory notes section, regarding Article 13.
[236] GMT Code, please refer to the 'toelichting' (explanatory notes) to Article 13.
[237] GMH Code, Articles 9(2c), 10(2c), 11(2c), 12(2c).
[238] GMH Code, Meetings organized by independent third parties, Article 9 (2c), accredited meetings organized by suppliers, art. 11(2c), other meetings organized by suppliers, art. 12(2c).
[239] For more information, please see, GMH Code: Explanatory Notes on the Code of Conduct for Medical Devices, Article 13 and GMH: Advies A 12.004 - vergoeden van business class vlucht, available at: http://gmh.nu/images/adviesaanvragen/Advies%20GMH%20A12%20004%20versie%20website.pdf

Gifts

Under the GMH Code, occasional gifts of little value (i.e. max € 50 including VAT) are allowed. Gifts should be related to the business of the HCP, be of benefit to patient care or fulfil a purely educational function. Mentioning the brand in the gift is allowed. In addition, a company may not give more than three gifts/HCP/year. Cash or cash equivalents are not permitted[240].
The requirements on gifts in the Policy Rules on Inducements Medical Device Act (paragraph 3.2.3) are identical.

Promotion & advertisement

Regarding specific rules as to promotion and advertisement in the Netherlands, please refer to Article 4 of the Code of Conduct for Medical Devices – GMH and the Code for Public Promotion Medical (self-care) devices[241]

[240] GMH Code Article 7.
[241] Code for Public Promotion Medical (self-care) devices , available at: https://www.keuringsraad.nl/keuringsraad.nl/media/KoagKag/Downloads/CPMH-2019.pdf

MEDICAL DEVICES: FHI

Updated: 18 October 2022

Code	
MTE Code transposition	5.3.2020
Phase-out Direct Sponsorship	5.3.2020
National CVS	no
Transparency	yes[242]
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	yes
Promotion & advertisement	yes
Competition law guidelines	no
Virtual Events guidelines/rules	yes[243]
Discounts guidelines/rules	no
Others	no

About FHI

The Dutch medical device association FHI[244] is also part of GMH. In addition to the information provided under the Nefemed chapter, note that FHI fully transposed the MedTech Europe Code and making it binding to all its members in March 2020.

For information regarding the other sections, please refer to the Nefemed chapter above.

Promotion & advertisement

Please refer to the NEFEMED Chapter.

[242] Please refer to GMH Code, Articles 22-26, available at: chrome- chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/http://www.gmh.nu/images/Gedragscode_GMH_-_May_2022_English.pdf
[243] The same rules as for in-person events apply to Virtual Events.
[244] FHI: https://fhi.nl/medischetechnologie/

IN VITRO DIAGNOSTICS: DIAGNED

Updated: 18 October 2022

Code	
MTE Code transposition	September 2020
Phase-out Direct Sponsorship	1.1.2021/1.7.2021
National CVS	no
Transparency	law
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	no
Others	no

About Diagned

Diagned[245], in addition to NEFEMED and FHI, the Dutch Medical Devices associations, is a party to the GMH Code.
Please note that the General Assembly of Diagned has accepted the ban on direct sponsorship in September 2020, becoming effective on 1 January 2021. There will be an additional implementation period until 1 July 2021 for sponsorships for which companies have already engaged. The ban will be statuary binding to all members of Diagned, including members that are not MedTech Europe members.

For more information, please refer to the Nefemed chapter above.

Promotion & advertisement

Please refer to the NEFEMED Chapter.

[245] Diagned is the association representing the Dutch manufacturers and importers of In Vitro Diagnostics technology: http://www.diagned.nl/

NORWAY

MEDICAL DEVICES & IVD: MELANOR

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 30 September 2021

Code	
MTE Code transposition	1.1.2019
Phase-out Direct Sponsorship	1.1.2011/ 1.1.2019
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	no[246]
Discounts guidelines/rules	no
Others	no

About the Melanor Code

On 1 January 2019, the Norwegian Medical Device association Medtek Norge and the Norwegian In-Virtro Diagnostic association Lab Norge merged, becoming "Melanor"[247]. Medtek Norge had transposed the MTE Code in 2016; with the merge effective on 1 January 2019, the MedTech Europe Code became applicable to all the members of the association. The Melanor Code, that follows the MedTech Europe Code, is available here.

[246] The same rules as for in-person events apply to Virtual Events.
[247] Melanor is the Norwegian MD and IVD association: https://www.melanor.no/nb/

Transparency

Melanor and MedTech Europe members should disclose their data via the Transparent MedTech platform.[248]

Educational Grants

Melanor has negotiated identical agreements with the four regional health authorities concerning the interactions between HCPs and the medical technology industry. According to these agreements, direct sponsorship has been banned for all employees in public hospitals since 2011. Consequently, all invitations to courses and congresses should go to the health institution. Attendance should be approved by the managing director or the person to whom this authority has been delegated. The HCP in question is personally responsible for obtaining such approval. The invitation must always contain information as to who is arranging and who is paying for an activity. Travel and accommodation expenses are covered by the health institution[249]. For HCPs of the private sector, direct sponsorship has been phased out as of 1.1.2019.

Arrangements with consultants

A written agreement is required which describes the scope and objectives as well as how financial compensation will be paid. The compensation should be reasonable and proportional to the services rendered. Furthermore, full transparency is required in relation to these agreements (e.g. prior approval of the health institution before entering in the agreement or approval of fees for consulting activity etc.).

Meals, travel and accommodation expenses

Please see the Section above on “Educational Grants”.

Gifts

Under Norwegian law on gifts to healthcare professionals, it is generally illegal for companies to give gifts to HCPs unless they are of insignificant value[250].

[248] Transparent MedTech platform, available at: https://www.ethicalmedtech.eu/transparent-medtech/
[249] Medtek Norge publication “Clear rules for interaction”: Samarbeidsavtale-mellom-Helse-Sør-Øst-RHF-og-LFH_Rc2ZiXo.pdf (overcastcdn.com)
[250] Art. 9 Act relating to health personnel (Lov om Helsepersonell), January 2001 and Art. 2, Regulation on restrictions with regards to receipt by health personnel of gifts, commission, services or other contributions (Forskrift om begrensninger i helsepersonells adgang til å motta gave, provisjon, tjeneste eller annen ytelse); 1 September 2005.

POLAND

MEDICAL DEVICES: POLMED

Updated: 4 October 2022

Code	
MTE Code transposition	2017
Phase-out Direct Sponsorship	1.1.2018
National CVS	yes
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	no
Virtual Event guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About the POLMED Code

The POLMED [251] Code of Ethical Business Practice ("POLMED Code") (Kodeks Etycznych Praktyk Biznesowych IZBY POLMED) was revised in 2017, when the POLMED General Assembly voted to incorporate the MTE English version into the organization's statutes. Subsequently, in December of the same year, the Management Board of POLMED adopted a new code, which is a transposition of the MTE Code of Ethical Business Practice. The Polish version of the Code did not change any of the MTE Code's rules; it simply adjusted some language and concepts to the Polish legal landscape. The new Code entered into force on 1st of January 2018. Alongside the new POLMED Code, POLMED also adopted local guidelines — Polish Q&As, which further clarify some practical questions as well as provide additional rules on matters left up to Member Associations (e.g. value limits for Gifts).

[251] POLMED (OIGWM POLMED - The Polish Chamber of Commerce of Medical Devices POLMED) - is the most important organization in Poland for representing the medical devices industry: http://www.polmed.org.pl/

National CVS

POLMED has signed a cooperation agreement with MedTech Polska regarding the local CVS (SOWE) and therefore POLMED and MedTech Polska member companies are obliged to follow the local CVS assessment. POLMED has implemented a national Conference Vetting System named "SOWE"[252]. The system is fully operational and all national events in scope need to be vetted through the local CVS.

The SOWE system is built as an internet platform. The system has detailed assessment criteria which are based on the POLMED Code. The assessment criteria are the same as the ones used by MedTech Europe. It provides a complex questionnaire for third party organizers only (members companies are not allowed to request an event assessment). The questionnaire provides support to the compliance officer by applying some of the criteria to the received request for assessment. SOWE makes public the result of the final assessment as well as the status of the request being processed.

Transparency

The POLMED Code does not provide for additional obligatory reporting by member companies. The POLMED has published in its internet site a set of document templates to support member companies. The set consists of grant/sponsorship/cooperation agreements as well as disclosure clauses related to member companies' cooperation with HCPs.

Gifts

Polish Q&As adopted by POLMED clarify that educational items and/or gifts which meet POLMED Code principles may be provided but of value not exceeding 100 PLN gross. Occasionally the limit can be exceeded in case of gifting an educational article for the needs of a given HCO, for the benefit of patients and in accordance with the Code.

Promotion & advertisement

The Medical Devices Act of 7 April 2022 introduced new broad rules[253] for the advertising of medical devices, which will enter into force on 1 January 2023.
The new rules for the advertising of medical devices and IVDs in Poland as provided by the Medical Device Act of 7 April 2022 are the following:

- Products not intended to be use by a layman person cannot be advertised to the public. The practical impact is that medical devicesfor professional use may be advertised only to HCPs while manufacturers of such devices need to limit information on their websites/social media (no infomation on medical

[252] The national Conference Vetting System "SOWE" is accessible at: https://sowe.org.pl/sowe/o-sowe/
[253] Please refer to the Medical Device Act of 7 April 2022, available at: https://www.sejm.gov.pl/sejm9.nsf/PrzebiegProc.xsp?nr=1764

devices for professionals) or restrain access to their websites to HCPs only. Also, conferences/educational events regarding such devices need to be limited only to HCPs. and the advertisement of services provided with such devices to the general public is also banned.

- Advertising may only be carried out by or on the commission of an economic operator (i.e. manufacturer, EU Rep, importer, distributor). The practical impact is that if the advertising is conducted by a third party on an economic operator's commission, then such advertisement needs to be accepted in writing by the economic operator.
- All ad materials intended for the general public (i.e. influencer materials, social media posts, open websites, leaflets for patients, etc.) should be properly marked, including obligatory warnings. Ads for medical devices will need to have an obligatory warning such as the following example: "This is a medical device. For your safety, use it according to the instructions or label. If in doubt, consult a specialist, as this medical device may not be suitable for you.". Medical devices adds will also need to have information about the intended use of the device and risks associated with its use – as provided in the devices IFU.
- HCPs cannot advertise medical devices to the general public.
- New rules for visiting HCPs – e.g., a visit requires the prior consent of the hospital management and may happen only "after work hours", etc.
- Severe sanctions for breach of the Polish ad regulations - up to PLN 2 million (420.000 EUR), breach of art. 7 of MDR/IVDR – up to PLN 5 million (1.050.000 EUR).

Moreover, as of 28 July 2022, a draft regulation of the Minister of Health on the advertising of medical devices is currently processed at the pre-parliamentary stage. The draft will introduce additional regulations on the advertising of medical devices in Poland. The regulation is supposed to enter into force 1 January 2023, but the text of the draft is not final yet.

MEDICAL DEVICES: TECHNOMED

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 6 August 2020

Code	
MTE Code transposition	1.1.2020
Phase-out Direct Sponsorship	1.1.2020
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Others	no

About Technomed

Technomed[254] is the Polish association representing entrepreneurs operating for the health sector. Their members are manufacturers and distributors of medical devices, as well as entrepreneurs providing services for entities performing medical activities.

Technomed adopted the MedTech Europe Code beginning of 2020.

[254] The Polish association Technomed: http://technomed.org.pl/

IN VITRO DIAGNOSTICS: MedTech Poland/Polska

Updated: 4 October 2022

Code	
MTE Code transposition	1.1.2017
Phase-out Direct Sponsorship	1.1.2018
National CVS	yes
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	yes[255]
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About the MedTech Poland/Polska Code

In February 2016, MedTech Poland/Polska (previously called IPDDL)[256] and POLMED established a joint working group responsible for revising and implementing the new MTE Code. The result of this joint group was the transposition of the MTE Code into the new MedTech Poland Code, which the working group approved and sent to the MedTech Poland Board in November 2016. On 1 January 2017, the new MedTech Poland Code of Ethics ("MedTech Poland Code") (Kodeks Etyki branży technologii medycznych) was published and formally approved[257]. After a one-year transition period, the MedTech Poland Code came into effect on 1 January 2018.

[255] For more information, please refer to the FMV Section of the Chapter.
[256] The Polish IVD association MedTech Polska/Poland: https://medtechpolska.org/
[257] MedTech Poland Code of Ethics (former called IPDDL Code), https://www.ethicalmedtech.eu/wp-content/uploads/2017/06/KODEKS-ETYKI_-10.01.2017_www-MedTech-Polska.pdf, December 2016.

National CVS

MedTech Polska has signed a cooperation agreement with POLMED regarding the local CVS (SOWE) and therefore MedTech Polska and POLMED member companies are obliged to follow the local CVS assessment.

For additional information on the SOWE system, please refer to the POLMED Chapter.

Transparency

Some of MedTech Poland's larger member companies are reporting to their parent companies and those parent companies then report directly to MedTech Europe via the Transparency platform.

MedTech Poland is about to set up a National Grants Registry ("SEGE") which will be a public platform analogously to the Transparent MedTech- Ethical MedTech platform, available after logging in. All details related to this platform will be determined in 2022/2023.

Educational Grants

MedTech Poland has also created for the use of its members a Grant Request Application Form, as well as an Educational Grant Agreement template.

FMV

The MedTech Poland Code contains some wording on Fair Market Valuestating that HCPs engaged by member companies a consultants/ advisors should be remunerated according to FMV. Further, the remuneration shall not depend on the value of the products or services that consultants / advisers can purchase, rent, recommend, rewrite, use, supply or order as part of their professional activity, or which may be purchased, rented, recommended, prescribed, used, supplied or ordered by the HCO in which they conduct their professional activities[258]. For more information, please review the MedTech Poland Code.

Additionally, the Fair Market Value Catalogue for MedTech Polska Members is not ready yet.

[258] Please see MedTech Poland Code, Chapter 5, point 3.

PORTUGAL

MEDICAL DEVICES: APORMED

Updated: 4 October 2022

Code	
MTE Code transposition	29.11.2017
Phase-out Direct Sponsorship	1.7.2018
National CVS	no
Transparency	law
National Ethical Charter	yes
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	yes
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About the Apormed Code

APORMED[259] revised its new Code[260] ("APORMED Code") (Código de Boas Práticas Comerciais) in November of 2017. The new Code is a direct adaptation of the MedTech Europe Code of Ethical Business Practice and came into effect on 1st of July 2018.[261]

[259] APORMED, Associação Portuguesa das Empresas de Dispositivos Médicos, is the main association representing the medical technology industry in Portugal: www.apormed.pt
[260] There is no English version available.
[261] During the vote of the Annual General Assembly in November 2017, there were two options for its entry into force: either July 2018 or January 2019, giving 6 months or 1 year for APORMED members to make the necessary changes to adapt to the new ethical Code., July 2018 was approved by a majority.

Transparency

The February 2017 Decree Law on Transparency and Publicity of Medical Devices also extended the transparency system that was already in place for medical products to medical devices. It mandates that all benefits granted to a HCP or an entity—financial or otherwise—are reported to the national regulatory agency, (INFARMED already mentioned above).[262] The decree law stipulates that any benefit above sixty (60) euros must be reported to INFARMED on its Transparency and Publicity platform. This must be done within thirty days from the date of the benefit[263]. Consequently, Educational Grants would appear to qualify as a "benefit" and therefore need to be registered on the INFARMED platform.
Furthermore, any sponsorship given by companies to an event must be notified to INFARMED 10 days prior to the organisation of the event with the agenda, the date and the localisation of the event[264].

The General Regime for the Prevention of Corruption (RGPC) was approved by Decree-Law No. 109-E/2021, on December 9, 2021, and published in an Annex to it, having entered into force on June 07, 2022 (180 days after publication), with the exception of Chapter IV (Sanctions Regime) of the RGPC which only takes effect on 7 June 2024 for medium-sized companies (companies employing more than 50 persons and less than 250 persons and whose annual turnover or annual balance sheet total exceeds 10 million euros and does not exceed 50 million euros or whose annual balance sheet total does not exceed 43 million euros), and on 7 June 2023 for the other companies. The provisions of the RGPC only applies to companies based in Portugal and to branches of legal persons headquartered abroad employing 50 or more workers and they are cross-cutting, applying to all sectors/industries.
Companies covered by the RGPC must, under penalty of incurring an administrative offence liability, adopt and implement a Normative Compliance Program that is composed, at least, of the following instruments:

- Prevention Plan of Risks of Corruption and Related Infringements ("PPR"),
- Code of Conduct,
- Training programme, and
- Whistleblowing channel, among others.

The purpose of the Normative Compliance Program is to prevent, detect and sanction acts of corruption and related infringements carried out against or through companies. The responsibility for its adoption and implementation lies with the board of directors or management body of the companies covered by the RGPC. The covered companies must also designate a person from the upper management or equivalent as responsible for normative compliance, who ensures and controls the application of the Normative Compliance Program.

National Ethical Charter

Apormed has its own National Ethical charter.

[262] Portuguese Legislative Decree No. 5/2017 of 6 January 2017, Art. 11 (5) and following,
[263] Portuguese Legislative Decree No. 5/2017 of 6 January 2017, Art. 52(5).
[264] Portuguese Legislative Decree No. 5/2017 of 6 January 2017, Art. 11 (1).

Educational Grants

As of 1 July 2018, indirect support for HCPs attendance at Third Party Organised events is only possible through Educational Grants.
On 5 February 2017, the Decree-Law on Transparency and Publicity of Medical Devices came into force[265]. This Decree-Law prohibits the sponsoring or holding of any promotional activity or event in the hospitals (i.e. within the services and establishments of the Portuguese National Health Service (NHS))[266]. However, the law also states that hospitals may request an authorization from INFARMED[267], the national regulatory agency, whenever they wish to receive a sponsorship from companies (i.e. Educational Grants or sponsorship for a scientific event)[268]. Scientific activities can still occur within the premises of the NHS, even if sponsored by companies[269], as can the regular activities of medical delegates[270].

Meals, travel, and accommodation expenses

Travel and lodging should be reasonable in value and in connection with the event[271]. Concerning meals, the companies may offer meals to HCPs up to the maximum value of 60 euros in the national Portuguese territory. Internationally the maximum value should be in accordance with the applicable law or local codes of conduct. Companies may as well offer meals, at third party organized events, in accordance with this maximum ceiling and only if the program of the event does not include specifically this meal[272].

Gifts

The APORMED Code authorises gifts if they are modest in value and related to the HCP's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents[273]. The modest value is fixed at a maximum of 60 euros[274].

Promotion & advertisement

In Portugal, the advertising of medical devices is regulated by Decree-Law no. 145/2009[275] of June 17, specifically chapter XVIII, Articles 43 to 57. The publication of the Decree-Law that implements the MDR and revokes Decree-Law no. 145/2009 is awaited in Portugal.

---

[265] Decreto-Lei nº 5/2017-Aprova os princípios gerais da publicidade a medicamentos e dispositivos medicos (Portuguese Legislative Decree No. 5/2017 of 6 January 2017)
[266] Portuguese Legislative Decree No. 5/2017 of 6 January 2017, Art. 9(3).
[267] The Portuguese National Authority of Medicines and Health Products.
[268] Based on information provided by APORMED.
[269] However, please note that if it involves sponsorship, there is the need to obtain an authorization.
[270] Portuguese Legislative Decree No. 5/2017 of 6 January 2017, Art. 9(4).
[271] APORMED Code, Art. 9 and 10.
[272] See Q&A 10, https://www.apormed.pt/images/apoio/QA_Codigo_de_Etica.pdf
[273] Art. 38 of the APORMED Code and Article 51(1) of Legislative Decree No. 145/2009
[274] In accordance with the Order nº1542/2017 (Despacho nº1542/2017).
[275] For more information on Decree-Law no.145/2009, please see: https://dre.pt/pesquisa/-/search/494558/details/maximized

Decree-Law no. 145/2009 regulates specific advertising of medical devices, as it must also comply with the general law contained in the Advertising Code. APORMED does not have additional guidelines on promotion and advertisement for members.

IN VITRO DIAGNOSTICS: APIFARMA

Updated:4 October2022

Code	
MTE Code transposition	18.12.2017
Phase-out Direct Sponsorship	1.1.2018
National CVS	no
Transparency	law
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	yes
Discounts guidelines/rules	no
Others	no

About the Apifarma Code

APIFARMA[276] has revised its Code of Ethics for Promotional Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Institutions, Organisations or Associations comprising Healthcare Professionals ("APIFARMA Code") (Código Deontológico para as Práticas Promocionais da Indústria Farmacêutica e para as Interacções com os Profissionais de Saúde e Instituições, Organizações ou Associações constituídas por Profissionais de Saúde). On 18 December 2017, the new Code was approved by the General Assembly and consequently, it entered into force on 1st January 2018. There is also an English version available. The new Code transposed the MTE Code albeit with a few adjustments to take local legislation into account. Also, since 1st of January 2022, APIFARMA has a Code of Conduct for interactions between the pharmaceutical industry and patient organizations. The code applies to

[276] APIFARMA is the Portuguese Association of the pharmaceutical and In Vitro Diagnostics industries: https://www.apifarma.pt/

pharmaceutical companies that market medicines.[277] It does not apply to in vitro diagnostic medical device companies.

Transparency

The January 2017 Decree-law[278] also extended the transparency system that was already in place for medical and pharmaceutical products to medical devices. As discussed above, it mandates that all benefits—financial or otherwise—granted to a HCP or an entity are reported to the Portuguese National Authority of Medicines and Health Products (INFARMED). The law stipulates that any benefit above sixty euros[279] must be reported to INFARMED on its Transparency and Publicity platform[280]. This must be done within thirty days from the date of the benefit[281]. Consequently, Educational Grants qualify as a "benefit" and therefore need to be registered on the INFARMED platform.

Educational Grants

As of 1st January 2018, indirect support for HCPs attendance at Third Party Organised events is only possible through Educational Grants.
Since February 2017[282] interactions between companies and Portuguese NHS entities have new rules. According to article 9 of Decree-Law no. 5/2017 NHS entities that wish to receive an educational grant from a company need to request an authorization from the national regulatory agency.[283]

Meals, travel and accommodation expenses

Hospitality should only be provided to HCPs that are participants in their own right and be restricted to the main purpose and duration of the event. In addition, the hospitality provided should not be conditioned on the prescription of any member product and should be consistent with what the HCP would pay for him or herself. Sponsorship of any entertainment is not allowed.
The cost of the meals provided to HCPs should not be greater than 60€ in national events and 90€ in international events, except if in the country where the event takes place the Code of ethics or the national legislation establishes a different amount, in which case the mentioned amount is to be applied[284].

[277] Please see here.
[278] Decree-Law no. 5/2017 of 6 January amended article 52 of Decree-Law No. 145/2009.
[279] Dispatch no. 1542/2017 published on 15 February 2017.
[280] Transparência e Publicidade (Transparency Platform), Infarmed, (last visited 29 September 2021))
[281] Art. 52(5) of Decree-Law No. 145/2009 amended by Decree-Law no.5/2017 of 6 January.
[282] Decree-Law no. 5/2017 of 6 January 2017.
[283] Dispatch no. 6289/2017 published on 18 July 2017.
[284] APIFARMA Code, Art. 24(2).

Gifts

The APIFARMA Code authorises promotional gifts if they have a low cash value and are related to the HPC's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the as less than 25€[285].

Virtual Events

APIFARMA has guidelines [286] regarding Virtual Events, however the document is available only in Portuguese. According to the guidelines, meals during virtual events are not allowed in Portugal. The complete rule states that any type of hospitality (meals, including coffee break) is not allowed for healthcare professionals provided by Associated Companies at events held through digital channels, and in which healthcare professionals attend remotely. Member Companies may, however, hold conferences or other events through digital channels in which speakers and/or some participants meet in person at the event location defined by the Member Company and remote audience is admissible. In these circumstances, it is permissible for Associated Companies to provide a meal to speakers and other face-to-face participants, as long as the schedule justifies it. In case there are mixed conferences, in which part of the participants are in a room and the rest are watching remotely, it is permissible to provide meals to face-to-face participants, as long as the agenda justifies it.

[285] APIFARMA Code, Art. 14 and Decree-Law No. 145/2009, Article 51.1.
[286] For more information, please refer to APIFARMA's guidelines for Virtual Events, "GUIA PARA A UTILIZAÇÃO DE CANAIS DIGITAIS", Article 9, available at: https://www.apifarma.pt/wp-content/uploads/2021/07/Guia-para-a-utilizacao-de-canais-digitais_29062021_aprovadoRD.pdf

ROMANIA

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 4 October 2021

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: AFPM

Code	
MTE Code transposition	14.2.2018
Phase-out Direct Sponsorship	14.2.2018
National CVS	no
Transparency	law
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Others	no

About AFPM

The Romanian association AFPM adopted its new Code of Ethics on 5 November 2020[287] (the "AFPM Code") (Cod de Conduită şi Etică în Afacer), which follows the MedTech Europe Code (the Code is the exact version of the MedTech Europe Code including the Q&As updated in April 2020).

[287] AFPM is the Romanian Medical Products Suppliers Association: http://www.afpm.ro/

Transparency

In February 2014 Romania amended the Healthcare Reform Law and introduced certain transparency provisions into the legal framework. In particular, in accordance with the amended rules, medical device and pharmaceutical companies as well as their third-party representatives in Romania are required to report to the National Agency of Medicines and Medical Devices (ANMDM) all sponsorship activities and any other costs covered for HCPs, patients' organisations and other healthcare associations. The information reported by medical device companies is published on the Ministry of Health website including company names as well as HCPs who benefit from support[288]. Companies must also publish this information on their websites. The deadline for the reporting of the data to the ANMDM was 31 March 2016, and the deadline for publishing the information on the company's website is the 31 October 2015[289]. In 2017, the deadline for companies to report their data to the ANMDM was 31 March 2017.290 For the data of 2019, the deadline was the 3.1.2020.[291] The submission must be made in Romanian, specifying the value of the financial contributions in Romanian Leus (RON), and through a specific form[292], both electronically and in hard copy.

Consultancy arrangements

Where no national requirements are prescribed, members shall maintain appropriate transparency by requiring that prior written notification is made to the hospital administration, the HCP's superior or other locally designed competent authority, disclosing the purpose and scope of the consultancy arrangement.

[288] Article 129 introducing a new article 7991 in the Healthcare Reform Law by Government Emergency Order Nr. 2/2014 amending Healthcare Reform Law nr. 95/2006 and other acts (published in the Official Gazette nr. 104, 11 February 2014).
[289] Order no. 874/2015 approving the reporting forms for sponsoring activities for medical devices and sanitary materials, published in the Romanian Official Gazette on Friday, 24 July 2015.
[290] Based on the information from the Ministry of Health.
[291] All the latest information on the reporting, including the deadlines, can be found here: https://www.anm.ro/dispozitive-medicale/sponsorizari-dispozitive-medicale/.
[292] The form can be found in Order 874/2015, Annex I.

RUSSIA

MEDICAL DEVICES: IMEDA

Updated: 4 October2022

Code	
MTE Code transposition	10.12.2019
Phase-out Direct Sponsorship	21.11.2011
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	no
Virtual Events guidelines/rules	no[293]
Discounts guidelines/rules	yes
Others	no

About the IMEDA Code

The latest version of the IMEDA[294] Code of Ethics ("IMEDA Code") (IMEDA Кодекс деловой этики) was approved end of 2019. An English version is also available. The new IMEDA Code follows the MedTech Europe once, with some adjustments to the Russian legal and regulatory environment.
From 1 January 2020 until 31 December 2020, there is a transition period during which companies can decide to either apply the new Code or the old one (from 2013) for another year. From 1 January 2021, all member companies of IMEDA are required to apply the new Code.

[293] Rules for in-person events apply to Virtual Events.
[294] IMEDA is the Russian medical device industry association: http://www.imeda.ru/

Phase-out of direct sponsorship

Direct sponsorship of individual HCPs to attend Third Party Organised Educational Conferences has been prohibited by law in Russia since 2011[295].

Transparency

IMEDA recommends Companies to disclose the relevant information on their websites. If this is not possible, the information must be provided for publication on IMEDA website. For more information, please consult IMEDA's Disclosure Guidelines[296].

Company Organised Events

Please note that the IMEDA Code lays down some additional conditions for the so called "Information meetings" (similar to the "Product and Procedure Training and Education Events")[297]. In particular, those meetings should, as a general rule, occur close to the Healthcare Professional's place of business and it is not appropriate for travel or accommodation support to be provided to HCPs by Companies[298].

Consultancy arrangements

According to the Law on Health Protection, HCPs may receive remuneration under agreements for clinical trials of medicinal preparations or clinical studies of medical devices; as well as agreements related to teaching and/or scientific activities[299]. Accordingly, the current IMEDA Code allows contractual agreements between member companies and HCPs provided that they are limited to research, scientific or educational activities. In addition, the conditions laid down in Chapter 5: Service Arrangements of the IMEDA Code must also be observed, e.g. prior approval from the HCP's employer, written agreement in place with legitimate purpose identified in advance, compensation at fair market value, etc.[300].

Meals, travel and accommodation expenses

As noted above, the new Law on Health Protection explicitly prohibits the direct sponsorship of individual HCPs. In accordance with the Law, the IMEDA Code provides that member companies are not allowed directly or through third parties (e.g. travel agencies, distributors, etc.) to provide any support to individual HCPs for participation at Third Party Organised Educational Conferences including covering their travel, accommodation and other expenses. However, the conference organisers may allocate part of funds

[295] Federal Law No. 323-FZ dated 21 November 2011 on the Fundamentals of Citizens' Health Protection in the Russian Federation (Law on Health Protection) (ФедеральногозаконаОбосновахохраныздоровьягражданвРоссийскойФедерации, утвержденного 21.11.2011 №323 ФЗ).
[296] IMEDA Code, PART 2: Disclosure Guidelines.
[297] Please consult the Glossary of the IMEDA Code.
[298] IMEDA Code, Chapter 3, 3 on Information meetings.
[299] Law 323, Article 74, par. 1, p. 1.
[300] All conditions are laid down in Chapter 5: Service Arrangements of the IMEDA Code.

received from the member companies to cover reasonable expenses related to HCPs' participation in such conferences[301]. In addition, according to the IMEDA Code, member companies may sponsor or organise reasonable meals and hospitality in connection with Third Party Organised Educational Conferences if these are provided to all conference attendees, are subordinate in time as well as focus on scientific or educational purpose of the conference and comply with applicable laws and business practices. In addition, the IMEDA Code specifies what is meant by the term of "hospitality": it includes buffet style meals or meals and accommodation, if provided to the Healthcare Professionals engaged by Companies under the permitted service arrangements. Entertainment is not allowed in relation to such meals, nor the attendance guests of HCPs[302]. Lastly, accommodation provided to HCPs engaged by Companies under the permitted service arrangements should not cover a period of stay beyond the official duration of the Event, with a possibility to arrive one day before the Event and one day after the Event in case there is a logistics necessity[303].

Gifts

Any gifts, including those in the form of cash, or payments for entertainment and holiday travel, are prohibited under the Law on Health Protection[304].
Consequently, the IMEDA Code states that Companies may not gift educational items and/or gifts to Healthcare Professionals. However, they can temporarily provide to HCPs materials necessary for the purposes of the event (for example, coats), which should be returned once the event has ended[305].

Promotion & advertisement

In Russia, the General Law on Advertisement contains an information on the advertisement of medical devices and medicines[306]. IMEDA has no specific guidelines on promotion & advertisement.

[301] IMEDA Code, Chapter 1, 4: Reasonable hospitality.
[302] IMEDA Code, Please see Chapter 1, 3: Guest and Chapter 1, 4: Reasonable hospitality,
[303] IMEDA Code, See Chapter 1, 4: Reasonable hospitality.
[304] Law 323, Article 74, par. 1, p. 1.
[305] IMEDA Code, Chapter 8 and please see also Q&A 45 of the IMEDA Code.
[306] For more information, please refer to Article 24 of the Russian General Law on Advertisement, available at: http://www.consultant.ru/document/cons_doc_LAW_58968/8fbc3d05dbc778e17bfc1b45fb7339df525c1985/

SLOVAKIA

MEDICAL DEVICES: SK-MED

Updated: 4 October 2022

Code	
MTE Code transposition	1.1.2018
Phase-out Direct Sponsorship	1.2.2018
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no[307]
Others	no

About the SK-MED Code

SK-MED[308] adopted the MedTech Europe Code in January 2018, the new 'Code of Ethics of the Association of Legal Entities' ("SK-MED Code"). There is also an English version available. The SK-MED Code has been binding on its members as of the 1st of February 2018.

In addition, please note that SK+MED signed memorandum for cooperation with the orthopedic and trauma society in Slovakia in September 2019.

[307] In Slovakia there is no specific law, but there is a local regulation from the Ministry of Health from 2012, which allows a maximum discount of 20% for voucher types of medical devices and 10% for special medical devices.
[308] SK+MED is the Slovak Association of Medical Devices Suppliers: http://www.skmed.sk/

Transparency

SK-MED recommends that its member companies publish information relating to grants provided to support third party organised educational conferences on the MedTech Transparency platform.[309]

Law 362/2011 amended other legislation and introduced certain reporting obligations to pharma companies as well as the HCPs. For pharma companies the following obligations were introduced: 1) to report amounts of direct and indirect marketing materials provided to Slovakian HCPs annually for previous year and 2) to report list of HCPs who attended the educational event. The competent authorities will publish these reports on their respective websites. Currently, the reporting requirements do not cover the medical device sector. Furthermore, Law 362/2011 also amended the taxation legislation and laid down new obligations on HCPs. In particular, HCPs have to declare the income received from financial and non-financial interactions with both pharmaceutical and medical device companies to the state authority. This also covers the non-financial benefits received in relation to the sponsorship to attend educational conferences.

Educational Grants

Please note that national Law no. 362/2011, which came into force on 1 December 2011 introduced some limitations to the pharmaceutical sector related to the sponsorship of HCPs to attend certain events[310].

Company Organised Events

The SK+MED Code provides some basic guidelines with regards to Company Organised Events[311].

Meals, travel and accommodation expenses

The SK-MED Code allows companies to cover conference attendance costs as well as reasonable travel and accommodation expenses of individual HCPs, provided that the conference is primarily focused on the support of the related HCP and educational activities. Such support must be in conformance with Slovak legal regulations and clearly specified before the event[312].

Arrangements with consultants

[309] SK-MED Code of Ethics, Section XI.
[310] However, these limitations do not apply to the medical device companies. Act No. 362/2011 Coll. on drugs and medical aids and on amendments to certain acts (Law 362/2011) (Zákon č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach a o zmene a doplnení niektorých zákonov), September 13, 2011.
[311] Please see SK+MED Code, Chapter 3: Product Training and Educational Events Supported by Member Companies, p. 5
[312] Section III, Guidelines on Application of the Principles of the Code of Ethics and On Cooperation with Medical Staff - Attachment to SK-MED Code of Ethics (SK-MED Code of Ethics) (SMERNICA O UPLATŇOVANÍ ZÁSAD ETICKÉHO KÓDEXU A O SPOLUPRÁCI SO ZDRAVOTNÍK - príloha Etického kódexu asociácie SK-MED), 1 January 2013

Consulting agreements are permitted under the SK-MED Code of Ethics. Reasonable fees can be paid to medical staff for such services. Consultancy agreements should comply with the criteria provided in Section VI of the Code[313]:

- The contract must specify the services to be provided by the HCP and must conform to valid Slovak legal regulations
- Consultancy contract should be signed only with pre-determined legitimate purpose of the services
- Consultants should be selected based on their qualification and experience
- Financial compensation for the services provided should be based on the nature of the service provided, be adequate to the extent of such service and should be of current market value, etc.

Gifts

Although gifts are generally not allowed, the SK-MED Code permits the offering of small gifts of modest value and in accordance with valid legal regulations of Slovak Republic. In addition, such gifts should benefit patients, improve working conditions of medical staff or be exclusively of educational nature. Gifts may not be given in the form of cash[314].

Others

Please note that the SK+MED Code also contains provisions on samples and demonstration products.

[313] For all criteria, please see Section VI of the SK-MED Code of Ethics.
[314] SK-MED Code of Ethics, Section VI.

IN VITRO DIAGNOSTICS: SEDMA

Updated: 5 October 2022

Code	
MTE Code transposition	24.10.2019
Phase-out Direct Sponsorship	24.10.2019
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	no[315]
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About the SEDMA Code

SEDMA[316] adopted its Code of Ethics on 24 October 2019. It follows the MedTech Europe Code.

Transparency

Law 362/2011 amended the legislation and introduced certain reporting obligations to pharma companies as well as to HCPs. For pharma companies the following obligations were introduced: 1) to report amounts of direct and indirect marketing materials provided to Slovakian HCPs annually for previous year and 2) to report list of HCPs who attended the educational event. The competent authorities will publish these reports on their respective websites. Currently, the reporting requirements do not cover the medical device sector.

[315] No, but there is a general obligation to adhere to laws regulating harmful competition, competition law and fair trade.
[316] SEDMA is the Slovak Association of In vitro Diagnostics manufacturers and suppliers: http://www.sedma-ivd.sk/

Furthermore, Law 362/2011 also amended the taxation legislation and laid down new obligations on HCPs. Specifically, HCPs must declare the income received from financial and non-financial interactions with both pharmaceutical and medical device companies to the state authority. This also covers the non-financial benefits received in relation to the sponsorship to attend educational conferences.

Promotion & advertisement

The value of promotional items cannot exceed 17 euros excluding VAT.

SLOVENIA

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: MedTech Slovenia

Updated: 4 October 2022

Code	
MTE Code transposition	1.1.2018
Phase-out Direct Sponsorship	1.1.2018
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About the MedTech Slovenia Code

SIEDMA and SLO-MED have formally merged to become MedTech Slovenia. The MedTech Slovenia Code of Conduct[317] ("MedTech Slovenia Code") (Kodeks MEDTech) entered into force on 1 January 2018 and is an exact transposition of the MedTech Code.

In 2017, the two Slovenian National Associations, SLO-MED and SIEDMA, put a joint working group into place, with the purpose to work together on the transposition of the MedTech Code of Ethics. They translated it into Slovenian and adopted it as their own Code and thus, the same rules apply as for the MedTech Europe

[317] There is an English version available of this document, please see here: https://www.medtecheurope.org/wp-content/uploads/2017/06/medtech-europe-code-of-ethical-business-practice-qa-dg.pdf

Code[318]. The joint working group prepared a strategy plan in 2017, with the goal to accomplish on internal stakeholders in 2018, and in 2019, on the external ones.

Phase-out of direct sponsorship

In Slovenia, direct sponsorship of individual HCPs to attend Third Party Organised Educational Conferences is not allowed by law[319] as well as by the MedTech Slovenia Code as of 1 January 2018.

Slovenia's Law on Civil Servants[320] regulates the interactions between industry and the public sector and direct sponsorship is not used. Currently, Grants and Donations are used to provide financial support to the public sector (e.g. HCPs). A public HCO sends a request for financial support for educational purposes, and if accepted, a contract is signed with the public institution. The public healthcare institution will then be permitted to use the Grant for participation in a Third Party Organised Educational Conference.

Transparency

There are no specific applicable regulations on financial transparency, only a generic Integrity Law[321] which does not impose disclosure obligations on life sciences companies.

Gifts

Please refer to the MTE Code section on Educational Items and Gifts[322]. The Slovenian law does impose restrictions on gifts to individuals working in the public sector[323]. Such gifts are typically prohibited, with an exception made for gifts of "low-value," which the law sets at a total value of 125 euros a year[324].

[318] They translated the first version of the MedTech Europe Code, January 2015.
[319] Decree on the limitations and duties imposed upon public servants with respect to receiving gifts (Ur.l. RS št. 58/03 and 56/15); Art. 11, Part II, Civil Servants Act (Ur. l. RS št. 63/07).
[320] Civil Servants Act (Ur. l. RS št. 63/07).
[321] Integrity and prevention of corruption act (ZintPK).
[322] MTE Code, Part 1, Chapter 8 on Educational Items & Gifts.
[323] Decree on the limitations and duties imposed upon public servants with respect to receiving gifts, Article 3 (Ur.l. RS št. 58/03 and 56/15).
[324] Decree on the limitations and duties imposed upon public servants with respect to receiving gifts, Article 2(3) (Ur.l. RS št. 58/03 and 56/15).

SPAIN

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: FENIN

Updated: 4 October 2022

Code	
MTE Code transposition	20.12.2016
Phase-out Direct Sponsorship	1.1.2018
National CVS	yes
Transparency	yes
National Ethical Charter	yes
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	yes
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About the FENIN Code

On 20 December 2016, FENIN[325] approved its new Code of Ethics of the Healthcare Technology Sector[326] (Código Etico del Sector de Tecnologia Sanitaria). The FENIN Code entered into force on 1st January 2018[327]. This new FENIN Code is a transposition of the MTE Code, with the exception of a few small differences, which are discussed below.

[325] FENIN is the Spanish association representing medical technology manufacturers, importers and distributors: https://www.fenin.es/

[326] FENIN Code of Ethics of the Healthcare Technology Sector (FENIN Code) (Código Etico del Sector de Tecnologia Sanitaria), April 2019, available at: http://panelfenin.es/uploads/fenin/documentacion_buenas_practicas/documento_23.pdf (last visited 28th July 2021)

[327] FENIN Code, Chapter XX, p 58.

The Deontological Committee, the Ethics and Compliance Unit and the Ethics Code Monitoring Committee, in cooperation with the Jury of the Association for the Self-Regulation of Commercial Communication (Autocontrol), are the bodies responsible for the implementation and enforcement of the new FENIN Code[328]. The Deontological Committee is appointed by FENIN's Board of Directors, the Ethics and Compliance Unit reports to the General Secretariat and has full independence from the governing bodies of the Federation, Autocontrol is in charge of compliance and interpretation of the Code and there is no appeal possible once Autocontrol has taken its decision[329]. Meanwhile, the Monitoring Committee is responsible for analysing the implementation of the Code and proposing any revisions to the Code[330]. The FENIN Board has approved Competition Guidelines, but they are separate from the Code. However, the new FENIN Code does include a reference to complying with all regulations in order to respect free market competition.[331]

As of April 2019, FENIN revised its Code of Ethics of the Healthcare Technology Sector.[332] .

The FENIN Code has a specific chapter on prizes and competitions organised and/or sponsored by companies. Chapter X, Section 3[333] establishes that companies can only organise/sponsor this type of activities when they are organised as a reward for a scientific-medical activity and not only for participation or registration. As an exception to this, there is the possibility of sponsoring charity raffles. Furthermore, prizes and competitions organised by companies cannot have as a prize money, but rather prizes related to professional, training or research activity.

Additionally, a mandatory guide for interactions between the medtech sector and patient associations[334] was included as an Annex to the FENIN Code. The guide is binding for all members and defines patient organisations for the purpose of the Code. Also, introduces an obligation to document the transparency measures to which companies and patient organisations are obliged to commit. The guide provides that contributions must have a purpose and should not be unconditional donations to patient associations, which become a source of financing and support for these associations.

National Ethical Charter & CVS

Under the new FENIN Code, all entities which organize educational events for HCPs may request the Seal of Adherence to the Code of Ethics[335]. This stamp functions as proof of the entity's commitment to the principles and ethical provisions of the Healthcare Technology Sector and acts as an intermediary between member companies and event organizers and HCOs providing certainty in the use of the funds. FENIN will publish the list of entities with the seal on its website[336].

[328] FENIN Code, Chapter XIX, p 45.
[329] FENIN Code, Chapter XIX, p 45-49.
[330], FENIN Code, Chapter XIX, p 50-51.
[331] FENIN Code, Chapter XVIII, p 44.
[332] Revised FENIN Code of Ethics of the Healthcare Technology Sector (FENIN Code) April 2019, available at: https://fenincodigoetico.org/static/docs/codigo-etico-sector-tecnologia-sanitaria-fenin.b96a2d33a87c.pdf
[333] For more information, please refer to the FENIN Code, Chapter X, Section 3, available at: https://fenincodigoetico.org/static/docs/codigo-etico-sector-tecnologia-sanitaria-fenin.b96a2d33a87c.pdf
[334] Please refer to the English version of the guide, available here.
[335] FENIN Code, Chapter VII, p 21.
[336] Ibid.

Lastly, FENIN also has a national system, the '*Sistema de Validación de Eventos (SVE)"* that reviews the compliance of third-party educational events with the FENIN Code of Ethics[337]. It follows the logic of MedTech Europe's Conference Vetting System.

Transparency

FENIN has decided to use the MedTech Europe platform for grant disclosures[338].

Meals, travel and accommodation expenses

The new FENIN Code provides that indirect support of HCPs for attendance at Third Party Organised Educational Conferences is limited to the payment of registration fees, travel expenses, accommodation and meals. Additionally, flights should be economy class—unless over five hours—in which case business will be allowed. For train rides economy tickets should also be purchased—unless travel is longer than one hour[339]. The FENIN Code states that amounts provided for meals should not exceed 80 euros[340]. One difference in the new FENIN Code with the MTE Code is that whenever a member company sponsors a HCP to attend either a Company Event or Third Party Organized Educational Event for training in clinical techniques and procedures, it specifies that it must give prior written notification to the manager ("Gerente") of the health center or the department manager ("supervisor") [341]. This notification should indicate the scope and purpose of the financial assistance.

Gifts

The new FENIN Code has stricter rules pertaining to gifts. It provides that gifts to HCPs are not allowed unless they are of minor value, i.e. less than EUR 10[342]. Gifts over EUR 10 are only acceptable if they have a genuine training role for the HCPs and have a direct benefit for the care or assistance of patients (e.g. scientific books or anatomical models)[343].

Promotion & advertisement

Chapter XV[344] of the FENIN Code covers Promotion and Advertisement. It states that good faith in advertisement and promotional activities is presumed when the activity has been previously vetted by Autocontrol.

---

[337] Please see also: (https://fenincodigoetico.org/procedimientos/1/
[338] For more information please visit the EthicalMedTech website: https://www.ethicalmedtech.eu/transparent-medtech/ (last visited on the 30.09.2021).
[339] FENIN Code, Chapter VI(5), p 17.
[340] FENIN Code, Chapter VI(4), p 17.
[341] FENIN Code, Chapter VI(7), p. 8 & p. 18 (this is a more specific requirement than included in the MTE Code as it indicates the exact person).
[342], FENIN Code, Chapter XVI, p. 42 (the CFP previously allowed for gifts up to 30 euros).
[343] FENIN Code, Chapter XVI, p. 42.
[344] Fenin Code, p.42.

Any promotional activity must showcase the brand of the product or the company's logo to be considered promotional material.

Additionally, the Spanish government is working on a new Law for the advertisement of medical devices and potentially it will come into force soon.

Also, FENIN's Code of Ethics Monitoring Committee is also working on developing specific advertisement guidelines but these are not yet in force.

SWEDEN

MEDICAL DEVICES: SWEDISH MEDTECH

Updated: 4 October2022

Code	
MTE Code transposition	N/A
Phase-out Direct Sponsorship	N/A (2015)
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	yes[345]
Virtual Events guidelines/rules	no[346]
Discounts guidelines/rules	no
Others	no

About Swedish MedTech

Swedish Medtech is a party to a multi-party "Cooperation Agreement" (Samverkansregler)), which came into force on 1 January 2014. The following parties are signatories to the Cooperation Agreement: Swedish Labtech, Swedish Medtech, the Swedish pharmaceutical association (LIF) and the Swedish Association of Local Authorities and Regions (SKR).

[345] Swedish Medtech has Competition Law provisions included in the Business Code.
[346] There are no specific rules for virtual events, however, meals during virtual events are banned in Sweden.

It has recently been revised and starting from 1 January 2020, the Agreement has a new structure. An English version is also available[347]. It consists of an Agreement on Collaboration Regulations with a specification of types of collaboration. Overall, it follows the rules of the previous agreement.
Additionally to the Cooperation Agreement, Swedish Medtech also hasa Business Code (Affärskod),[348].
As Swedish Medtech has already aligned with the main principles of the MTE Code via the Cooperation Agreement and its own Code, there is no revision planned for the moment.

Educational Grants

Since 1 January 2015 companies cannot cover congress registration, travel, meals and accommodation costs of individual HCPs. The prohibition was introduced by the Cooperation Agreement[349] and applies to any kind of support, whether direct or indirect, for HCPs attending a third-party conference.

Company Events

Under the Cooperation Agreement, medtech companies may sponsor product trainings for HCPs if a purchase agreement regarding the relevant product is in place. In this case, the company providing service information[350] may cover all relevant costs for enabling the service information to be carried out, including reasonable travel and accommodation.

Arrangements with consultants

The arrangment has to be agreed upon in writing between the HCP, the HCP's employer and the company. With a public employer, the agreement constitutes a public document. Remuneration for work must be reasonable in relation to the content of the task and the time spent. Where applicable, reimbursement of expenses shall be paid in accordance with the HCPs employer's rules for travel and expenses. No other benefits, remuneration or gifts may occur. Compensation for work carried out as a part of normal work duties shall be paid to the employer[351].

Meals, travel and accommodation expenses

As provided above, companies are no longer able to cover, directly or indirectly, travel and accommodation costs of individual HCPs related to their attendance at Third Party Organised Educational Conferences. However, medtech companies may cover such costs when HCPs attend their product training if it is necessary to bring the HCP to a location that entail costs for meals, travel and/or accommodation.

[347] All the documents are available under the following link: https://www.swedishmedtech.se/sidor/de-nya-samverkansreglerna-1.aspx
[348] Swedish Medtechs affärskod, 2014, please see also http://www.swedishmedtech.se/sidor/swedish-medtechs-affarskod.aspx.
[349] Please see: https://www.swedishmedtech.se/sidor/de-nya-samverkansreglerna-1.aspx
[350] Service information i.e. providing information and advice on the daily operation and management of medical technology products, which are used or will be used in the healthcare unit where the service information is provided.
[351] Please see the Cooperation Agreement, available at: https://www.swedishmedtech.se/sidor/de-nya-samverkansreglerna-1.aspx

When it comes to meals, at meetings arranged by or in collaboration with companies, the companies may offer a moderate meal in connection with the meeting. Hospitality including alcohol in connection with a meeting shall be restrictive and only occur at meals. Spirits may never be offered. Non-alcoholic alternatives shall always be made available[352].

There are no rules regarding costs for hospitality since prices vary quite broadly in Sweden.

[352] Cooperation Agreement, Section 4b.

IN VITRO DIAGNOSTICS: SWEDISH LABTECH

Updated: 4 September 2022

Code	
MTE Code transposition	N/A
Phase-out Direct Sponsorship	N/A (2015)
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	yes
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	yes[353]
Virtual Events guidelines/rules	no[354]
Discounts guidelines/rules	no
Others	no

About Swedish Labtech

Swedish Labtech[355] is also a party to the Cooperation Agreement (Samverkansavtal) mentioned in the section on the Medical Devices above. In addition, Swedish Labtech has adopted its Business Code (Swedish LabTech Affärskod), which refers to the Cooperation Agreement. Members of Swedish Labtech should apply the Business Code for their activities and members have to apply the Cooperation Agreement between Healthcare Principles Medical Technology, Laboratory Industry, and Pharma[356]. Since Swedish Labtech has already aligned with the main principles of the MTE Code via the Cooperation Agreement, there is no revision of its Code planned.

[353] Swedish Labtech has Competition Law provisions included in the Business Code.
[354] There are no specific rules for virtual events, however, meals during virtual events are banned in Sweden.
[355] Swedish Labtech is the Swedish instrument and diagnostics trade association: http://www.swedishlabtech.se/
[356] Swedish Labetch, Affarskod (Business Code).

Since Swedish Labtech, is a party to the Cooperation Agreement, please refer to the Swedish Medical Devices chapter above for further information on financial support of HCPs, consultancy arrangements, gifts, etc.

SWITZERLAND

MEDICAL DEVICES: Swiss Medtech

Updated: 4 October 2022

Code	
MTE Code transposition	12.6.2017
Phase-out Direct Sponsorship	1.1.2018
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	yes[357]
Virtual Events guidelines/rules	no
Discounts guidelines/rules	yes
Others	yes

About the Swiss MedTech Code

In 2017, Swiss Medtech[358] adopted its Code of Business Conduct ("Swiss Medtech Code")[359], which transposes the MedTech Europe Code. The Swiss Medtech Code entered into force on 12 June 2017, with the exception of the section on the restriction on providing direct material or financial support to HCPs for Training Events Organized by third parties (i.e. direct sponsorship) and the disclosure obligations, which came into force on 1 January 2018[360].

[357] Swiss Medtech has Competition Law guidelines (Wettbewerbsrechtliche Compliance an Swiss Medtech Sitzungen).
[358] The Swiss Medical Device Association Swiss Medtech: https://swiss-medtech.ch/fr. Swiss Medtech was founded in 2017, after the merge of FASMED and Medical Cluster.
[359] Swiss Medtech Code of Business Conduct (Swiss Medtech Code). The Code is available in French (Code Swiss Medtech de pratique commerciale éthique) and German (Swiss Medtech-Kodex zum ethischen Geschäftsverhalten), June 12, 2017.
[360] This restriction is discussed in Chapter 2 and in Section 3 of Chapter 4 of the Swiss Medtech Code.

Additionally, Swiss Medtech published "Application guidelines" in the form of a Q&A-Guidance document on their Code[361].

Transparency

On 1 January 2018, Swiss Medtech published a Transparency Guidance[362]. According to the Guidance and the Swiss Medtech Code[363], all Member Companies must observe certain disclosure requirements. This includes publishing every year, by the 31 August, all Educational Grants they provided for financial support to HCPs[364]. Member Companies may choose to publish the data either on their own, or on the Swiss Medtech website. The deadline for submissions is 30 June of each year. According to the Transparency Guidance, Member Companies started to collect the data in 2018 and the first disclosures were published in 2019.
Further, Swiss Medtech decided to amend the above-mentioned Q&A-Guidance document with a provision that allows members that publish Educational Grants on the MTE Transparent Platform to consequently put a respective note and the corresponding link on either their own website or on the Swiss Medtech website so that they do not need to disclose two times the same data.

Additionally, a new Swiss Integrity and Transparency Ordinance came into effect as of 1 January 2020. The legislation regulates the details on integrity and the duty of transparency according to Articles 55 and 56 of the Swiss Therapeutic Products Act. It provides, inter alia, the definition of gifts of modest value, an overview of the rules around educational support for HCPs, and the Transparency obligations under the Swiss regime (available in German, French and Italian[365]). However, for medtech - for the time being - only the *transparency* rules apply whereas the integrity rules (and the transparency rules) apply for pharmaceutical products. The procedure to amend Article 55 and the corresponding provision in the Integrity and Transparency Ordinance was launched by the authorities by which the integrity rules will also cover medtech products. They will most likely not be in effect.

Gifts

There is a provision in the Integrity and Transparency Ordinance related to gifts which foresees a cap of CHF 300/HCP/year. However, this provision does not apply to medtech companies for the moment. Overall, Swiss MedTech uses a general cap for gifts of CHF 150/HCP/year.

---

[361] Available in German and French. Anwendungshilfe vom 8.12.2017 zum Swiss Medtech-Kodex zum ethischen Geschäftsverhalten vom 12.6.2017; Aide à l'application du 8 décembre 2017 relative au Code Swiss Medtech de pratique commerciale éthique du 12 juin 2017; See also https://www.swiss-medtech.ch/en/ethics-code-and-documentation (30.09.2021).
[362] German version, *Transparenzrichtlinien vom 1.1.2018*, French version, *Directives sur la transparence du 1er janvier 2018* (last visited on 30.09.2021) , English version : Transparency Guidelines of 1 January 2018.
[363] SWISS MEDTECH Code; same as for the MedTech Europe Code (PART 2), Chapter 4, par. 3.
[364] SWISS MEDTECH Code, Chapter 4, par. 3.
[365] Verordnung über die Integrität und Transparenz im Heilmittelbereich; Ordonnance sur l'intégrité et la transparence dans le domaine des produits thérapeutiques; Ordinanza concernente l'integrità e la trasparenza nel settore degli agenti terapeutici.

Promotion & advertisement

In Switzerland, there are specific provisions on advertisement in the Federal Act on Medicinal Products and Medical Devices and in the Medical Devices Ordinance.

Article 51 of the Federal Act on Medicinal Products and Medical Devices states that the Federal Council may, in order to protect health and prevent fraud, restrict or prohibit the advertising of certain medical devices and enact regulations concerning cross-border advertising[366]. On this basis, the Federal Council enacted Article 69 of the Medical Devices Ordinance[367] stipulating that:

- Claims for products must only contain statements that correspond to the product information;
- Misleading statements, particularly concerning the intended purpose, safety and performance of a device, are prohibited;
- Devices intended solely for use by professionals must not be advertised to the public.

Discounts

There is a provision in the Federal Act on Medicinal Products and Medical Devices (Article 56)[368] and a corresponding provision in the Swiss Integrity and Transparency Ordinance (Article 10)[369] – a transparency obligation.

Other

On 25 September 2015, a major change to the Swiss Criminal Code was adopted: the anti-corruption provisions were revised and came into force on 1 July 2016. According to Article 322*octies* and 322*novies*, corruption and acts of bribery in the private sector now fall under the Swiss Criminal Code (StGB).[370] This revision of the law—aptly dubbed "*lex FIFA*"—applies also to the public health sector and could impact the relationship between the industry and HCPs, especially with regards to undue advantages. This is because under the terms of Article 102 of the StGB not only the involved individuals, but also companies themselves may be subject to prosecution if they failed to take all reasonably required organisational measures in order to prevent the bribery or undue advantage.[371] In accordance with the new provisions, an advantage is not considered undue if it is negligible or has been agreed to in a written contract by a third party[372].

[366] Federal Act on Medicinal Products and Medical Devices, Article 51, available at: https://www.fedlex.admin.ch/eli/cc/2001/422/en
[367] Medical Devices Ordinance, Article 69, available at: https://www.fedlex.admin.ch/eli/cc/2020/552/en
[368] For more information, please refer to the Federal Act on Medicinal Products and Medical Devices, Article 56, available at: https://www.fedlex.admin.ch/eli/cc/2001/422/en
[369] For more information, please refer to the Swiss Integrity and Transparency Ordinance (French only), Article 10, available at: https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte/integr-transp-obligation.html
[370] Swiss Criminal Code, Art, 322octies and Art. 322novies.
[371] Swiss Criminal Code, Art. 102 Para 2.
[372] Swiss Criminal Code, Art. 322decies.

Revisions were also made to the Swiss Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).[373] In particular Article 55 of the revised Therapeutic Act, which entered into force on 1 January 2020, contains an integrity provision governing the interaction between industry and HCPs/HCOs[374] . It bans undue advantages provided to or received by HCPs/HCOs and includes a list of permitted advantages. However, the integrity provision is for the moment only applicable to medical products and not to medical devices. A revision to also include medical products was launched (see remarks under transparency).

At the beginning of 2022, the provisions for market-dominant companies were extended to companies with relative market power. A company is considered to have relative market power if other companies are dependent on it for the supply of or demand for a good or service in such a way that there are no sufficient and reasonable possibilities to switch to alternative sources (article 4 section 2bis of the antitrust law). Companies with relative market power behave unlawfully if, by abusing their position on the market, they hinder other companies in entering or exercising competition or disadvantage the market opponent (article 7 of the antitrust law[375]).”

[373] Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 18 March 2016.
[374] Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 18 March 2016.
[375] Please see here: https://www.fedlex.admin.ch/eli/cc/1996/546_546_546/en

IN VITRO DIAGNOSTICS: SVDI/ASID

Updated: 30 September 2021

Code	
MTE Code transposition	15.5.2019
Phase-out Direct Sponsorship	15.5.2019
National CVS	no
Transparency	no
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	no
Others	no

About the SVDI Code

Since May 2019, SVDI/ASID[376] applies MedTech Europe Code as it is.

Please also check the Swiss Medical Device section above to consult the information on the modifications to the Swiss Criminal Code of Conduct and on the Swiss Integrity and Transparency Regulation.

[376] SVDI is the Swiss In Vitro Diagnostics industry association: https://www.svdi.ch/

(German) Schweizerischer Verband der Diagnostica- und Diagnostica-Geräte-Industrie (SVDI)
(French) Association suisse de l'industrie des équipements et produits diagnostiques (ASID).

TURKEY

MEDICAL DEVICES & IN VITRO DIAGNOSTICS: ARTED

Updated: 4 October 2022

Code	
MTE Code transposition	21.2.2019
Phase-out Direct Sponsorship	21.2.2019
National CVS	no
Transparency	law
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	yes
Company Organised Events	no
Consultancy arrangements	yes
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	yes[377]
Virtual Events guidelines/rules	yes
Discounts guidelines/rules	no[378]
Others	yes

About the ARTED Code

ARTED[379] published its revised Code of Ethics[380] on the Principles of Communication with Healthcare Professionals, Ethical Rules and Codes of Business Practice (the "ARTED Code") in 2019. There is also an English version available[381]. Considering the revision of the MedTech Europe Code in 2022, the ARTED Code will be revised accordingly.

[377] The ARTED Code contains Competition Law guidelines and Digital Media and Social Media Usage guidelines: http://arted.org.tr/en/business-ethics/
[378] There is no specific legislation on pricing and discount procedures for medical devices in Turkey. However, the general rules of Competition Law such as ban of destructive pricing shall be applied for the pricing and discount practices.
[379] Turkish Association of Research Based Medical Technologies Manufacturers: http://www.arted.org.tr/
[380] Available at: http://arted.org.tr/en/business-ethics/
[381] Available at: http://arted.org.tr/en/business-ethics/

Please note that the Medical Device Regulation ("Turkish MDR") prepared in accordance with the EU Medical Device Regulation numbered 2017/745 ("MDR") has been published in the Official Gazette no. 31499 from 2 June 2021[382] and has been updated on 29 July 2022[383].

Transparency

On 27 April 2020 the Turkish Pharmaceutical and Medical Device Authority ("Authority") amended the Guidelines on Scientific Meetings and Educational Activities that are carried out within the scope of the Medical Device Sales, Advertisement and Promotion Regulation. These Guidelines provide further clarifications as to the application/notification system that is maintained by the Authority and specifies the documents that must be provided by sales centres[384].

One of the most important clarifications in the Guidelines is the provision stating that in the event that a sales centre provides a donation to an association/charity for the purpose of organizing or supporting a scientific meeting/educational activity/simulation or cadaver training, an official letter by the association/charity explaining how the donation was used should be uploaded onto the notification system by the sales centre. The Guidelines also state that any HCP whose conference participation has been supported in this manner, will be regarded as a participant within the scope of the Medical Device Sales, Advertisement and Promotion Regulation. This, in turn, will mean that the sales centre providing the support will be under the obligation to submit the information relating to said HCP, both for the pre-approval and follow-up notifications for the conference.
On 11 June 2020 the Authority clarified, via an amendment of the Guidelines on Scientific Meetings and Educational Activities that there is no need to notify the Authority for web-based meetings where technical hardware support is not provided (all kinds of devices, apparatus, software, etc.) and/or value is not transferred. In addition to define web-based meetings as scientific meetings or educational activities, it provides that web-based meetings shall be considered scientific activities and therefore deducted from the meeting participation quota of the HCPs.

Educational Grants

On 15 May 2014, the Turkish government passed a Regulation on Sales, Advertisement and Promotion of Medical Devices[385]. In addition to other aspects, the Regulation introduced certain rules regulating

[382] New noteworthy provisions are the definition of medical device, classification of products, distance sales, manufacturer, importer, and distributor liabilities when placing products on the market, the EUDAMED system, clinical research in medical devices, notified bodies. In order to provide a transition period for the new regulations introduced by the Regulation, various effective dates have been foreseen for several articles in accordance with the EU transition process.

[383] A noteworthy amendment is that the reprocessing of single-use devices placed on the market will remain in accordance with the former Medical Device Regulations and will continue for 18 months from the date EUDAMED is functional.

[384] Companies that are engaged in the sales of medical devices in Turkey must be certified as an official sales centre as per the Medical Device Sales, Advertisement and Promotion Regulation.

[385] Regulation regarding the Sales, Advertisement and Promotion of Medical Devices (Regulation) (Tıbbi Cihaz Satış, Reklam Ve Tanıtım Yönetmeliği), 15 May 2014.

interactions between medical device companies and HCPs. In particular, the following requirements were introduced for congress sponsorship:

- Companies must submit all details related to congress sponsorship to the Ministry of Health's (MoH) online database and obtain an online approval before the attendance takes place. There is also a second round of data submission after attendance takes place;
- An HCP can receive a maximum of four[386] congress sponsorships from companies per year. Maximum two of these sponsorships may come from the same company and maximum of two of them can be international congresses;

Under the Regulation on Sales, Advertisement and Promotion of Medical Devices, the type of donations/grants that can be made by sales centres in Turkey are strictly regulated. As per the relevant provision, sales centres can provide donations to public or non-profit healthcare organizations and institutions under the following conditions;

- Obtain permission from the receiving organization or institution,
- Donation/grant will not affect tender decisions relating to medical devices,
- Donation/grant is not linked to any unethical action that could be associated with sales of medical devices,
- One of the purposes of the donation/grant is research, education, health or improving patient care,
- It is for the general use of the organization or institution and not for individual use,
- Donation/grant must be recorded in their official records.

It should also be noted that events may not be organised in touristic destinations during the relevant touristic seasons, which are, for ski resorts, between 1 December and 1 March, and for beach resorts, between 15 June and 15 September[387].

Consultancy arrangements

Arrangements with consultants are allowed provided that they are permitted by applicable laws and regulations. Services of HCPs must be compensated with a fair market price, in line with relevant laws and regulations[388]. In addition, consultancy contracts between the HCPs and member companies must comply with the rules outlined in article 5.3 of the ARTED Code.

Since 18 January 2014[389] it is prohibited for all HCPs employed by state and university hospitals to directly provide any income generating activity outside of their employing institution, for example, *inter alia,* to operate private clinics, or to provide consultancy services. More specifically, such HCPs are no longer allowed to conduct private practices including consultancy arrangements inside or outside of their working hours. A

[386] Regulation amending the Regulation regarding the Sales, Advertisement and Promotion of Medical Devices, Article 4, 25 July 2015 (TIBBİ CİHAZ SATIŞ, REKLAM VE TANITIM YÖNETMELİĞİNDE DEĞİŞİKLİK YAPILMASINA DAİR YÖNETMELİK).
[387] Regulation amending the Regulation regarding the Sales, Advertisement and Promotion of Medical Devices, Article 4, 25 July 2015.
[388] ARTED Code, Section 5.3,
[389] Law on the Amendment of the Decree Law Regarding the Organization and Duties of the Ministry of Health and Affiliated Institutions and Other Laws (SAĞLIK BAKANLIĞI VE BAĞLI KURULUŞLARININ TEŞKİLAT VE GÖREVLERİ HAKKINDA KANUN HÜKMÜNDE KARARNAME İLE BAZI KANUNLARDA DEĞİŞİKLİK YAPILMASINA DAİR KANUN), 18 January 2014.

consultancy service can be obtained from the state institution which will appoint the HCP. The payment must be done to the state institution. This requirement covers all public service employees in Turkey.
Nevertheless, the provisions of the law prohibiting the public HCPs from conducting any private practices was referred to the Constitutional Court for annulment in 2014. According to the Constitutional Court's decision, only those who have established their private clinics before 18 April 2014 can continue engaging in income generating activities in their private clinics, therefore provide consultancy services and directly get honorarium. Consequently, as per the Full-Time Law, the main rule is that state physicians are not allowed to receive any payments individually as they act as government officials. Any payments to be made to the HCPs working in the public sector should be made to the HCOs by which they are employed.

Meals, travel and accommodation expenses

According to the ARTED Code, members may cover reasonable travel, meals and accommodations costs of HCPs in relation to the scientific meetings organized by third parties[390]. There is no regulation on covering meal costs in the web-based meetings either in the legislation or ARTED Code.
The applicable provisions[391] provide the following distinction (1) being the "scientific meetings" where all content is strictly scientific with no product promotion; and (2) "educational activity" where device promotion is also possible. Irrespective of whether organized by the member companies or not, scientific meetings will be covered by article 22 of the Regulation thus the notification and quota requirements for sponsorships will be applicable. On the other hand, no HCP attendance sponsorship (attendance, travel, accommodation) is possible for educational activities. These activities must take maximum one day and be conducted in cities where the invited HCPs are assigned to work. Since there is no sponsorship for these events, there are no quota requirements.
Also since 22 September 2016, trainings given to HCPs and technical support employees working for HCOs, within the simulation or cadaver centres are not considered as scientific meetings or educational activities.[392] This implies that the above-mentioned specific conditions will not be required for these types of activities. However, despite not being subject to the same limitations as scientific meetings and educational activities, training events at simulation centres and cadaver centres must still be notified to the MoH.

In addition, member sponsored hospitality in connection with the consultant meetings must be modest in value; its duration must be in parallel with the scientific program and focused on the purpose of the meeting.[393] The ARTED Code does not provide the maximum amounts for hospitality.

Gifts

Companies may occasionally offer monetarily modest gifts, having symbolic value, branded or non-branded products if they are compliant with laws, regulations and codes of ethics. The gifts must relate to the

[390] ARTED Code, Section 5.2,
[391] The MoH on Guidelines on Scientific Meetings and Educational Activities.
[392] Regulation amending the Regulation regarding the Sales, Advertisement and Promotion of Medical Devices, 22 September 2016 (TIBBİ CİHAZ SATIŞ, REKLAM VE TANITIM YÖNETMELİĞİNDE DEĞİŞİKLİK YAPILMASINA DAİR YÖNETMELİK), Article 2.
[393] ARTED Code, Section 5.3.

professional practices of the HCPs, be beneficial for the patients and have an educational function. It is forbidden to give gifts in cash or cash equivalents[394]. It is important to note that the Regulation introduced a maximum limit for promotional materials of 2.5% of the minimum monthly wage (i.e. approximately 7 EUR)[395].

Promotion and Advertisement

The most important amendments made in September 2020 to the Regulation on Sales, Advertisement and Promotion of Medical Devices related to the restrictions imposed on medical device sales and advertising activities and regulations on notices to be made in personnel changes.

Accordingly, advertising of the following devices is allowed:

- Devices that are sold, adapted or implemented only in hearing aid centers, tailored prosthetics and orthosis centers, opticians or dental prosthetics laboratories,
- Devices that are intended to be used or implemented exclusively by healthcare professionals or that require implementation in medical device sales centers,

Advertising of devices addressed to the consumer, is prohibited for the following devices:

- Devices other than these devices, only in the internet environment where the device is sold, addressed to the consumer,
- Devices included in Annex-3, without limitation.

It has been stated that in case it is determined that an advertisement violates the provisions of the Regulation, the medical device sales centre will be warned to eliminate the relevant impropriety, and if the impropriety is not resolved within three business days from the notification date of the warning then the sales activities of the medical device sales centre will be temporarily ceased for 15 days.
Promotion provisions have not been amended since 2014. In addition, the ARTED Code also regulates similar promotion provisions and for the legislative gaps, high ethical standards directing members have been implemented.

Virtual Events

In addition, regulations on web-based (Virtual Events) scientific meetings and educational activities were included. There is no regulation on covering meal costs in the web-based meetings either in the legislation or the ARTED Code.
Lastly, in the latest revision of the Guidelines on the Scientific Meetings and Educational Activities, which took place in April 2020, the Authority also included some rules on web-based/ Virtual Events: a notification before the meeting is not needed if 1) technical hardware support is not provided (all kinds of devices, apparatus, software, etc.) and / or 2) where no value/ sponsorship is provided. However, a notification to the Authority is still required after the meeting.

[394] ARTED Code, Section 5.13.b.
[395] Article 4(p) of the Regulation.

Others

ARTED also developed Guidelines on Digital Media and Social Media usage[396].

[396] Available at: http://arted.org.tr/en/business-ethics/

UK

MEDICAL DEVICES: ABHI

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 30 September 2021

Code	
MTE Code transposition	1.5.2017
Phase-out Direct Sponsorship	1.1.2019
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	yes
Gifts	yes
Miscellaneous	
FMV	no
Promotion & advertisement	yes
Competition law guidelines	yes[397]
Virtual Events guidelines/rules	no
Discounts guidelines/rules	no
Others	no

About the ABHI Code

ABHI[398] carried out a complete transposition of the MTE Code—ABHI Code of Business Practice—which it published in May 2017. In July 2018, they updated the Code, with some minor changes such us the Q&A section. The ABHI Code is an exact transposition of the MTE Code, with the exception of the addition of sections on advertising and promotional activities, complaints, and Sponsored Posts.

[397] Competition Law Compliance Guidelines, including Dos and Don'ts, available at: https://www.abhi.org.uk/resource-hub/
[398] ABHI is the Association of British HealthTech Industries: https://www.abhi.org.uk.

The new ABHI Code came into force in two steps: On 1 January 2017, the new complaints adjudication procedure came into force[399] (a relatively minor change) and on 1 January 2018, the new Code came into force, which banned direct sponsorship as of 1January 2019.

Transparency

According to the ABHI Code, Educational Grants will be documented and publicly disclosed by member companies to ensure increased transparency of the funds allocated to medical education. ABHI has elected to use the MedTech Europe platform for grant disclosures[400]. The first reporting took place in 2018 (1 January to 31 December)[401]. The ABHI Code includes also four Annexes that provide further clarification on the disclosure guidelines, including an example methodology note.[402]

It is expected that as a result of the 'First, Do No Harm' report (The Cumberlege review 403), recommendation 8 particularly, the Department of Health will be considering making the reporting of transparency data 'mandatory', but this has yet to be determined.

Meals, travel and accommodation expenses

Members may provide HCPs with reasonably priced meals, hospitality and travel costs in connection with the event and in compliance with the regulations of the country where the HCP is licensed to practice[404]. In early February 2017, the National Health Service (NHS) in England released a guidance document[405], which is aimed at the management of conflicts of interest. One of the main changes was the setting of upper limits for meals and refreshments at £75[406]. ABHI's Code was amended to take these spending limits into consideration[407].

Gifts

There is no maximum amount for gifts[408] or other specific legal requirements. However, the NHS has set the limit for these types of gifts at £6[409]. While this figure is only directly applicable to the NHS in England, ABHI has indicated that this amount should be used as a benchmark for what is acceptable throughout the rest of the UK[410].

---

399 ABHI Code of Business Practice (ABHI Code), Part 4: Complaints Procedure & Panel Constitution, July 2019.
400 ABHI Code, Part 2: Disclosure Guidelines, p. 46,July 2019.
401 ABHI Code, Part 2: Disclosure Guidelines, Q&A 7, p. 51, July 2019
402 ABHI Code, Part 6: Annexes, Annex II & III, p. 75 f., July 2019.
403 https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report
404 ABHI Code, Part 1 Ch. 1 – General Criteria for Events, p 9 f., July 2019.
405 Managing Conflicts of Interest in the NHS (Guidance came into force on 1 June 2017). Please find the guidance slides here: https://www.england.nhs.uk/wp-content/uploads/2017/02/guidance-managing-conflicts-of-interest-nhs.pdf (last visited 30 September 2021).
406 Managing Conflicts of Interest in the NHS, Hospitality, p. 11.
407 ABHI Code, Part 1 Chapter 1: General Criteria for Events, FN 1, July 2019.
408 ABHI Code, Part 1, Chapter 9: Educational Items & Gifts, p. 41, July 2019.
409 Managing Conflicts of Interest in the NHS, p. 11.
410 ABHI Code, Part 1, Chapter 9: Educational Items & Gifts, FN 1, July 2019.

In addition, the ABHI Q&As provide further guidance on gifts[411].

Promotion & Advertisement

The ABHI Code includes a section (Part III) on advertising and promotional activities in an attempt to more directly address these types of activities when they are aimed solely or primarily at HCPs.[412] It lays out principles which apply to all such advertising that is issued by or on behalf of ABHI members where it is directed at HCPs in the UK, but as they are based on existing laws and codes of practices, they are also generally applicable to all medical device advertising.
Some examples of the types of advertising that would fall within the ambit of these guidelines include but are not limited to:

- Advertisements in HCP journals, brochures, leaflets, etc.
- Posters and other promotional media in public places at HCP events
- Audio-cassettes, films, records, tapes, video recordings intended solely or primarily for release or use at HCP events[413]

Finally, when positions within a HCO are funded or sponsored by a member company the ABHI Code requires safeguards to ensure that this does not cause any conflicts of interest. This includes a requirement that the sponsorship be with the HCO and not the HCP, the HCO request the sponsorship via a formal and transparent procurement process and the existence of a written agreement stating under what circumstances the HCO may withdraw from the sponsorship[414].

[411] ABHI Code, Part 1, Chapter 9: Educational Items & Gifts, Q&A 41 f., July 2019.
[412] ABHI Code, Part 3: Guidelines on advertisements and promotions addressed solely or primarily to HCPs, p. 53, July 2019.
[413]ABHI Code, Part 3: Guidelines on advertisements and promotions addressed solely or primarily to HCPs, p. 53 f., July 2019.
[414] ABHI Code, Part 1, Chapter 5: Sponsored Posts, p. 32, July 2019.

IN VITRO DIAGNOSTICS: BIVDA

***Disclaimer*: Please note that this Chapter has not been updated in 2022 and it is based on information from previous years.**

Updated: 24 September 2020

Code	
MTE Code transposition	2018
Phase-out Direct Sponsorship	1.1.2018
National CVS	no
Transparency	yes
National Ethical Charter	no
Additional requirements/information different than those of the MTE Code	
Educational Grants	no
Company Organised Events	no
Consultancy arrangements	no
Meals, travel and accommodation expenses	no
Gifts	no
Miscellaneous	
FMV	no
Promotion & advertisement	no
Competition law guidelines	yes
Others	no

About the BIVDA Code

In January 2018, BIVDA[415] transposed the MedTech Europe Code. The BIVDA Code is now in line with the MedTech Europe Code.
In addition, BIVDA has recently revised its code –in April 2020 – which is available here. The Code does also contain competition law guidelines.

[415] The British In Vitro Diagnostics Association (BIVDA) is the British industry association for companies in the in vitro diagnostics industry: https://www.bivda.org.uk/

Enforcement mechanisms

One key-principle of any self-regulation is enforcement. The Code provides specific guidance to National Associations with regards to the set-up of an effective national enforcement mechanism.
As a reminder, the principle is that disputes are best resolved amicably and efficiently by conciliation, mediation or mutual settlement, and at national level, by national panels. It is only in specific cases that a dispute would involve the independent MedTech Europe's Compliance Panel[416].
Currently, about two-third of the National Associations have a national enforcement mechanism in place.

Those resolution mechanisms can typically be divided into three different categories:

- external/independent,
- internal mechanisms, and
- mixed.

The first are composed by external individuals of the association (e.g. external lawyers, industry experts etc.). The second by individuals such as Members of the Board of Directors, representatives of the Secretariat (e.g. legal counsel, CEO etc.) or other designated representatives from Member Companies (who are part of a specific working group, or who are coming from a specific sector). Lastly, they can also have a mixed composition.

The table below provides a detailed overview of the type of mechanism in place (if at all) as well as any specific sanctions that would be available[417].

Country	National Association	Enforcement mechanism	Sanctions
Austria	Austromed	Arbitration College, consisting of an external lawyer—who acts as the chair—and two members nominated by the Board and the General Assembly. For more information, please refer to AUSTROMED's Association Statutes.[418] AUSTROMED also has its Competition Law Guidelines available on their website.	Reprimand under threat of exclusion; exclusion; public announcement of exclusion in the Association's publications For more information, please refer to AUSTROMED's Association Statutes.[419]

[416] See the Code, PART 3, Article 7; for more information on the Panel Members, please visit the Ethical MedTech website: https://www.ethicalmedtech.eu/conference-vetting-system/compliance-panel/.
[417] National Associations without a Dispute resolution mechanism are not included in the table.
[418] Please refer to AUSTROMED's Association Statutes, § 20.
[419] Ibid.

Belgium	BeMedTech	Ethics Commission composed of an independent lawyer, four independent experts from the medical technology industry and the director of beMedTech, without voting right	Reprimand; injunction to cease or correct; fines between EUR 5000 and EUR 20000; publication of decision; exclusion
Croatia	CROMED	Ethical Committee	Possible termination of membership
Cyprus	SAIEEK	Board of SAIEEK in cooperation with the Ethics and Compliance committee and in case of issues external legal advice is requested	Case by case decision, possible sanctions are the Board's discretion
Czech Republic	CzechMed	Association Board, based on recommendations of the Working Group for Ethics. An appeal procedure is available	Fines up to EUR 40 000; exclusion
	CZEDMA	Ethics Committee with external specialists.	Case by case up to expulsion
Denmark	Medicoindustrien	Dispute Settlement Panel consisting of two lawyers as President and Vice President and four other members with industry knowledge. They are elected by the General Assembly	Expression of criticism resulting in a command to adjust, change, rectify or cancel activities that are not in line with the ethical guidelines; a fee that can be as high as 25.000 Danish crowns; recommendation to the board to exclude the company from Medicoindustrien.
	DiaLab	Members must adhere to the DiaLab code of ethics, as well as Medtech Europe's code of ethics.	Non-compliance with the ethical guidelines may lead to exclusion.
Finland	Sai Lab - MedTech Finland	Independent panel	Notification, fines, publication of the decision, expulsion
France	SNITEM	The Commission for the Promotion of Ethics and Mediation (CPEM) consisting of six members elected from the members of the Board of Directors	Warning; Formal notice; Inspection and audit by a third party at the company's expense;

			Publication of corrective action decisions; Suspension/expulsion from membership; Publication of sanction
	SIDIV	Deontology Commission composed of at least five members, not involved in the dispute, and it then appoints a Chairman from among its members	Warnings; publication of the decision; expulsion
Germany	BV Med	Mediation procedure conducted by the Healthcare Compliance Committee, which is nominated by the Board	No predefined sanctions, to be decided during the mediation
	VDGH	FSA (Free Self-Control of Pharmaceutical Industry), an association which was created to implement the Code of Ethics of the German pharmaceutical industry	Fines (EUR 5.000 – EUR 400.000); in case of serious or repeated breaches: public reprimand
Greece	SIEV	Board of Directors and SIEV's legal counsel	No specific sanctions, to be decided on a case by case basis.
Hungary	AMDM	Ethics Committee composed of association members	Injunction to cease; written notices; exclusion
	ETOSZ	Mediation or ethical procedure conducted by the Ethics Committee	Reprimand, sanctions, expulsion
	HIVDA	HIVDA President decides whether it is necessary to convene an ad-hoc Ethics Committee	Case by case up to expulsion
Ireland	HealthTech Ireland	Ethics and Compliance Group chaired by independent chairperson. Initial findings of the Ethics and Compliance Group may be appealed, and any further finding would be referred to HealthTech Ireland's Board to decide	Any possible sanctions at the discretion of the Board
	Irish Medtech Association	Panel constituted following the Complaints Procedure	Reprimand; partial or full suspension or expulsion.
Italy	Confindustria Dispositivi Medici	Control Commission and Jury, which consists of an independent Chairman and a member for each "under-association" in Confindustria Dispositivi Medici. They are also responsible for the appeals procedure for the Italian	Reprimand; partial or full suspension or expulsion

		conference vetting system, the "Sistema di Valutazione delle Conferenze" (SVC)	
Middle East - Africa	Mecomed	Compliance officer of the accused Member Company and the Mecomed Compliance officer. For more information, please refer to the Mecomed Code, Part 3.5.	No specific sanctions, to be decided on a case-by-case basis
Norway	Melanor	Ethics Council, which is composed by of association members and external stakeholders.	Warning, Reprimand, Fines, Exclusion/Suspension, Publication of decision
Poland	Polmed	Disciplinary Court composed of member companies, appointed by the General Assembly. The proceedings have two instances	Reminder, reprimand; an obligation to discontinue an activity or to implement remedial actions (including internal audit); temporary suspension of the membership of the Chamber; expulsion of a member from the Chamber.
	MedTech Polska/ Poland	Peer Tribunal formed by members companies, rotating for each case. Appeals can be made to the Appeal Board, also composed of rotating members	Reprimand; fine up to six times the amount of monthly membership fees; suspension/exclusion
Portugal	Apormed	Disciplinary Committee composed of three members: the President of the General Assembly, the Chairman of the Fiscal Council, and an independent professional appointed by the Board. Appeals can be made to the General Assembly and from this to the common courts	Warning; written reprimand; fine; temporary suspension or expulsion
	Apifarma	Ethics Committee and appeals can be made to the General Assembly.	Warning; suspension; fine up to five years membership fees.
Romania	AFPM	Compliance Committee composed of external stakeholders	Warning; suspension; if appropriate, expulsion;

			fines up to 30 monthly contributions
Russia	IMEDA	*Executive Director and the IMEDA Secretariat, as well as members of the Taskforce*	A warning; obligation to pass the training on the Code; report the breach to the headquarters of the offending company; publicise the breach, including the name of the offending company, on the IMEDA website; report the breach to MedTech Europe if the offending company is a member; recommend to the General Meeting of IMEDA that the offending company be expelled from IMEDA; any combination of the above-mentioned sanctions
Slovakia	SK-MED	Ethics Committee composed of association members and one external advisor. Appeals can be made to the General Assembly.	Warning; written reprimand; fine; temporary suspension or expulsion
	SEDMA	Ethics Committee consisting of four internal members and one external legal consultant. Appeals can be made to the SEDMA General Meeting.	Sanctions, reprehension or corrective actions, expulsion
Slovenia	MedTech Slovenia	Ethics Committee as an independent body, composed 4 members of MedTech Slovenia and one neutral member that oversees compliance and interpretation of the Code and takes care that members operate in accordance with the Code.	N/A
Spain	FENIN	Deontological Committee and the Ethics and Compliance Unit, in cooperation with the Autocontrol Jury. The Deontological Committee is appointed by the Board, the Ethics and Compliance Unit reports to the General Secretariat, and Autocontrol is in	Fines ranging from EUR 1000 to EUR 100000

		charge of compliance and interpretation of the Code; no appeal is possible.	
Sweden	Swedish Medtech - Labtech	Joint enforcement mechanism where a Dispute Settlement Panel reviews complaint. Based on the review, decision is made by the respective Boards. Members may appeal only if the sanction is expulsion. A summary of the decision is published inter alia on the respective association's website. The Panel is composed of external stakeholders. The Panel is appointed by joint decision of the two Boards	Reprimand; warning; expulsion from the respective association
Switzerland	Swiss MedTech	The General Counsel of Swiss Medtech, who is elected by the Committee of Swiss Medtech, is responsible for the implementation of the mediation process.	Recommendation; exclusion
The Netherlands	NEFEMED – FHI - DIAGNED	Industry wide Code Committee (a lawyer and lay people with expertise on medical devices and interactions between industry and HCPs) and an Appeals Board (independent lawyers)	Injunction to cease or correct; reprimand; publication
Turkey	ARTED	Ethics Board composed of association members. Appeals can be made to the Supreme Ethics Board.	Notice; warning; reprobation; suspension; exclusion
UK	ABHI	ABHI Complaints Adjudication Panel composed of individuals with a background in the industry and who have relevant expertise	Publication; withdrawal of "Compliant company" logos; formal reprimands; suspension or expulsion
	BIVDA	Executive Committee which investigates the complaint and issues a decision and/or recommendation. Appeals can be made to an independent council.	Injunction; expulsion

Overview meal limits

Country	Specific limits on meals for Medical Devices & IVDs manufacturers **Green: Legal limit** **Blue: Non-legal limit**	EFPIA/Pharma limits[420]
Austria	No, but meals should be of a standard that HCPs would routinely expect if they were paying for them out of their own pockets.	Advised not to go above 75 EUR per meal inc. VAT and gratuities.
Belgium	**Yes, 80** EUR for dinner and **40** EUR for lunch (drinks included)	
Croatia	No	500 HRK (65EUR+-) per meal
Cyprus	No, but the standard of hospitality should be no more than that which might reasonably be offered by the (HCP) in return	70 EUR exc. Taxes and gratuities per meal
Czech Republic	No	1500 CZK for the entire day (55 EUR+-) inc. VAT & gratuities per meal if less than 6 hours of scientific activity, 3000CZK if over 6 hours. Neither lunch or dinner can go over 1500 CZK individually.
Denmark	No	Maximum per day: 1200 DKK (160EUR), 400 DKK for lunches and 700 DKK for dinner.
Finland	No	45 EUR for lunch, 100 EUR for dinner per HCP.
France	**Yes:** No formalities for unplanned **30** EUR or less meal, maximum twice a year per company. Declaration up to 8 days before if planned less than **50** EUR or “breaks” under **15** EUR. Authorisation 2 months before hospitality procured if above **50** EUR or “breaks” above **15** EUR.	
Germany	No, but the local associations recommend that the maximum	60 EUR inc. VAT

[420] Taken from a list compiled by EFPIA and made public in their website: https://www.efpia.eu/media/589820/scorecard-meals-and-drinks-20210421.pdf

	amount for meals should not exceed 50-**60** € per person. In exceptional situations (meals in expensive cities in foreign countries), higher costs might be appropriate if duly justified. Booth catering at congresses in a single-digit euro range is permitted.	
Greece	**Yes, 70** EUR per day per HCP in Greece (the **Pharma** table indicates 150 EUR per day if interaction taking place abroad)	
Hungary	**Yes,** the daily amount spent on hospitality may not exceed **5%** of the official minimum wage (2020 min. wage: 161,000 HUF, i.e, + 8000 HUF) (approx. EUR 447)	50 EUR per meal, 90 EUR max. per entire day, 7450 HUF for promotional events
Ireland	No	80 EUR inc. VAT, exc. Gratuities per meal per HCP.
Italy	No	60 EUR per meal.
Netherlands	No	75 EUR inc. VAT per meal.
Norway	No	Max. 244 NOK per HCP for lunch for shorter meetings or at workplace, 930 NOK for meetings of more than 90 mins.
Poland	No	200 PLN inc. VAT per meal.
Portugal	**Yes,** up to **60** EUR per meal per HCP in Portugal, **90** EUR abroad for APIFARMA members (unless illegal in that country).	60 EUR inc. VAT per meal.
Romania	No	150 RON inc. VAT per meal, max. 300 RON inc. VAT for the entire day.
Russia	No	Meals and drinks allowed only in buffets at meetings.
Slovakia	No	100 EUR max. per day, 75 EUR per meal max.
Slovenia	No	60 EUR per meal inc. VAT
Spain	**Yes,** up to **80** EUR per meal per HCP.	60 EUR inc. VAT per meal.
Sweden	No	300 SEK (28 EUR+-) per lunch, 850 SEK (80 EUR+-) per dinner per HCP.

Switzerland	No	100CHF per meal.
Turkey	No	380 TRY (61 EUR+-) exc. meals per HCP.
United Kingdom	**Yes, 75** GBP per meal and HCP, only appropriate in exceptional circumstances.	

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health.
MedTech Europe's mission is to make innovative medical technology available to more people, while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations. It also promotes medical technology's value for Europe focusing on innovation and stakeholder relations, using economic research and data, communications, industry events and training sessions.
MedTech Europe started as an alliance in October 2012 formed by two organisations – EDMA, representing the European in vitro diagnostic industry; and Eucomed, representing the European medical devices industry.

For more information visit http://www.medtecheurope.org.